
Tuesday
October 3, 1989

Federal Register

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THE FEDERAL REGISTER

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- FOR:** Any person who uses the Federal Register and Code of Federal Regulations.
- WHO:** The Office of the Federal Register.
- WHAT:** Free public briefings (approximately 3 hours) to present:
1. The regulatory process, with a focus on the Federal Register system and the public's role in the development of regulations.
 2. The relationship between the Federal Register and Code of Federal Regulations.
 3. The important elements of typical Federal Register documents.
 4. An introduction to the finding aids of the FR/CFR system.
- WHY:** To provide the public with access to information necessary to research Federal agency regulations which directly affect them. There will be no discussion of specific agency regulations.

WASHINGTON, DC

WHEN: October 19; at 9:00 a.m.
WHERE: Office of the Federal Register,
 First Floor Conference Room,
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NEW YORK, NY

WHEN: October 24; at 1:00 p.m.
WHERE: Room 305A,
 28 Federal Plaza,
 New York, NY.
RESERVATIONS: Call Arlene Shapiro or Stephen Colon at
 the New York Federal Information Center.
 212-264-4810.

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Title 3—

Executive Order 12692 of September 29, 1989

The President

Continuance of Certain Federal Advisory Committees

By the authority vested in me as President by the Constitution and laws of the United States of America, and in accordance with the provisions of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), it is hereby ordered as follows:

Section 1. Each advisory committee listed below is continued until September 30, 1991:

(a) Advisory Committee on Small and Minority Business Ownership; Executive Order No. 12190 (Small Business Administration).

(b) Committee for the Preservation of the White House; Executive Order No. 11145, as amended (Department of the Interior).

(c) Federal Advisory Council on Occupational Safety and Health; Executive Order No. 12196, as amended (Department of Labor).

(d) President's Commission on White House Fellowships; Executive Order No. 11183, as amended (Office of Personnel Management).

(e) President's Committee on the Arts and the Humanities; Executive Order No. 12367 as amended (National Endowment for the Arts).

(f) President's Committee on the International Labor Organization; Executive Order No. 12216 (Department of Labor).

(g) President's Committee on Mental Retardation; Executive Order No. 11776 (Department of Health and Human Services).

(h) President's Committee on the National Medal of Science; Executive Order No. 11287 as amended (National Science Foundation).

(i) President's Council on Physical Fitness and Sports; Executive Order No. 12345, as amended (Department of Health and Human Services).

(j) President's Export Council; Executive Order No. 12131, as amended (Department of Commerce).

(k) President's National Security Telecommunications Advisory Committee; Executive Order No. 12382, as amended (Department of Defense).

Sec. 2. Notwithstanding the provisions of any other Executive order, the functions of the President under the Federal Advisory Committee Act that are applicable to the committees listed in Section 1 of this order, except that of reporting annually to the Congress, shall be performed by the head of the department or agency designated after each committee, in accordance with guidelines and procedures established by the Administrator of General Services.

Sec. 3. The following Executive orders, which established committees that have terminated or whose work is completed, are revoked:

(a) Executive Order No. 12462, as amended by Executive Order No. 12533, establishing the President's Advisory Committee on Mediation and Conciliation.

(b) Executive Order No. 12592, establishing the President's Commission on Compensation of Career Federal Executives.

(c) Executive Order No. 12668, establishing the President's Commission on Federal Ethics Law Reform.

(d) Executive Order No. 12607 establishing the President's Commission on Privatization.

(e) Executive Order No. 12296, as amended by Executive Order No. 12309, establishing the President's Economic Policy Advisory Board.

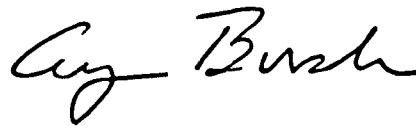
(f) Executive Order No. 12528, as amended by Executive Order No. 12604, establishing the Presidential Board of Advisors on Private Sector Initiatives.

(g) Executive Order No. 12601, as amended by Executive Order No. 12603, establishing the Presidential Commission on the Human Immunodeficiency Virus Epidemic.

Sec. 4. Executive Order No. 12610 is superseded.

Sec. 5. This order shall be effective September 30, 1989.

THE WHITE HOUSE,
September 29, 1989.



Presidential Documents

Executive Order 12693 of September 29, 1989

Exclusion of the Defense Mapping Agency Reston Center and Elements Under the Joint Special Operations Command From the Federal Labor-Management Relations Program

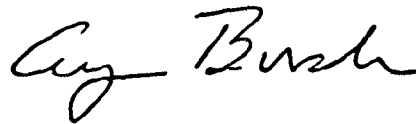
By the authority vested in me as President by the Constitution and laws of the United States of America, including section 7103(b)(1) of title 5 of the United States Code, and having determined that the Defense Mapping Agency Reston Center and the elements under the operational control of the Joint Special Operations Command have as a primary function intelligence, counterintelligence, investigative, or national security work and that the provisions of Chapter 71 of title 5 of the United States Code cannot be applied to those organizations in a manner consistent with national security requirements and considerations, Executive Order No. 12171 of November 19, 1979, as amended, is further amended as follows:

Section 1. Section 1-212(v) is amended by deleting the period and inserting in lieu thereof "and all elements under its operational control."

Sec. 2. A new section is inserted after section 1-214 as follows:

"1-215. The Defense Mapping Agency Reston Center, Department of Defense."

THE WHITE HOUSE,
September 29, 1989.



[FR Doc. 89-23580

Filed 10-02-89; 11:09 am]

Billing code 3195-01-M

Rules and Regulations

Federal Register

Vol. 54, No. 190

Tuesday, October 3, 1989

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 AGRICULTURE

Food Safety and Inspection Service

9 CFR Part 319

[Docket No. 88-029F]

Meat Inspection; Incorporation by Reference; Updating of Text

AGENCY: Food Safety and Inspection Service, USDA.

ACTION: Final rule.

SUMMARY: This document changes the Federal meat inspection regulations to update two references to the "Official Methods of Analysis of the Association of Official Analytical Chemists" (AOAC). A 1984 edition of this publication was published subsequent to the initial incorporation by reference. Although there are no substantive changes in the methods, the referenced pay numbers of the AOAC publication have changed. The Food Safety and Inspection Service (FSIS) is amending its regulation provisions that reference AOAC methods of analysis to reflect the most recent edition of the AOAC publication. In accordance with § 51.11 of title 1 of the Code of Federal Regulations (1 CFR 51.11), an Agency wishing to change information incorporated by reference into its regulations must first provide notice of the change in the Federal Register and amend the Code of Federal Regulations as appropriate. It must also ensure that a copy of the amended or revised reference is on file at the Office of the Federal Register.

EFFECTIVE DATE: October 3, 1989.

FOR FURTHER INFORMATION CONTACT: Mr. Ralph Stafko, Director, Policy Office, Policy and Planning Staff, Food Safety and Inspection Service, U.S. Department of Agriculture, Washington, DC 20250, (202) 447-8168.

SUPPLEMENTARY INFORMATION: Executive Order 12291

The Department has determined in accordance with Executive Order 12291 that this final rule is not a "major rule." It will not result in an annual effect on the economy of \$100 million or more. There will be no major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions. It will not have a significant adverse effect on competition, employment, investment, productivity, or the ability of United States-based enterprises to compete with foreign-based enterprises in domestic or export markets. This rule only changes the citations to material that previously has been approved for incorporation by reference.

Effect on Small Entities

The Administrator, Food Safety and Inspection Service, has determined that this final rule will not have a significant economic impact on a substantial number of small entities, as defined by the Regulatory Flexibility Act (5 U.S.C. 601). The final rule places no new requirements on industry. It only reflects changed citations to methods of analysis already approved for incorporation by reference. Therefore, small entities will not be affected.

Background

Title 1 of the Code of Federal Regulations (1 CFR part 51) requires that an Agency seeking approval of a change to a publication that is approved for incorporation by reference in the Code of Federal Regulations must publish notice of the change in the Federal Register and amend the Code of Federal Regulations; ensure that a copy of the amendment or revision is on file at the Office of the Federal Register; and notify the Director of the Federal Register in writing that the change is being made.

Accordingly, FSIS has reviewed the materials pertaining to meat and meat food products and poultry and poultry products that have been approved for incorporation by reference by the Director of the Office of the Federal Register. It was determined that references to the AOAC publication approved for incorporation in §§ 319.5 and 319.700 of title 9 needed to be updated to reflect the 1984 edition and new page numbers. The Agency,

therefore, finds it necessary to amend these regulations to reflect changes in the AOAC publication that is approved for incorporation.

Because this amendment merely updates the citations to material that has been previously approved for incorporation by reference, it is found upon good cause that public participation in this rulemaking procedure is impracticable and unnecessary, and good cause is found for making the amendment effective less than 30 days after publication in the Federal Register (5 U.S.C. 553).

A copy of the 14th edition of the "Official Methods of Analysis of the Association of Official Analytical Chemists" is on file at the Office of the Federal Register, and may be obtained directly from the AOAC at the address noted below.¹

List of Subjects in 9 CFR Part 319

Meat and meat food products, Mechanically separated (species), Standards of identity or composition, Food labeling, Incorporation by reference, Margarine, oleomargarine.

PART 319—DEFINITIONS AND STANDARDS OF IDENTITY OR COMPOSITION

1. The authority citation for part 319 continues to read as follows:

Authority: 34 Stat. 1260, 81 Stat. 584, as amended (21 U.S.C. 601 *et seq.*); 72 Stat. 862, 92 Stat. 1069, as amended (7 U.S.C. 1901 *et seq.*); 76 Stat. 663 (7 U.S.C. 450 *et seq.*).

2. Section 319.5, paragraph (e)(2) is amended to replace the four sentences starting with the words "Finished product samples" as follows:

§ 319.5 Mechanically separated (species).

(e)(2) Finished product samples shall be analyzed in accordance with "Official Methods of Analysis of the Association of Official Analytical Chemists (AOAC), 14th ed. 1984, sections 24.005 (page 431), 24.006-24.008 (page 431), 24.027 (page 434), and 43.212-43.216 (page 869), which are incorporated by reference, or if no AOAC method is available, in accordance with the "Chemistry Laboratory Guidebook, U.S.

¹ Association of Official Analytical Chemists, 2200 Wilson Boulevard, Suite 400, Arlington, Virginia 22201.

Department of Agriculture, Washington, DC, March 1986 edition, sections 6.011-6.013, Revised June 1987 (pages 6-35 through 6-65). Alternative methods of analysis may be submitted to the Administrator to determine their acceptability based upon their accuracy, repeatability, reproducibility, and lowest level of reliable measurement, as demonstrated by at least 3 laboratories. Copies of AOAC's "Official Methods" may be obtained from: AOAC, 2200 Wilson Boulevard, Suite 400, Arlington, VA 22201. Copies of USDA's Chemistry Laboratory Guidebook may be obtained from: Superintendent of Documents, Government Printing Office, Washington, DC 20402.

3. Section 319.700 is amended by revising the first sentence of paragraph (a) and redesignating footnotes 2, 3 and 4 as 1, 2, and 3, and by revising newly redesignated footnote 2. The text of newly redesignated footnote 1 is republished.

§ 319.700 Oleomargarine or margarine.

(a) Margarine or oleomargarine is the food in plastic form or liquid emulsion, containing not less than 80 percent fat determined by the method prescribed under section 16.206 of the "Indirect Methods," in "Official Methods of Analysis of the Association of Official Analytical Chemists (AOAC), 14th Edition 1984."²

Done at Washington, D.C., on: September 27 1989.

Lester M. Crawford,
*Administrator, Food Safety and
Inspection Service.*

[FR Doc. 89-23241 Filed 10-2-89; 8:45 am]

BILLING CODE 3410-DM-M

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 89-NM-171-AD; Amdt. 39-6342]

Airworthiness Directives; Boeing Models 727 737-100, -200, and -200C Series Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

Insofar as the standard contains provisions relating to margarine or oleomargarine which does not contain any meat food products, such provisions merely reflect the applicable standard under the Federal Food, Drug, and Cosmetic Act.

Copies of the AOAC methods may be obtained from the Association of Official Analytical Chemists, 2200 Wilson Boulevard, Suite 400, Arlington, VA 22201.

ACTION: Final rule.

SUMMARY: This amendment adopts a new airworthiness directive (AD), applicable to all Boeing Model 727 and Model 737-100, -200 and -200C series airplanes, which requires inspection of engine mount cone bolt nuts, changing of maintenance procedures, and reporting findings of engine mount cone bolt nuts which are not in accordance with the type design of the airplane. This amendment is prompted by recent reports of counterfeit engine mount cone bolt nuts installed by the operators during maintenance. Since the structural quality of counterfeit nuts manufactured without quality control procedures cannot be determined, the engine mount strength cannot be assured. This condition, if not corrected, could lead to engine separation.

EFFECTIVE DATE: October 16, 1989.

ADDRESSES: The applicable service information may be obtained from Boeing Commercial Airplanes, P.O. Box 3707 Seattle, Washington 98124. This information may be examined at the FAA, Northwest Mountain Region, Transport Airplane Directorate, 17900 Pacific Highway South, Seattle, Washington, or the Seattle Aircraft Certification Office, 9010 East Marginal Way South, Seattle, Washington.

FOR FURTHER INFORMATION CONTACT: Mr. Steven C. Fox, Airframe Branch, ANM-120S; telephone (206) 431-1923. Mailing address: FAA, Northwest Mountain Region, 17900 Pacific Highway South, C-68966, Seattle, Washington 98168.

SUPPLEMENTARY INFORMATION: On June 30, 1989, the manufacturer informed the FAA of a recent report from an operator of Boeing Models 727 and 737 series airplanes who had discovered a discrepancy with the engine mount cone bolt nuts, Boeing Part Number 69-59074-1. The operator discovered that the engine mount cone bolt nuts were marked with the Boeing part number and NAS1805 in different locations on the nuts from those previously purchased from other sources. The operator also stated that these counterfeit nuts had been used in ninety-four engine overhauls prior to this discovery. The FAA has determined that more than one source manufactured the counterfeit nuts to unknown quality control standards. One of the manufacturers indicated that it had sold in excess of 2,600 nuts to more than thirty operators, aircraft repair station, and aircraft part distributors worldwide.

On July 21, 1989, the manufacturer released Telegraphic Service Letter M-7272-89-3551 to all operators, field

service bases, the Air Transport Association, and Boeing resident service representatives for Boeing 727 and 737-100, -200, and -200C airplanes, indicating that counterfeit engine mount cone bolt nuts had been discovered and specifying a methodology to determine the authenticity of the approved parts.

Since the release of the Boeing Service Letter, the FAA has determined, in conjunction with the Federal Bureau of investigation, that various new versions of counterfeit engine mount cone bolt nuts have been produced to unknown quality control standards and that the distribution is widespread. Since the structural quality of the various counterfeit nuts cannot be determined, the engine mount strength cannot be assured. This condition, if not corrected, could lead to engine separation.

The FAA has reviewed the Boeing Service Letter M-7272-89-3551, dated July 21, 1989, which describes procedures for identifying the counterfeit engine mount cone bolt nuts. However, since new configurations of counterfeit nuts have been found subsequent to the release of that Service Letter, the FAA has determined that the method described in the Service Letter will not reliably determine an authentic engine mount cone bolt nut.

The only FAA-approved sources for the 69-59074-1 engine mount cone bolt nuts are The Boeing Company and Standard Press Steel. The authentic part markings of the engine mount cone bolt nuts are labeled on the vertical rim of the nut base at the largest diameter; nuts produced prior to 1969 may have this part marking on the sloping surface in lieu of vertical rim. An authentic engine mount cone bolt nut is identified as -SPS 69-59074-1- with a single space between the "S" and "6" and absolutely no other markings. Several counterfeit nuts have been produced with the marking "69-59074-1 SPS" with the "SPS" sometimes separated from the marking "69-59074-1" by more than one space; or with "NAS1805" in addition to other marks; or with the Bristol logo " * B+ * " in addition to the other marks; or with "ENGW-10A" in addition to other marks; and an unknown quantity may have been produced with the part marking "SPS 69-59074-1" instead of -SPS 69-59074-1-"

Since this condition is likely to exist on other airplanes, this AD requires the inspection for authentic engine mount cone bolt nuts on all Boeing Model 727 and Model 737-100, -200, -200C series airplanes engine installations, and reporting of all findings to the FAA. Additionally, this AD requires a revision

to the FAA-approved maintenance program to ensure that only authentic engine mount cone bolts nuts are installed on the engine mount cone bolt.

Since a situation exists that requires immediate adoption of this regulation, it is found that notice and public procedure hereon are impracticable, and good cause exists for making this amendment effective in less than 30 days.

Information collection requirements contained in this regulation have been approved by the Office of Management and Budget (OMB) under the provisions of the Paperwork Reduction Act of 1980 (Pub. L. 96-511) and have been assigned OMB Control Number 2120-0056.

The regulations adopted herein 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. Therefore, in accordance with Executive Order 12612, it is determined that this final rule does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

The FAA has determined that this regulation is an emergency regulation and that it is not considered to be major under Executive Order 12291. It is impracticable for the agency to follow the procedures of Order 12291 with respect to this rule since the rule must be issued immediately to correct an unsafe condition in aircraft. It has been further determined that this action involves an emergency regulation under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979). If it is determined that this emergency regulation otherwise would be significant under DOT Regulatory Policies and Procedures, a final regulatory evaluation will be prepared and placed in the regulatory docket (otherwise, an evaluation is not required). A copy of it may be obtained from the Rules Docket.

List of Subjects in 14 CFR Part 39

Air transportation; Aircraft, Aviation safety, Safety.

Adoption of the Amendment

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

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.

§ 39.13 [Amended]

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

Boeing: Applies to all Model 727 and Model 737-100, -200, and -200C series airplanes certificated in any category. Compliance required as indicated, unless previously accomplished.

To prevent engine separation, accomplish the following:

A. Within the next 5 days after the effective date of this AD, revise the FAA-approved maintenance program to indicate that only FAA-approved engine mount cone bolt nuts specified in the table below shall be installed on the engine mount cone bolt on Boeing Models 727 and 737-100, -200, -200C airplanes.

Line No.	FAA-approved engine mount cone bolt nut
Boeing Model 727: 1-193	BACN10B-10L or BACN10GW-10 or NAS1804-10 or LHEB220-108 or 69- 59074-1
194-692	LHEB220-108 or 69- 59074-1
693-1832	69-59074-1
Boeing Model 737-100, -200, -200C: 1-124	LHEB220-108 or 69- 59074-1
125-1585	69-59074-1

No substitute shall be used for the LHEB220-108 or Boeing 69-59074-1 engine mount cone bolt nut.

B. Within 60 days after the incorporation of paragraph A., above, conduct an inspection to verify that each installed engine mount cone bolt nut conforms to the approved type design as described in paragraph A., above, and, if the 69-59074-1 is installed, verify its authenticity. If the authenticity of the engine mount cone bolt nut 69-59074-1 cannot be verified, replace it with an authentic 69-59074-1 engine mount cone bolt nut prior to further flight. The authenticity of the FAA-approved 69-59074-1 engine mount cone bolt nut is determined by the following method:

The only FAA-approved sources for the 69-59074-1 engine mount cone bolt nuts are The Boeing Company and Standard Press Steel. The authentic part markings of the engine mount cone bolt nuts are labeled on the vertical rim of the nut base at the largest diameter; nuts produced prior to 1969 may have the part marking on the sloping surface in lieu of the vertical rim. The authentic cone bolt nut is identified as -SPS 69-59074-1- with a single space between the "S" and "6" and absolutely no other markings.

C. Within 10 days after completion of the inspection required by paragraph B., above, for each airplane, submit a report of findings of counterfeit engine mount cone bolt nuts installed on the airplane to the Manager, Manufacturing Inspection Office, ANM-108,

FAA, Transport Airplane Directorate, 17900 Pacific Highway South, C-68966, Seattle, Washington 98168. This report must include the model of the airplane inspected, the date of inspection, and the number of cycles flown since the last engine maintenance where engine mount cone bolts were installed.

Note: The report should be forwarded through the assigned air carrier Principal Maintenance Inspector (PMI), who will then send it to the Manager, Manufacturing Inspection Office, ANM-108.

D. An alternate means of compliance or adjustment of the compliance time, which provides an acceptable level of safety, may be used when approved by the Manager, Seattle Aircraft Certification Office, FAA, Northwest Mountain Region.

Note: The request should be forwarded through an FAA Principal Maintenance Inspector (PMI), who will either concur or comment and then send it to the Manager, Seattle Aircraft Certification Office.

E. Special flight permits may be issued in accordance with FAR 21.197 and 21.199 to operate airplanes to a base in order to comply with the requirements of this AD.

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

This amendment becomes effective October 16, 1989.

Issued in Seattle, Washington, on September 20, 1989.

Leroy A. Keith,

Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 89-23285 Filed 10-2-89; 8:45 am]

BILLING CODE 4910-13-M

14 CFR Part 39

[Docket No. 89-NM-172-AD; Amdt. 39-6329]

Airworthiness Directives; Boeing Model 747-400 Series Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This amendment adopts a new airworthiness directive (AD), applicable to certain Boeing Model 747-400 series airplanes, which requires a revision to the FAA-approved maintenance program and Airplane Flight Manual (AFM) to specify actions

to be performed on the Integrated Display System (IDS) prior to release of the airplane to the flightcrew. This amendment is prompted by laboratory test results which documented the inability, under certain conditions, to record some airplane status messages on the STATUS page of the IDS. This condition, if not corrected, could result in equipment failures on the airplane, unknown to the crew or maintenance personnel. This could result in subsequent dispatch of an airplane in an unairworthy condition.

EFFECTIVE DATE: October 17 1989.

ADDRESSES: The applicable service information may be obtained from Boeing Commercial Airplanes, P.O. Box 3707 Seattle, Washington 98124. This information may be examined at the FAA, Northwest Mountain Region, Transport Airplane Directorate, 17900 Pacific Highway South, Seattle, Washington, or Seattle Aircraft Certification Office, 9010 East Marginal Way South, Seattle, Washington.

FOR FURTHER INFORMATION CONTACT: Mr. Kenneth J. Schroer, Systems and Equipment Branch, ANM-130S; telephone (206) 431-1937 Mailing address: FAA, Northwest Mountain Region, 17900 Pacific Highway South, C-68966, Seattle, Washington 98168.

SUPPLEMENTARY INFORMATION: The manufacturer of the Integrated Display System (IDS) installed on the Model 747-400 has reported that, during validation testing of an updated version of the IDS software, it was found that certain Engine Indication and Crew Alerting System (EICAS) status messages may not be retained for corrective maintenance action on the status page at the completion of the flight. In such cases, maintenance personnel, upon reviewing the status level messages after flight, would be unaware of the equipment malfunctions and unable to take corrective action prior to the next flight dispatch. This condition is only true for certain status level EICAS messages which must be maintained for post-flight maintenance activities. Flight and engine control sensors that are vital to the airworthiness of the airplane are monitored and maintained by this system. Memo, Caution, Advisory, and Warning level messages are not affected. This condition, if not corrected, could result in equipment failures on the airplane unknown to the crew or maintenance personnel. This could result in subsequent dispatch of an airplane in an unairworthy condition.

The FAA has reviewed and approved Boeing Telegraphic Maintenance Tip (M-7201-89-1141), dated July 27 1989,

which describes maintenance action required prior to dispatch if preparation of the airplane involved erasing any EICAS messages.

Since this condition is likely to exist or develop on other airplanes of the same type design, this AD requires a revision of the FAA-approved maintenance program to implement a maintenance procedure in accordance with the telegraphic maintenance tip previously described, and a revision to the Airplane Flight Manual (AFM) that cautions the flightcrew not to erase Status Messages from the IDS.

This is considered interim action. The FAA may consider revising this AD to require the replacement of the Integrated Display System software with an updated version, after development of such software and subsequent approval by the FAA is accomplished.

Since a situation exists that requires immediate adoption of this regulation, it is found that notice and public procedure hereon are impractical, and good cause exists for making this amendment effective in less than 30 days.

The regulations adopted herein will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, in accordance with Executive Order 12612, it is determined that this final rule does not have sufficient federalism implications to warrant the preparation of a Federal Assessment.

The FAA has determined that this regulation is an emergency regulation and that it is not considered to be major under Executive Order 12291. It is impracticable for the agency to follow the procedures of Order 12291 with respect to this rule since the rule must be issued immediately to correct an unsafe condition in aircraft. It has been further determined that this action involves an emergency regulation under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979). If it is determined that this emergency regulation otherwise would be significant under DOT Regulatory Policies and Procedures, a final regulatory evaluation will be prepared and placed in the regulatory docket (otherwise, an evaluation is not required). A copy of it, if filed, may be obtained from the Rules Docket.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Safety.

Adoption of the Amendment

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

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.

§ 39.13 [Amended]

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

Boeing: Applies to Model 747-400 series airplanes, with Integrated Display System (IDS) software installed as identified in Boeing Telegraphic Maintenance Tip (M-7201-89-1141), dated July 27 1989, certificated in any category. Compliance required within 10 days after the effective date of this AD, unless previously accomplished.

To preclude the possibility of airplane status messages not being properly latched into memory which may prevent maintenance from properly dispatching the airplane, accomplish the following:

A. Change the FAA-approved maintenance program, with concurrence of the assigned FAA Principal Maintenance Inspector, to include the following special procedures, as described in Boeing Telegraphic Maintenance Tip 747-400 MT 31-12 (transmitted by Boeing message M-7201-89-1141, dated July 27 1989):

1. If preparation of the airplane involved erasing any EICAS messages, as the final maintenance action prior to dispatch, simultaneously cycle power to the three electronic interface units (EIU).
2. Pull the following circuit breakers:

Location	Nomenclature
P7-1 F09.....	EIU L
P7-1 F10.....	EIU C
P7-2 F15.....	EIU R

3. After three seconds, restore all three circuit breakers to the power-on position.

B. Add the following to the Limitations Section of the FAA-approved Airplane Flight Manual (AFM). This may be accomplished by inserting a copy of this AD in the AFM.

"Due to an IDS anomaly, information necessary for dispatch of subsequent flights may be lost if EICAS status messages are erased. To preclude this possibility, do not erase any EICAS status messages.

C. An alternate means of compliance or adjustment of the compliance time, which provides an acceptable level of safety, may be used when approved by the Manager, Seattle Aircraft Certification Office, FAA, Northwest Mountain Region.

Note: The request should be forwarded through an FAA Principal Maintenance Inspector (PMI), who will either concur or comment, and then send it to the Manager, Seattle Aircraft Certification Office.

D. Special flight permits may be issued in accordance with FAR 21.197 and 21.199 to operate airplanes to a base in order to comply with the requirements of this AD.

All persons affected by this directive who have not already received the appropriate service information from the manufacturer may obtain copies upon request to Boeing Commercial Airplanes, P.O. Box 3707 Seattle, Washington 98124. This information may be examined at the FAA, Northwest Mountain Region, Transport Airplane Directorate, 17900 Pacific Highway South, Seattle, Washington, or Seattle Aircraft Certification Office, 9010 East Marginal Way South, Seattle, Washington.

This amendment becomes effective October 3, 1989.

Issued in Seattle, Washington, on September 12, 1989.

Darrell M. Pederson,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.
[FR Doc. 89-23273 Filed 10-2-89; 8:45 am]

BILLING CODE 4910-13-M

14 CFR Part 39

[Docket No. 89-NM-182-AD; Amdt. 39-6343]

Airworthiness Directives; Boeing Model 747 Series Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This amendment adopts a new airworthiness directive (AD), applicable to certain Boeing Model 747 series airplanes, which requires the installation of protective sleeves on wire breakouts and oxygen lines in the upper deck left sidewall. This amendment is prompted by inspections of several airplanes that revealed certain wire bundles could contact oxygen lines at six locations. This condition, if not corrected, could result in chafing of the wires, which could then arc and possibly burn through to an adjacent oxygen line; this would create a fire hazard should the oxygen line be pressurized.

EFFECTIVE DATE: October 16, 1989.

ADDRESSES: The applicable service information may be obtained from Boeing Commercial Airplanes, P.O. Box 3707 Seattle, Washington 98124. This information may be examined at the

FAA, Northwest Mountain Region, Transport Airplane Directorate, 17900 Pacific Highway South, Seattle, Washington, or Seattle Aircraft Certification Office, 9010 East Marginal Way South, Seattle, Washington.

FOR FURTHER INFORMATION CONTACT:

Mr. David M. Herron, Systems and Equipment Branch, ANM-130S; telephone (206) 431-1949. Mailing address: FAA, Northwest Mountain Region, 17900 Pacific Highway South, C-68966, Seattle, Washington 98168.

SUPPLEMENTARY INFORMATION:

Inspections of several airplanes at the manufacturer's facility, revealed that wire bundles could contact oxygen lines at six locations. A chafed wire could result in arcing and possible burn-through of the adjacent oxygen line. If the oxygen system were pressurized for any reason, the arcing could provide an ignition source, where there is a concentration of oxygen in the sidewall of the airplane.

The FAA has reviewed and approved Boeing Service Bulletin 747-35-2059, dated August 17, 1989, which describes the installation of protective sleeves on wire breakouts and oxygen lines at six locations in the upper deck left sidewall.

Since this condition is likely to exist or develop on other airplanes of the same type design, this AD requires the installation of protective sleeves on wire breakouts and oxygen lines at six locations in the upper deck left sidewall, in accordance with the service bulletin previously described.

Since a situation exists that requires immediate adoption of this regulation, it is found that notice and public procedure hereon are impracticable, and good cause exists for making this amendment effective in less than 30 days.

The regulations adopted herein will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, in accordance with Executive Order 12612, it is determined that this final rule does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

The FAA has determined that this regulation is an emergency regulation and that it is not considered to be major under Executive Order 12291. It is impracticable for the agency to follow the procedures of Order 12291 with respect to this rule since the rule must be issued immediately to correct an unsafe condition in aircraft. It has been

further determined that this action involves an emergency regulation under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979). If it is determined that this emergency regulation otherwise would be significant under DOT Regulatory Policies and Procedures, a final regulatory evaluation will be prepared and placed in the regulatory docket (otherwise, an evaluation is not required). A copy of it, if filed, may be obtained from the Rules Docket.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Safety.

Adoption of the Amendment

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

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.

§ 39.13 [Amended]

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

Boeing: Applies to Model 747 series airplanes, listed in Boeing Service Bulletin 747-35-2059, dated August 17, 1989, certificated in any category. Compliance required within 60 days after the effective date of this AD, unless previously accomplished.

To prevent the chafing of wire bundles, subsequent arcing and burn-through of adjacent oxygen lines, and a resulting potential fire hazard, accomplish the following:

A. Install protective sleeves on wire breakouts and oxygen lines in the upper deck left side wall in accordance with Boeing Service Bulletin 747-35-2059, dated August 11, 1989.

B. An alternate means of compliance or adjustment of the compliance time, which provides an acceptable level of safety, may be used when approved by the Manager, Seattle Aircraft Certification Office, FAA Northwest Mountain Region.

Note: The request should be forwarded through an FAA Principal Maintenance Inspector (PMI), who will either concur or comment, and then send it to the Manager, Seattle Aircraft Certification Office.

C. Special flight permits may be issued in accordance with FAR 21.197 and 21.199 to operate airplanes to a base in order to comply with the requirements of this AD.

All persons affected by this directive who have not already received the

appropriate service information from the manufacturer may obtain copies upon request to Boeing Commercial Airplanes, P.O. Box 3707 Seattle, Washington 98124. This information may be examined at the FAA, Northwest Mountain Region, Transport Airplane Directorate, 17900 Pacific Highway South, Seattle, Washington, or Seattle Air Craft Certification Office, 9010 East Marginal Way South, Seattle, Washington.

This amendment becomes effective October 16, 1989.

Issued in Seattle, Washington, on September 20, 1989.

Leroy A. Keith,

Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 89-23282 Filed 10-2-89; 8:45 am]

BILLING CODE 4910-13-M

14 CFR Part 39

[Docket No. 89-NM-176-AD; Amdt. 39-6347]

Airworthiness Directives; Boeing Model 747 Series Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This amendment adopts a new airworthiness directive (AD), applicable to certain Boeing Model 747 series airplanes equipped with a Door 5 crew rest area, which requires replacement of the oxygen generator release cable assemblies. These cable assemblies are used in the oxygen modules installed in the crew rest area. This action is prompted by reports of broken release pins found during inspection of the same part on Boeing Model 767 series airplanes. This condition, if not corrected, could result in failure of the oxygen generator to activate and supply oxygen to the crew members in the crew rest area.

EFFECTIVE DATE: October 19, 1989.

ADDRESSES: The applicable service information may be obtained from Boeing Commercial Airplanes, P.O. Box 3707 Seattle, Washington 98124. This information may be examined at the FAA, Northwest Mountain Region, Transport Airplane Directorate, 17900 Pacific Highway South, Seattle, Washington, or Seattle Aircraft Certification Office, 9010 East Marginal Way South, Seattle, Washington.

FOR FURTHER INFORMATION CONTACT: David M. Herron, Systems and Equipment Branch, ANM-130S; telephone (206) 431-1949. Mailing address: FAA, Northwest Mountain

Region, 17900 Pacific Highway South, C-68966, Seattle, Washington 98168.

SUPPLEMENTARY INFORMATION: Recently, two operators of Boeing Model 767 series airplanes reported finding broken oxygen generator release pins. If the release pin breaks while attempting to activate the oxygen generator, the firing mechanism will not be activated and oxygen will not be produced. These same passenger oxygen supply units are used in the Door 5 crew rest area on Boeing Model 747 series airplanes. Units affected by the release pin deficiency are only used in the Door 5 crew rest area. The Model 747 passenger oxygen supply units (PSU) do not use an oxygen generator and are not affected by this AD.

The release cable assembly pins used on these airplanes have now been correctly drilled to prevent the fractures from occurring and color coded green for easy recognition.

The FAA has reviewed and approved Boeing Alert Service Bulletin 747-35A2065, dated August 3, 1989, which describes the replacement of the release cable assembly to ensure proper operation of the oxygen generator.

Since this condition is likely to exist or develop on other airplanes of this same type design, this AD requires replacement of the oxygen generator release cable assembly in accordance with the service bulletin previously described.

Since a situation exists that requires immediate adoption of this regulation, it is found that notice and public procedure hereon are impracticable, and good cause exists for making this amendment effective in less than 30 days.

The regulations adopted herein will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, in accordance with Executive Order 12812, it is determined that this final rule does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

The FAA has determined that this regulation is an emergency regulation and that it is not considered to be major under Executive Order 12291. It is impracticable for the agency to follow the procedures of Order 12291 with respect to this rule since the rule must be issued immediately to correct an unsafe condition in aircraft. It has been further determined that this action involves an emergency regulation under DOT Regulatory Policies and Procedures

(44 FR 11034; February 26, 1979). If it is determined that this emergency regulation otherwise would be significant under DOT Regulatory Policies and Procedures, a final regulatory evaluation will be prepared and placed in the regulatory docket (otherwise, an evaluation is not required). A copy of it, if filed, may be obtained from the Rules Docket.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Safety.

Adoption of the Amendment

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

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.

§ 39.13 [Amended]

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

Boeing: Applies to Model 747 series airplanes equipped with a Door 5 crew rest area, certificated in any category. Compliance required within the next 60 days after the effective date of this AD, unless previously accomplished.

To ensure proper operation of the oxygen generators, accomplish the following:

A. Replace the oxygen generator release cable assembly in accordance with Boeing Alert Service Bulletin 747-35A2065, dated August 3, 1989.

B. An alternate means of compliance or adjustment of the compliance time, which provides an acceptable level of safety, may be used when approved by the Manager, Seattle Aircraft Certification Office, FAA, Northwest Mountain Region.

Note: The request should be forwarded through an FAA Principal Maintenance Inspector (PMI), who will either concur or comment, and then send it to the Manager, Seattle Aircraft Certification Office.

C. Special flight permits may be issued in accordance with FAR 21.197 and 21.199 to operate airplanes to a base in order to comply with the requirements of this AD.

All persons affected by this directive who have not already received the appropriate service documents from the manufacturer may obtain copies upon request to Boeing Commercial Airplanes, P.O. Box 3707 Seattle, Washington 98124. These documents may be examined at the FAA, Northwest Mountain Region. Transport

Airplane Directorate, 17900 Pacific Highway South, Seattle, Washington, or Seattle Aircraft Certification Office, 9010 East Marginal Way South, Seattle, Washington.

This amendment becomes effective October 19, 1989.

Issued in Seattle, Washington, on September 22, 1989.

Darrell M. Pederson,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 89-23283 Filed 10-2-89; 8:45 am]

BILLING CODE 4910-13-M

14 CFR Part 39

[Docket No. 88-NM-201-AD; Amdt. 39-6349]

Airworthiness Directives; Boeing Model 767 Series Airplanes, Equipped With Pratt and Whitney JT9D Series Engines or General Electric CF6-80A Series Engines

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This amendment adopts a new airworthiness directive (AD), applicable to Boeing Model 767 series airplanes, which requires modifications to the electromagnetic protection shielding of the wires to the respective engine electronic engine controls (EEC). This amendment is prompted by a review of the wiring installation between the engine fan case and the strut, which has shown that not all engine and EEC wires requiring electromagnetic protection shielding have been shielded. This condition, if not corrected, could lead to an electrical transient from a lightning strike to one engine, which could cause damage or malfunction to the unstruck engine's EEC, this may affect the thrust of the unstruck engine, as well as that of the struck engine. A lightning strike during takeoff, causing maximum EEC downtrim on both engines, could result in a thrust loss greater than the loss of one engine.

EFFECTIVE DATE: November 8, 1989.

ADDRESSES: The applicable service information may be obtained from Boeing Commercial Airplanes, P.O. Box 3707 Seattle, Washington 98124. This information may be examined at the FAA, Northwest Mountain Region, Transport Airplane Directorate, 17900 Pacific Highway South, Seattle, Washington, or Seattle Aircraft Certification Office, 9010 East Marginal Way South, Seattle, Washington.

FOR FURTHER INFORMATION CONTACT: Mr. Bernie Gonzalez, Propulsion Branch, ANM-140S; telephone (206) 431-1964. Mailing address: FAA Northwest Mountain Region, 17900 Pacific Highway South, C-68966, Seattle, Washington 98168.

SUPPLEMENTARY INFORMATION: A proposal to amend part 39 of the Federal Aviation Regulations to include an airworthiness directive, applicable to certain Boeing Model 767 series airplanes equipped with Pratt and Whitney JT9D series engines or General Electric CF6-80A series engines, which requires improvement of the electromagnetic protection shielding of the wires to the respective engine electronic engine controls, was published in the Federal Register on February 14, 1989 (54 FR 6692).

Interested persons have been afforded an opportunity to participate in the making of this amendment. Due consideration has been given to the comments received.

Comments were received from Boeing Commercial Airplanes and from the Air Transport Association (ATA) of America on behalf of three of its members.

Boeing suggested word changes to the description of the unsafe condition to reflect that a lightning strike could cause a "maximum EEC downtrim" rather than a "shutdown" on both engines leading to a thrust loss greater than the loss of one engine. The FAA concurs and this comment has been incorporated in the Summary section of this preamble.

One ATA member disputed the contention that the lightning strike induced thrust loss would be greater than the loss of thrust of a single engine. The member indicated that to its knowledge, the downtrim authority of the CF6-80A engine EEC was in the ten percent (10%) N_1 speed range and equivalent to approximately 12,000 lbs. of thrust at takeoff power. It stated that the total thrust loss would therefore be approximately 24,000 lbs., which is much less than the loss of thrust from a single engine (48,000 lbs.). The ATA indicated that if this member's contention is correct, the FAA should withdraw the AD for lack of justification. The FAA does not concur. A review of the downtrim authority of the EEC provided by the airframe manufacturer, has indicated that, on the Pratt and Whitney JT9D-7R4D/E and the General Electric CF6-80A/80A2 engines installed on the Model 767-200/300 airplanes, the electronic engine controls (EEC) operate by downtrimming the hydromechanical engine fuel control. The authority of this trim is limited by the fuel control N_2

speed governor. Approximate values for these authority limits are 24.8% N_2 and 10.9% N_2 for the respective Pratt and Whitney and General Electric engines. The manufacturer also indicated that the fuel control limits EEC authority so that the engines cannot be downtrimmed below normal idle levels. An EEC failure resulting in the maximum downtrim being applied to the hydromechanical control would result in a significant thrust loss. The magnitude of this thrust loss depends upon the ambient conditions (e.g., ambient temperature, pressure altitude) prevailing at the time of failure. For both engine types, the manufacturer has indicated the loss may exceed 50% thrust at some operating conditions. Should both engine EEC's experience a maximum downtrim, as with a lightning strike induced failure, the loss of thrust would be greater than the loss of a single engine. For the CF6-80A engine noted by the ATA member, a 10.9% N_2 downtrim would result in approximately a 25.8% N_1 speed change under standard day sea level conditions and would be equivalent to a thrust change of 25,600 lbs. for each engine. As the total loss of 51,200 lbs. is greater than the 48,100 lbs. thrust of a single CF6-80A engine at takeoff power, the FAA has determined that an unsafe condition exists, thus justifying the issuance of this AD action.

The ATA also indicated that most of its members intend to accomplish the modification but are opposed to the proposed compliance time of one year. Several members suggested that the compliance time be extended to two or three years, based upon the manufacturer's revised delivery schedule of 40 weeks for the modification parts and the operators' desire to accomplish the modification without removing airplanes from scheduled airline service. The ATA members prefer accomplishing the modification during airplane and engine base maintenance periods/C-check. The FAA does not concur with the suggested three-year compliance time. Since issuance of the NPRM, the availability of modification parts schedule was revised to 40 weeks but, in addition, subsequent revision of the applicable Service Bulletin allows for optional modification parts, increasing the quantity of parts available. The manufacturer indicates the required modifications can be accomplished in 4 to 11 1/2 hours. The FAA considers that accomplishment of this modification does not warrant C-check or base maintenance period scheduling. The FAA has determined that the required modifications can, therefore, be

accomplished within 15 months from the effective date of the AD, allowing for the parts availability, and has revised the AD compliance time to 15 months.

Since issuance of the NPRM, Boeing has issued Revision 1 and Revision 2 to Service Bulletin 767-71-0041, dated April 6, 1989, and June 29, 1989, respectively. These revisions provide for the installation of an optional wire bundle assembly (this will improve the availability of parts, as discussed above), and contain certain procedural clarifications and clerical corrections. The AD has been revised to allow compliance to the later revisions of the service bulletin.

After careful review of the available data, including the comments noted above, the FAA has determined that air safety and the public interest require the adoption of the rule with the changes previously described. The FAA has determined that these changes will neither increase the economic burden on any operator nor increase the scope of the AD.

There are approximately 188 Model 767 series airplanes of the affected design in the worldwide fleet. It is estimated that 93 airplanes of U.S. registry will be affected by this AD, that it will take approximately 35½ manhours per airplane to accomplish the required actions, and that the average labor cost will be \$40 per manhour. The average parts cost per airplane would be \$7,554. Based on these figures, the total cost impact of the AD on U.S. operators is estimated to be \$833,185.

The regulations adopted herein will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, in accordance with Executive Order 12612, it is determined that this final rule does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

For the reasons discussed above, I certify that this action (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) 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 final evaluation has been prepared for this action and is contained in the regulatory docket. A copy of it may be obtained from the Rules Docket.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety; Safety.

Adoption of the Amendment

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

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.

§ 39.13 [Amended]

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

Boeing: Applies to Model 767 series airplanes, equipped with Pratt and Whitney JT9D series engines or General Electric CF6-80A series engines, specified in Boeing Service Bulletin 767-76-0041, dated September 22, 1988, certificated in any category. Compliance required within 15 months after the effective date of this AD, unless previously accomplished.

To minimize the potential for a thrust loss greater than the loss of one engine due to a lightning strike, accomplish the following:

A. Modify the engine electrical and electronic engine control wiring in accordance with Boeing Service Bulletin 767-71-0041, dated September 22, 1988; Revision 1, dated April 6, 1989; or Revision 2, dated June 29, 1989.

B. An alternate means of compliance or adjustment of the compliance time, which provides an acceptable level of safety, may be used when approved by the Manager, Seattle Aircraft Certification Office, FAA Northwest Mountain Region.

Note: The request should be forwarded through an FAA Principal Maintenance Inspector (PMI), who will either concur or comment, and then send it to the Manager, Seattle Aircraft Certification Office.

C. Special flight permits may be issued in accordance with FAR 21.197 and 21.199 to operate airplanes to a base in order to comply with the requirements of this AD.

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

This amendment becomes effective November 8, 1989.

Issued in Seattle, Washington, on September 22, 1989.

Darrell M. Pederson,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 89-23281 Filed 10-2-89; 8:45 am]

BILLING CODE 4910-13-M

14 CFR Part 39

[Docket No. 89-NM-87-AD; Amdt. 39-6346]

Airworthiness Directives; British Aerospace Model BAe 125-800A Series Airplanes, Equipped with Grumman Aerospace Corporation Engine Exhaust Duct Part No. C46P13100-3 or C46P13100-103 (Not Applicable to Airplanes Equipped With Dee Howard Thrust Reversers)

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This amendment adopts a new airworthiness directive (AD), applicable to certain British Aerospace Model BAe 125-800A series airplanes, which requires installation of a strengthened engine exhaust duct. This amendment is prompted by one report of the tail pipe collapsing inward due to compressor stall. This condition, if not corrected, could lead to loss of required engine power.

EFFECTIVE DATE: November 8, 1989.

ADDRESSES: The applicable service information may be obtained from British Aerospace, PLC, Service Bulletin Librarian, P.O. Box 17414, Dulles International Airport, Washington, DC. This information may be examined at the FAA, Northwest Mountain Region, Transport Airplane Directorate, 17900 Pacific Highway South, Seattle, Washington, or the Standardization Branch, 9010 East Marginal Way South, Seattle, Washington.

FOR FURTHER INFORMATION CONTACT: Mr. William Schroeder, Standardization Branch, ANM-113; telephone (206) 431-1565. Mailing address: FAA, Northwest Mountain Region, 17900 Pacific Highway South, C-68966, Seattle, Washington 98168.

SUPPLEMENTARY INFORMATION: A proposal to amend part 39 of the Federal Aviation Regulations to include a new airworthiness directive, applicable to certain British Aerospace Model BAe 125-800A series airplanes, equipped with Grumman Aerospace Corporation engine exhaust duct Part No. C46P13100-3 or C46P13100-103 (not

applicable to airplanes equipped with Dee Howard thrust reversers), which requires installation of a strengthened engine exhaust duct, was published in the Federal Register on June 21, 1989 (54 FR 28053).

Interested persons have been afforded an opportunity to participate in the making of this amendment. Due consideration has been given to the single comment received.

The commenter supported the rule. However, the commenter recommended the compliance time be extended from the proposed 60 days to one year because of the long turn around time for modification of removed exhaust ducts. The FAA agrees with this commenter's suggestion to extend the compliance time. Review of new information concerning parts availability and modification turn around time indicates it takes about 90 days for a part to be modified after it is received at the modification facility. Considering the number of airplanes remaining to be modified in the U.S. fleet, parts modification time, and availability of modified ducts for exchange, it may take as long as 180 days from October 1, 1989, to complete the modification of the U.S. fleet. British Aerospace has also advised that its review indicates a sufficient number of exhaust ducts can be modified to complete the modification of the U.S. fleet within 120 days after October 1, 1989. In view of the fact that an engine compressor stall must occur during certain flight modes for this problem to occur on an exhaust duct and the rather low probability of a compressor stall occurring, the FAA has determined that the compliance time can be extended to 180 days after the effective date of the AD without a significant adverse effect on safety of the fleet. Accordingly, the compliance time in the final AD has been changed to 180 days after the effective date of the AD.

After careful review of the available data, including the comments noted above, the FAA has determined that air safety and the public interest require the adoption of the rule with the change noted above. The change will neither increase the economic burden on any operator, nor increase the scope of the rule.

It is estimated that 38 airplanes of U.S. registry will be affected by this AD, that it will take approximately 20 manhours per airplane to accomplish the required actions, and that the average labor cost will be \$40 per manhour. Based on these figures, the total cost impact of the AD on U.S. operators is estimated to be \$30,400.

The regulations adopted herein will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, in accordance with Executive Order 12612, it is determined that this final rule does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

For the reasons discussed above, I certify that this action (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) 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 final evaluation has been prepared for this action and is contained in the regulatory docket. A copy of it may be obtained from the Rules Docket.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Safety.

Adoption of the Amendment

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

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.

§ 39.13 [Amended]

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

British Aerospace: Applies to Model BAe 125-800A series airplanes equipped with Grumman Aerospace Corporation engine exhaust duct Part No. C46P13100-3 or C46P13100-103 (not applicable to airplanes with Dee Howard thrust reversers) certificated in any category. Compliance is required within 180 days after the effective date of this AD, unless previously accomplished.

To prevent collapse of the engine exhaust duct, accomplish the following:

A. Replace the left and right engine exhaust ducts in accordance with British Aerospace Service Bulletin 71-40-3213A, Revision 2, dated April 12, 1989.

B. An alternate means of compliance or adjustment of the compliance time, which provides an acceptable level of safety, may be used when approved by the Manager,

Standardization Branch, ANM-113, FAA, Northwest Mountain Region.

Note: The request should be forwarded through an FAA Principal Maintenance Inspector (PMI), who will either concur or comment and then send it to the Manager, Standardization Branch, ANM-113.

C. Special flight permits may be issued in accordance with FAR 21.197 and 21.199 to operate airplanes to a base in order to comply with the requirements of this AD.

All persons affected by this directive who have not already received the appropriate service documents from the manufacturer may obtain copies upon request to British Aerospace, PLC, Service Bulletin Librarian, P.O. Box 17414, Dulles International Airport, Washington, DC 20041. These documents may be examined at the FAA, Northwest Mountain Region, Transport Airplane Directorate, 17900 Pacific Highway South, Seattle, Washington, or the Seattle Aircraft Certification Office, 9010 East Marginal Way South, Seattle, Washington.

This amendment becomes effective November 8, 1989.

Issued in Seattle, Washington, on September 22, 1989.

Darrell M. Pederson,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.
[FR Doc. 89-23284 Filed 10-2-89; 8:45 am]

BILLING CODE 4910-13-M

14 CFR Part 39

[Docket No. 88-ASW-56; Amdt. 39-6340]

Airworthiness Directives; Sikorsky Aircraft Model S-61N and S-61NM Helicopters

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule; correction.

SUMMARY: This amendment amends an airworthiness directive (AD) which requires periodic inspections for cracks in the main landing gear (large sponson) truss assemblies; a one-time hardness test of the butt-welded lug of sponson truss components; and replacement of the components, as necessary, on Sikorsky Model S-61N and S-61NM series helicopters. This amendment is needed to correctly identify part numbers misidentified in the last amendment.

EFFECTIVE DATE: October 30, 1989.

Compliance: As indicated in the body of the AD.

ADDRESSES: The applicable service bulletin may be obtained from Sikorsky Aircraft, 600 Main Street, Stratford, Connecticut 06601-1381, or may be

examined in the Regional Rules Docket, Office of the Assistant Chief Counsel, FAA, 4400 Blue Mound Road, Bldg. 3B, Room 158, Forth Worth, Texas.

FOR FURTHER INFORMATION CONTACT:

Richard B. Noll, Boston Aircraft Certification Office, Engine and Propeller Directorate, Aircraft Certification Service, FAA, 12 New England Park, Burlington, Massachusetts 01803, telephone (617) 273-7111.

SUPPLEMENTARY INFORMATION: This amendment amends Amendment 39-6131 (54 FR 6512; February 13, 1989), AD 89-04-91, as amended by Amendment 39-6279 (54 FR 31505; July 31, 1989), AD 89-04-01 R1, which currently requires periodic inspections for cracks in the main landing gear (large sponson) truss assemblies; a one-time hardness test of the butt-welded lug of sponson truss components to determine if the hardness is within an approved range; and replacement of the components, as necessary, on Sikorsky Models S-61N and S-61NM series helicopters. The one-time hardness test is applicable to certain truss tube assemblies which have a butt-welded end fitting with a lug welded to the end fitting. A Tungsten inert gas (TIG)-welded single piece end fitting which has the lug as an integral part of the fitting does not require the hardness test.

Since issuing the AD, the FAA has determined that four part numbers included in the introductory text of paragraph (a) and one part number and location for the last truss listed in Table 1 were misidentified. Therefore, the FAA is amending AD 89-04-01, Amendment 39-6131, as amended by Amendment 39-6279, to correctly identify these part numbers.

Since this amendment is clarifying in nature only, and imposes no additional burden on any person, notice and public procedure hereon are unnecessary, and the amendment may be made effective in less than 30 days.

The regulations adopted herein will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, in accordance with Executive Order 12612, it is determined that this final rule does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

The FAA has determined that this regulation is clarifying in nature and imposes no further cost. Therefore, I certify that this action (1) is not a "major rule" under Executive Order 12291, (2) is not a "significant rule" under DOT

Regulatory Policies and Procedures (44 FR 10034; February 26, 1979). A copy of the final evaluation prepared for this action is contained in the regulatory docket. A copy of it may be obtained from the Regional Rules Docket.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Safety.

Adoption of the Amendment

Accordingly, pursuant to the authority delegated to me by the Administrator, the Federal Aviation Administration amends § 39.13 of part 39 of the Federal Aviation Regulations as follows:

PART 39—AIRWORTHINESS DIRECTIVES

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.

§ 39.13 [Amended]

2. Section 39.13 is amended by amending Amendment 39-6131 (54 FR 6512; February 13, 1989), AD 89-04-01, as amended by Amendment 39-6279 (54 FR 31505; July 31, 1989), AD 89-04-01R1, by revising paragraph (a) introductory text as follows; and by revising Table 1 by removing part number (P/N) 61250-51234-041 (sponson tube truss assembly column) and the words "clevis and lug hole" (inspection locations column) under the 2500 inspection interval section; and inserting P/N S6125-51217-1, -041 and the words "clevis lug hole" in their place in the 2500 inspection interval section:

Sikorsky Aircraft: Applies to Models S-61N and S-61NM helicopters certificated in any category [Docket No. 88-ASW-56]

(a) Within the next 50 hours' time in service after the effective date of this AD, conduct a hardness test of each welded lug of sponson truss tube assemblies, part number (P/N): S6125-51212-4 and 61250-51233-042, aft lower truss tube assembly-left side; S6125-51212-5 and 61250-51233-043, aft lower truss tube assembly-right side; S6125-51214-3 and 61250-51235-041, forward upper truss tube assembly-left and right side; and S6125-51214-4 and 61250-51235-042, aft upper truss tube assembly-left and right side, as follows:

This amendment becomes effective October 30, 1989.

This amendment amends Amendment 39-6131 (54 FR 6512; February 13, 1989), AD 89-04-01, as amended by Amendment 39-6279 (54 FR 31505; July 31, 1989), AD 87-04-01R.

Issued in Fort Worth, Texas, on September 19, 1989.

James D. Erickson,

Acting Manager, Rotorcraft Directorate, Aircraft Certification Service.

[FR Doc. 89-23272 Filed 10-2-89; 8:45 am]

BILLING CODE 4910-13-M

DEPARTMENT OF COMMERCE

Bureau of Export Administration

15 CFR Part 776

[Docket No. 81136-9154]

RIN 0694-AA06

Exports from Abroad of Foreign Products Incorporating U.S.-Origin Parts and Components

AGENCY: Bureau of Export Administration, U.S. Department of Commerce.

ACTION: Interim rule with request for comments.

SUMMARY: On December 7 1988, the Bureau of Export Administration (BXA) published a proposed rule (53 FR 49327) designed to implement section 5(a)(5)(A) of the Export Administration Act of 1979, as amended by the Omnibus Trade and Competitiveness Act of 1988. Having reviewed and considered the comments on the proposed rule, BXA is now issuing this interim rule that revises § 776.12 of the Export Administration Regulations (EAR) to reduce U.S. export controls on U.S.-origin parts and components incorporated in foreign-made products. This change applies a 25% exemption to all destinations, except that a 10% exemption—with no dollar value limitation—is continued for Country Groups S and Z, and Iran, Syria and the People's Democratic Republic of Yemen. Paragraph (h) of § 776.12, which addressed controlled in fact entities, has been removed because of the expansion of the 25% exemption.

This rule also creates a new exemption based on the Advisory Notes that indicate a likelihood of approval for exports to Country Groups Q, W, and Y. Like the 25% exemption, the QWY Advisory Note exemption applies to all destinations, except those located in Country Group S or Z, or in Iran, Syria or the People's Democratic Republic of Yemen. A 10% exemption—with no dollar value limitation—applies to these destinations.

The effect of this rule will be to reduce the licensing requirements that would apply to foreign products containing U.S.-origin parts and components.

The Commerce Department will consider comments on these changes; especially comments concerning the economic impact on U.S. firms of retaining a 10% exemption—with no dollar value limitation—on Iran, Syria, the People's Democratic Republic of Yemen, and Country Groups S and Z.

EFFECTIVE DATE: This rule is effective October 3, 1989. Comments must be received by November 2, 1989.

ADDRESSES: Written comments (six copies) should be sent to: Willard Fisher, Office of Technology and Policy Analysis, Bureau of Export Administration, Department of Commerce, P.O. Box 273, Washington, DC 20044.

FOR FURTHER INFORMATION CONTACT: Willard Fisher, Regulations Branch, Bureau of Export Administration, Telephone: (202) 377-3856.

SUPPLEMENTARY INFORMATION:

Background

The Omnibus Trade and Competitiveness Act amended section 5(a)(5)(A) of the Export Administration Act of 1979 (the Act), as amended, to require a reduction of U.S. controls on U.S.-origin parts and components incorporated in foreign products. Currently, when U.S.-origin parts and components are valued at \$10,000 or less and comprise 10% or less of the value of a foreign-made product, the Export Administration Regulations (EAR) permit the foreign-made product to be exported from abroad to any destination without written U.S. authorization. Written U.S. authorization is also not required for exports, from foreign countries, of foreign-made products with a U.S. content value of 25% or less to countries listed in Supplement No. 2 or 3 to part 773, except Ethiopia, Lebanon, and Nicaragua.

The U.S. Department of Commerce proposed, on December 7, 1988 (53 FR 49327), to amend § 776.12 of the Export Administration Regulations (15 CFR parts 730-799) by making three significant revisions:

(1) Expanding the existing 25% exemption to apply to countries not listed in Supplement No. 2 or 3 to part 773, and to Ethiopia, Lebanon, and Nicaragua, provided that the export of the foreign product to the new destination would be subject to U.S. national security controls only;

(2) Creating an exemption from written authorization requirements that applies to foreign-made products containing U.S.-origin content when none of the U.S. content, regardless of its value, exceeds the technical performance characteristics of any

Advisory Note on the Commodity Control List that indicates licenses are likely to be approved for export to satisfactory end-users in Country Groups Q, W, and Y—unless the new destination is in Ethiopia, Lebanon, or Nicaragua or in a country not listed in Supplement No. 2 or 3 to part 773 and the export of the foreign product would be subject to U.S. export controls other than, or in addition to, national security controls; and

(3) Revising the definition of "U.S. content value" in § 776.12(d) to exclude parts, components, or materials that could be exported from the United States to the new country of destination under General Licenses G-COCOM, G-COM, or GFW as well as General License G-DEST.

The Department received public comments from 12 firms and associations. In general, the comments were opposed to the restrictions that the proposed rule placed on countries not listed in Supplement Nos. 2 or 3, and to Ethiopia, Lebanon, and Nicaragua. Most comments stressed that the proposed exemptions should apply to all destinations, regardless of the reason for control. Comments concerning the definition of the term "U.S. content value"—which was revised to exclude components that may be exported to the new destination under General Licenses G-COCOM, G-COM, and GFW as well as General License G-DEST—were generally favorable.

In drafting this interim rule, the Department has reviewed the public comments that address the scope of the 25% and QWY Advisory Note exemptions. Both the 25% exemption and the QWY Advisory Note exemption described in the proposed rule are expanded to apply to all destinations—except for those located in Country Group S or Z, or in Iran, Syria or the People's Democratic Republic of Yemen—regardless of the reason for control. A 10% exemption—with no dollar value limitation—will apply to destinations located in Country Group S or Z, or in Iran, Syria or the People's Democratic Republic of Yemen.

This interim rule, like the proposed rule, revises the U.S. content that is to be counted when calculating "U.S. content value" as defined in § 776.12(d). Parts, components, or materials that could be exported from the United States to the new country of destination under General Licenses G-DEST, G-COCOM, G-COM, or GFW may be excluded from the calculation of "U.S. content value." Previously, under the EAR, only G-DEST items were excluded from this calculation.

Several comments expressed support for providing an exemption for U.S. origin parts and components incorporated in foreign-made supercomputers provided that the U.S. origin parts and components could be exported to the new destination under General Licenses G-COCOM, G-COM, and GFW, as well as General License G-DEST. These comments were not adopted. However, this rule does clarify the supercomputer restriction by stating that exports of U.S.-origin parts and components incorporated in foreign-made supercomputers may be made under § 776.12(b). Provided that these parts and components are eligible for export to the new destination under General License G-DEST. The Department will treat cases involving supercomputers on a case-by-case basis.

The interim rule also revises § 776.12(d). This section previously permitted U.S.-origin controlled spare parts to accompany a shipment of a foreign-made product incorporating U.S.-origin parts and components, provided that the value of the spare parts did not exceed the value of the controlled U.S. content in the foreign-made product. The interim rule limits the value of the U.S.-origin spare parts that may accompany such a shipment to 10% of the value of the foreign-made product. This change is made to ensure that only a reasonable complement of spares will be shipped.

Exporters are reminded that, in accordance with the provisions of § 779.8, a foreign-made product that is the direct product of U.S.-origin technical data may require U.S. authorization regardless of the U.S. content. Exporters should be also aware that this rule deals only with U.S.-origin parts and components incorporated in foreign-made products. Statutory provisions related to U.S.-origin technical data that are used to produce foreign-made products and to section 5(m) of the Act, "Goods Containing Controlled Parts and Components" will be implemented in separate rules.

Exporters have claimed that this change will significantly benefit exports of U.S.-origin parts and components by encouraging foreign manufacturers to continue to use or even expand their use of U.S.-origin parts and components in their products. Industry has not quantified the increase in exports that may result from this change. The Department does not have adequate data available to estimate the trade volume that might be affected by these changes.

The Commerce Department will consider comments that address the

changes made by this interim rule, including comments on the economic impact on U.S. firms of retaining a 10% exemption—with no dollar value limitation—for Iran, Syria, the People's Democratic Republic of Yemen, and Country Groups S and Z.

Rulemaking Requirements

1. This rule complies with Executive Order 12291 and Executive Order 12661.

2. This rule contains a collection of information subject to the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 *et seq.*). This collection has been approved by the Office of Management and Budget under control number 0694-0010. Public reporting burden for this collection of information is estimated to average 25 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to the Office of Security and Management Support, Bureau of Export Administration, U.S. Department of Commerce, Room 3889, Washington, DC 20230; and to the Office Information and Regulatory Affairs, Office of Management and Budget, Washington, DC 20503—ATTN: Paperwork Reduction Project (0694-0010). The effect of the rule will be to reduce the paperwork burden on the public.

3. This rule does not contain policies with Federalism implications sufficient to warrant preparation of a Federalism assessment under Executive Order 12612.

4. Because a notice of proposed rulemaking and an opportunity for public comment are not required to be given for this rule by section 553 of the Administrative Procedure Act (5 U.S.C. 553) or by any other law, under sections 603(a) and 604(a) of the Regulatory Flexibility Act (5 U.S.C. 603(a) and 604(a)) no initial or final Regulatory Flexibility Analysis has to be or will be prepared.

5. Section 13(a) of the Export Administration Act of 1979, as amended (50 U.S.C. app. 2412(a)), exempts this rule from all requirements of section 553 of the Administrative Procedure Act (APA) (5 U.S.C. 553), including those requiring publication of a notice of proposed rulemaking, an opportunity for public comment, and a delay in effective date. This rule is also exempt from these APA requirements because it involves a foreign and military affairs function of the United States. This rule is not

subject to the requirements of section 13(b) of the Export Administration Act because it is not imposing new controls. Further, no other law requires that a notice of proposed rulemaking and an opportunity for public comment be given for this rule.

However, because of the importance of the issues raised by these regulations, this rule is issued in interim form and comments will be considered in the development of final regulations. Accordingly, the Department encourages interested persons who wish to comment to do so at the earliest possible time to permit the fullest consideration of their views.

The period for submission of comments will close November 2, 1989. The Department will consider all comments received before the close of the comment period in developing final regulations. Comments received after the end of the comment period will be considered if possible, but their consideration cannot be assured. The Department will not accept public comments accompanied by a request that part or all of the material be treated confidentially because of its business proprietary nature or for any other reason. The Department will return such comments and materials to the person submitting the comments and will not consider them in the development of final regulations. All public comments on these regulations will be a matter of public record and will be available for public inspection and copying. In the interest of accuracy and completeness, the Department requires comments in written form. Oral comments must be followed by written memoranda, which will also be a matter of public record and will be available for public review and copying. Communications from agencies of the United States Government or foreign governments will not be made available for public inspection.

The public record concerning these regulations will be maintained in the Bureau of Export Administration Freedom of Information Records Inspection Facility, Room 4886, Department of Commerce, 14th Street and Pennsylvania Avenue, NW., Washington, DC 20230. Records in this facility, including written public comments and memoranda summarizing the substance of oral communications, may be inspected and copied in accordance with regulations published in part 4 of title 15 of the Code of Federal Regulations. Information about the inspection and copying of records at the facility may be obtained from Margaret Cornejo, Bureau of Export Administration Freedom of Information

Officer, at the above address or by calling (202) 377-2593.

List of Subjects in 15 CFR Part 776

Exports, Reporting and recordkeeping requirements.

Accordingly, part 776 of the Export Administration Regulations (15 CFR parts 730-799) is amended as follows:

1. The authority citation for 15 CFR part 776 continues to read as follows:

Authority: Pub. L. 96-72, 93 Stat. 503 (50 U.S.C. app. 2401 *et seq.*), as amended by Pub. L. 97-145 of Dec. 29, 1981, by Pub. L. 99-64 of July 12, 1985, and by Pub. L. 100-418 of August 23, 1988; E.O. 12525 of July 12, 1985 (50 FR 28757 July 16, 1985).

PART 776—[AMENDED]

3. Section 776.12 is amended by revising the section heading, by revising the introductory text, by revising paragraphs (a), (b), (c), (d), (e)(2)(i) through (e)(2)(ix), and (e)(3), by adding paragraphs (e)(2)(x) through (e)(2)(xii), by removing paragraph (h), and by adding a parenthetical phrase at the end of the section, as follows:

§ 776.12 Parts, components, and materials incorporated abroad into foreign-made products.

U.S. origin parts, components, materials, or other commodities incorporated abroad into a foreign-made product are subject to United States export controls under § 776.12. U.S. origin parts, components, materials, or other commodities that are not incorporated abroad into products are subject to the reexport provisions of part 774. U.S. origin peripheral or accessory devices that are merely rack mounted with or cable connected into foreign equipment are not deemed to be incorporated components even though intended for use with products made abroad. Rather, such items are treated as U.S. items that retain their identity and remain subject to the reexport provisions of part 774. The Department of Commerce asserts control over parts, components, and materials incorporated in foreign-made products to prevent the use of such U.S. origin parts, components, or materials in a manner detrimental to the national security or foreign policy of the United States. These controls do not apply if either the U.S. content or the foreign-made product is subject to control only for short supply reasons.

(a) *Calculation of values.* Use the following guidelines in determining values for establishing exemptions or for submission of a request for authorization:

(1) *U.S. content value.* (i) U.S. content value is the delivered cost to the foreign manufacturer of the U.S. origin parts, components, or materials. (When affiliated firms have special arrangements that result in lower than normal pricing, the cost should reflect "fair market" prices that would normally be charged to similar, unaffiliated customers.)

(ii) In calculating the U.S. content value, do not include parts, components, or materials that could be exported from the United States to the new country of destination under General License G-DEST, G-COCOM, G-COM, or GFW.

(2) The foreign-made product value is the normal export selling price f.o.b. factory (excluding value added taxes or excise taxes).

(b) *Determining approval requirements.* The prior written approval of the Office of Export Licensing is required for the export from a foreign country of a foreign-made supercomputer containing U.S. origin parts, components, or materials that are not G-DEST to the new destination, without exception. Prior written approval also is required for any other foreign-made product incorporating U.S. origin parts, components, or materials, unless:

(1) The export of the foreign-made product meets any of the conditions of § 774.2 (permissive reexports); or

(2) All of the U.S. content could be exported from the United States to the new destination under General License G-DEST or G-COCOM; or

(3) The U.S. content value is 10% or less; or

(4) The U.S. content value is 25% or less and the ultimate destination of the foreign-made product is not located in Country Group S or Z, or in Iran, Syria or the People's Democratic Republic of Yemen; or

(5) None of the technical performance characteristics of the U.S. content exceed those of any Advisory Note in the CCL that indicates licenses are likely to be approved for Country Groups Q, W, and Y and the ultimate destination of the foreign-made product is not located in Country Group S or Z, or in Iran, Syria or the People's Democratic Republic of Yemen.

Note: See § 776.12(g) for other controls that may apply even if the export would be exempted from prior written approval by paragraph (b) of this section.

(c) *Applicability of exceptions to approval requirements.* The exceptions to the approval requirements in paragraph (b) of this section apply only if the U.S. content is normal and usual for the product being exported and is

not physically incorporated in the foreign product as a device to evade the requirement for reexport authorization.

(d) *Spare parts.* Shipments of foreign-made products that incorporate U.S. origin components may be accompanied by U.S. origin controlled spare parts, provided that they do not exceed 10% of the value of the foreign-made product.

(e) How to request approval.

(1)

(2)

(i) In Item 4, insert "Parts and Components".

(ii) In Item 6, insert the foreign party who will be receiving the foreign-made product (if various, state "various" and list the specific countries, Country Groups, or geographic areas in Item 14 or on an attached sheet);

(iii) In Item 8, insert the foreign party who will be exporting the foreign-made product incorporating U.S. origin parts, components or materials;

(iv) In Item 9(a), specify the quantity for each foreign-made product, if known—otherwise insert "1".

(v) In Item 9(b), briefly describe the foreign-made product that will be exported, specifying type and model or part number. Attach brochures or specifications, if available. Show as part of the description in Item 9(b) the unit value, in U.S. dollars, of the foreign-made product (if more than one foreign-made product is listed on the application, specify the unit value for each type/model/part number). Also include in Item 9(b) a description of the U.S. content (including the applicable Export Control Commodity Number(s)) and its value in U.S. dollars. If more than one foreign-made product is identified on the application, describe the U.S. content and specify the U.S. content value for each foreign-made product. Provide sufficient supporting information to explain the basis for the stated values. To the extent possible, explain how much of the value of the foreign-made product represents foreign origin parts, components, or materials, as opposed to labor, overhead, etc. When the U.S. content varies and cannot be specified in advance, provide a range of percentage and value that would indicate the minimum and maximum U.S. content;

(vi) In Item 9(c), enter the applicable Export Control Commodity Number (ECCN) opposite the description of each foreign-made product;

(vii) In Item 9(d), "total price" insert "0" opposite the commodity description of each foreign-made product;

(viii) In Item 9(d), "total of entire transaction" insert "0".

(ix) Include separately in Item 9(b) a description of any U.S. origin spare

parts to be reexported with the foreign-made product, if they exceed the amount allowed by paragraph (d) of this section. Enter the quantity, if appropriate, in Item 9(a). Enter the ECCN for the spare parts in Item 9(c) and show the value of the spare parts in Item 9(d);

(x) In Item 11, indicate "Parts and Components Request" and describe the activity of the end-user (new ultimate consignee) and the end-use of the foreign-made product. Indicate the final configuration if the product is intended to be incorporated in a larger system. If end-use is unknown, state "unknown" and describe the general activities of the end-user;

(xi) In Item 13, check "Other" and insert "P & C".

(xii) If the foreign-made product is the direct product of U.S. origin technical data that was exported subject to written assurance, a request for waiver of that assurance, if necessary, may be made in Item 14. If U.S. origin technical data will accompany a shipment to Country Groups Q, S, W, Y or Z, or the People's Republic of China, explain in Item 14 what type of data and how it will be used.

(3) Multiple requests. OEL will consider requests on Form BXA-699P for authorization to export to multiple consignees or multiple countries. Such requests will not be approved for Country Groups S or Z and may be approved only in limited circumstances for Country Groups Q, W, Y, and the People's Republic of China. To submit such a request, insert "various" in Item 6 of Form BXA-699P and list the countries or Country Groups where the commodities will be marketed in Item 11 or 14.

(Approved by the Office of Management and Budget under control number 0694-0010).

Dated: September 28, 1989.

James M. LeMunyon,
Deputy Assistant Secretary for Export Administration.

[FR Doc. 89-23333 Filed 10-2-89; 8:45 am]

BILLING CODE 3510-DT-M

15 CFR Part 779

[Docket No. 60228-9157]

RIN 0694-AA17

General License GTDA: Technical Data Available to All Destinations

AGENCY: Bureau of Export Administration, U.S. Department of Commerce.

ACTION: Final rule.

SUMMARY: On Friday, May 16, 1986, a notice of proposed rulemaking was published in the *Federal Register* (51 FR 17986). It sought to provide clarified guidelines for the use of Export Administration Regulations § 779.3, General License GTDA: technical data available to all destinations, and invited comments from the public. This final rule includes some of the suggestions made in the public comments on that proposed rule. A detailed discussion of the public comments is contained in the SUPPLEMENTARY INFORMATION section of this document.

EFFECTIVE DATE: This rule is effective October 3, 1989.

FOR FURTHER INFORMATION CONTACT: Jim Seevaratnum, Bureau of Export Administration, Telephone: (202) 377-5695.

SUPPLEMENTARY INFORMATION:

Background

In addition to soliciting comments on the May 16, 1986 proposed clarification, the Department specifically requested public comments on the treatment of software and on the definition of "public availability."

The Department received thirty-six responses, including comments from 14 universities, six corporations, nine associations, and two individuals. The interagency Working Group on Export Controls and Scientific Communications, which had formulated the recommendations upon which the proposed changes were based, met twice to consider the responses and to make recommendations to the Department.

Most public comments were positive and urged adoption of the proposed rule, although a few responses suggested fundamentally different approaches or recommended that final adoption be postponed pending further study of the issues behind the proposed changes. There was general recognition that the guidelines clarified certain ambiguities in the regulations, and yet conformed with existing Commerce Department interpretations.

The proposed revisions to §§ 779.1 and 779.4 published in the May 1986 proposed rule were treated in the general revision to part 779 of the EAR, which was published in the *Federal Register* in proposed form on October 13, 1988 (53 FR 40074).

Specific comments were as follows:

1. *Treatment of software.* Public comment overwhelmingly favored retaining the treatment of software as proposed. The Working Group also recommended to Commerce that the treatment of software remain as

proposed in the draft regulation. Consequently, no change has been made.

2. *Definition of "publicly available" (section 779.3(b)).* Comments on 779.3(b) were generally very favorable.

Several commenters noted that because the term "public domain" is a term-of-art in copyright law, use of the same term in § 779.3(b) might cause confusion and unintentionally limit the meaning of the section to items with no copyright protection. They recommended that the phrase "become generally accessible to the interested public" be substituted for the phrase "are put into the public domain." The Working Group also recommended this change. Consequently, the subsection is changed to read as follows:

Information is made public and so becomes "publicly available" when it becomes generally accessible to the interested public in any form, including

One Government commenter suggested that § 779.3(b) state explicitly that information in issued patents available from the Patent and Copyright Office (that is, issued patents not covered by secrecy orders) is publicly available. A new subparagraph has been added to § 779.3(b) to this effect.

Other comments noted that the scope of the items listed in § 779.3(b)(1) should be expanded to include optical or laser disk media. The Working Group agreed that it was not its intent to exclude such items and recommended that the language of the subsection be broadened.

The Department concurs and the subsection has been revised to read as follows:

(b)

(1) Publication in periodicals, books, print, electronic, or any other media

Following interagency consultation, Commerce is clarifying the maximum price at which technical data and software not otherwise publicly available nonetheless qualifies for General License GTDA. Such maximum price may not exclude the costs of reproduction and distribution. This reflects the current practice of BXA. Many aspects of this provision of the rule are clarified in the question and answer section at the end of the rule. As to mass-market software, proposed General License GTDU will provide much of the additional relief software firms sought in the review of General License GTDA and during the broader technical data review now coming to a close.

Several other minor changes were suggested by a number of commenters, but none were deemed as significant.

3. *"Information resulting from fundamental research" § 779.3(c).*

Comments suggested that the phrase "trade secrets" as used in § 779.3(c)(2)(ii), "university-based research" was too narrow and restrictive. They argued that there is no significant difference between a sponsor's prepublication review for inadvertent disclosure of trade secrets and review for inadvertent disclosure of other proprietary information. The Working Group agreed and recommended that the subsection be revised as follows:

Prepublication review by a sponsor of university research solely to ensure that publication would not inadvertently divulge proprietary information that the sponsor has furnished to the researchers does not change the rule described in (c)(2)(i).

One comment from within the Government suggested that for clarity and closer conformity with § 779.3(f), § 779.3(c)(4) be revised slightly. The Working Group agreed and recommended that it read as follows:

Research conducted by scientists or engineers working for a business entity will be considered "fundamental research" at the time and to the extent that the researchers are free to make scientific and technical information resulting from the research publicly available without restriction or delay based on proprietary concerns or specific national security controls, as detailed in paragraph (f) of this section.

These recommendations have been adopted.

4. *Impact of regulation on corporate activities.* Several comments from industry stated that although the proposed rules resolved many outstanding issues for the scientific and educational communities, they posed concerns for industry that needed to be resolved:

a. *Proprietary research informally shared among scientists.* Commenters questioned the operational presumption of § 779.3(c)(4) that corporate research will be considered "fundamental research" only when researchers are free to make their work "available without restriction or delay based on proprietary or national security considerations." They argued that certain research, which one commenter termed "interim research" may be communicated between U.S. employees and foreign persons "at a point in time when it cannot yet be determined whether any prepublication review by the company is to be limited solely to non-compromise of patent rights or whether the company prepublication review will have a broader purpose." Put another way, certain data is

communicated informally between and among scientists—with the approval of the company—but is not allowed to be generally released by publication or to be otherwise made available without the prior review of the company. This type of data, it is argued, should be given the same treatment as “university-based research” in § 779.3(c)(2).

The difficulty is that there is no operational way to know, either before or after the fact, when these data are freed for open scientific communication other than by the company's own actions. The presumption that research results will be openly published does not hold for corporate research as it does for university-based research. Corporate research, generally speaking, is intended to be proprietary.

This limitation on corporate research in GTDA should not hamper commercial operations extensively. In many cases, General License GTDR offers full relief.

b. Prepublication review. Section 779.3(c)(2)(ii) permits research conducted at universities to be considered “fundamental research” despite a sponsor's right to prepublication review if the review is “solely” to ensure that the publication would not compromise patent rights or inadvertently divulge the sponsor's proprietary information provided by the sponsor to the researchers.

No similar exception was provided in § 779.3(c)(4) for corporate research. This difference in treatment was objected to as having no public policy justification. Section 779.3(c)(4) has been revised to eliminate the difference, and the sentences at issue now read as follows:

Prepublication review by the company solely to ensure that the publication would compromise no proprietary information provided by the company to the researchers is not considered to be a proprietary restriction under paragraph (c)(4)(i) of this section.

Prepublication review by the company solely to ensure that prepublication would compromise no patent rights will not be considered a proprietary restriction for this purpose, so long as the review causes no more than a temporary delay in publication of the research results.

c. Definition of “fundamental research” (§ 779.3(c)). A number of comments, including those from universities and other organizations, revealed confusion over the definition of “fundamental research” in § 779.3(c)(1). Some saw two hurdles to be overcome before qualifying under the section—the definition in paragraph (c)(1) and the requirements of paragraphs (c)(2) through (c)(4). Others saw contradictions between the definition and either the previously announced

Presidential policy or other parts of the section itself.¹

Section 779.3 (c)(2) through (c)(4) was written first and was always intended to serve as the operational definition of the term “fundamental research. Section 779.3(c)(1) was added later, but logically put first to clarify the intent behind the operational definitions. Section 779.3(c)(1) has been revised with the hope of ending any confusion and reads as follows:

Fundamental research. Paragraphs (c)(2) through (c)(4) and paragraph (f) provide specific operational rules that will be used to identify whether research in particular institutional contexts qualifies as “fundamental research. The intent behind those operational rules is to identify as “fundamental research” basic and applied research in science and engineering, where the resulting information is ordinarily published and shared broadly within the scientific community. Such research can be distinguished from proprietary research and from industrial development, design, production, and product utilization, the results of which ordinarily are restricted for proprietary or national security reasons.

5. “Patent applications” § 779.3(e). The Council on Governmental Relations (COGR) and several universities suggested expanding GTDA coverage to include information contained in a patent application when sent to a foreign country before or within six months following the filing of a United States patent application for the purpose of obtaining the signature of an inventor who was in the United States when the invention was made or who is a co-inventor with a person residing in the United States.

This suggested change has been added to § 779.3(e).

6. “Government-sponsored research covered by contract controls” § 779.3(f). There was considerable comment on this section. Many of the comments were the result of misunderstanding the nuances of the section itself and its relation to § 779.3(c) on “fundamental research” and to previously announced Presidential policy. The Interagency Working Group recommended that the subsection be unchanged, but it also recommended that a more detailed explanation of the intent behind the section be given.

Commenters correctly noted that the definition of “fundamental research” in § 779.3(c)(1) parallels that set forth in previously announced Presidential policy proclaiming as national policy that “the products of fundamental research remain unrestricted” and that

“where the national security requires control, the mechanism for control is classification”² The comments suggested that § 779.3(f), as presently formulated, is inconsistent with this policy.

Consistent with the previously announced Presidential policy, § 779.3(c)(1) defines “Fundamental research” to exclude work “the results of which are restricted for national security reasons. Section 779.3(f) deals with research that is indeed restricted for national security reasons by specific controls agreed on in a contract or other funding agreement. In effect, however, it only partially exempts such work from the general license made available for “fundamental research” Section 779.3(f)(1) states that the general license remains available “for any export of information resulting from the research that is consistent with the specific controls” The effect is to reinforce contract controls with the remedies available under the Export Administration Act, but to restrict scientific communication as minimally as possible consistent with those controls. In effect, moreover, an institution accepting such a contract needs to be concerned only about compliance with the contract controls it has agreed to, not with a second set of requirements under these regulations.

A number of rewordings were considered to make clearer the consistency of § 779.3(f) with the definition of “fundamental research” Each of them seemed either to allow an interpretation that would remove the intended partial availability of the general license, or to add too many extra words and complications, or both. Therefore no change has been made from the proposed regulation. Neither the intent nor the effect of the regulatory language detracts from the previously announced Presidential policy; on the contrary, these regulations provide a broader general license than would be strictly required by that policy.

7 “Consulting” § 779.3(g). One commenter noted that § 779.3(g) on consulting was not necessary because it had no operative effect and stated the obvious. The Working Group, which recommended the subsection, recognized that it is redundant. The Working Group continues to believe, however, that because consulting is an especially effective mechanism of technology transfer, the section should remain as a reminder to persons that while General License GTDA allows release of technical data described in

¹ See Statement by Principal Deputy Press Secretary to the President, 21 *Weekly Comp. Pres. Doc.* 1147 (Sept. 27, 1985).

² *Id.* at 1148.

§ 779.3(a)(1) by means of a consulting arrangement, it does not authorize release of other technical information or application abroad of other personal knowledge or technical experience acquired in the United States.

Other comments argued that training is also an effective means of technology transfer and should also be mentioned with consulting. The Working Group agreed and the provision has been revised accordingly.

Because the statement is merely cautionary, it has been redesignated as a note following § 779.3(g), rather than a paragraph within it. It now reads:

Note: Consulting and training. Technical data can be inadvertently exported in various ways. Consulting and training are especially effective mechanisms of technology transfer. The exporter should be aware that the Department of Commerce maintains controls on exports of technical data that do not qualify for General License GTDA as described in paragraphs (a)(1) through (a)(3) of this section, including application abroad of personal knowledge or technical experience acquired in the United States. (See also paragraph (g)).

Paragraph (h), Advice concerning uncontrolled information, has been redesignated as paragraph (g).

8. *The term "information" vs. "technical data"* One commenter urged that the word "information" be changed to "technical data" wherever that word appeared in the regulations, since not all "information" but only "technical data" is controlled to begin with.

"Information" was deliberately used in this section because it is clearer for persons unfamiliar with the terminology of export controls. The Department has added a sentence to § 779.3(a) to clarify that for the purposes of § 779.3, the word "information" means "technical data" as defined in § 779.1, including software.

9. *New supplement with questions and answers.* The Department has added a new supplement No. 5 to part 779 that provides questions and answers covering major areas of interest.

10. *Miscellaneous changes.* Some commenters read the final paragraph in § 779.3(a), that begins "However, see paragraph (f)" as implying an exception to subsection (1)-(4) that precede the paragraph. This was not the intent. The use of the word "However" to introduce the paragraph was intended only as a clarification of § 779.3(f) itself. Since the word "However" has caused confusion and is not necessary, it has been deleted from the final text.

Rulemaking Requirements

1. This rule is consistent with Executive Orders 12291 and 12661.

2. This rule involves export of information in connection with certain patent applications related to technical data. The patent information requirements, which are subject to the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 *et seq.*), have been cleared by the Office of Management and Budget under Control Number 0651-0011.

3. This rule does not contain policies with Federalism implications sufficient to warrant preparation of a Federalism assessment under Executive Order 12612.

4. Section 13(a) of the Export Administration Act of 1979, as amended (EAA) (50 U.S.C. app. 2412(a)), exempts this rule from all requirements of section 553 of the Administrative Procedure Act (APA) (5 U.S.C. 533), including those requiring publication of a notice of proposed rulemaking, an opportunity for public comment, and a delay in effective date. This rule is also exempt from these APA requirements because it involves a foreign and military affairs function of the United States. This rule is not subject to section 13(b) of the EAA because this rule does not impose new controls. Further no other law requires that a notice of proposed rulemaking and an opportunity for public comment be given for this rule. Nevertheless, to help ascertain the impact of this regulation upon the general public, the regulation was issued in proposed form and public comment was solicited.

5. Because a notice of proposed rulemaking and an opportunity for public comment were not required to be given for this rule by section 553 of the Administrative Procedure Act (5 U.S.C. 553) or by any other law, under section 603(a) and 604(a) of the Regulatory Flexibility Act (5 U.S.C. 603(a) and 604(a)) no initial or final Regulatory Flexibility Analysis was prepared.

These regulations are final. While the Department does not expect to make further changes to the rule published here, because of the importance of the issues raised by these regulations, the Department will consider further comments on this rule together with comments submitted in response to the proposed changes to the remainder of part 779, as published in the October 13, 1988 Federal Register (53 FR 40074).

List of Subjects in 15 CFR Part 779

Exports, Reporting and recordkeeping requirements.

Accordingly, part 779 of the Export Administration Regulations (15 CFR part 779) is amended as follows:

PART 779—[AMENDED]

1. The authority citation for 15 CFR part 779 continues to read as follows:

Authority: Pub. L. 96-72, 93 Stat. 503 (50 U.S.C. app. 2401 *et seq.*), as amended by Pub. L. 97-145 of Dec. 29, 1981, by Pub. L. 99-64 of July 12, 1985, and by Pub. L. 100-418 of Aug. 23, 1988; E.O. 12525 of July 12, 1985 (50 FR 28757 July 18, 1985); Pub. L. 95-223 of Dec. 28, 1977 (50 U.S.C. 1701 *et seq.*); E.O. 12532 of Sept. 9, 1985 (50 FR 36861, Sept. 10, 1985) as affected by notice of Sept. 4, 1986 (51 FR 31925, Sept. 8, 1986); Pub. L. 99-440 of Oct. 2, 1986 (22 U.S.C. 5001 *et seq.*); and E.O. 12571 of Oct. 27 1986 (51 FR 39505, Oct. 29, 1986).

2. Section 779.3 is revised to read as follows:

§ 779.3 General license GTDA; technical data available to all destinations.

Note: In this § 779.3 the word "information" means "technical data" as defined in § 779.1 including software.

(a) *Establishment of general license.* A General License GTDA is hereby established authorizing:

(1) Unrestricted export to any destination of information that is already publicly available or will be made publicly available as described in paragraph (b) of this section;

(2) Unrestricted export to any destination of information arising during or resulting from fundamental research, as described in paragraph (c) of this section;

Note: Paragraphs (a)(1) and (a)(2) of this section do not authorize the export of data contained in a patent application for purposes of filing and/or publishing for opposition abroad. Such exports are controlled by the U.S. Patent and Trademark Office and must be licensed by that office. See EAR § 770.10(j).

(3) Release of educational information, as described in paragraph (d) of this section; and

(4) Export of information in connection with certain patent applications, as described in paragraph (e) of this section.

Note 1: See paragraph (f) regarding Government sponsored research covered by contractual national security controls and the note following this section regarding consulting and training. Use of General License GTDA is subject to the prohibitions of § 771.2(c) (1), (4), and (9), but not to the other prohibitions of § 771.2(c).

Note 2: Supplement No. 5 to part 779 contains explanatory questions and answers about the use of General License GTDA. . . . Certain paragraphs of this § 779.3 are followed by references to relevant questions and answers in supplement No. 5.

(b) *Publicly available.* Information is made public and so becomes "publicly available" when it becomes generally

accessible to the interested public in any form, including:

(1) Publication in periodicals, books, print, electronic, or any other media available for general distribution to any member of the public or to a community of persons, such as those in a scientific or engineering discipline, interested in the subject matter either free or at a price that does not exceed the cost of reproduction and distribution (see Questions A(1) through A(6));

(2) Ready availability at libraries open to the public or at university libraries (see Question A(6));

(3) Patents available at any patent office; and

(4) Release at an open conference, meeting, seminar, trade show, or other open gathering.

(i) A conference or other gathering is "open" if all technically qualified members of the public are eligible to attend and attendees are permitted to take notes or otherwise make a personal record (not necessarily a recording) of the proceedings and presentations.

(ii) All technically qualified members of the public may be considered eligible to attend a conference or other gathering notwithstanding:

(A) A registration fee reasonably related to costs and reflecting an intention that all interested and technically qualified persons be able to attend, or

(B) A limitation on actual attendance, as long as attendees either are the first who have applied or are selected on the basis of relevant scientific or technical competence, experience, or responsibility (see Questions B(1) through B(6)).

This General License GTDA authorizes submission of papers to domestic or foreign editors or reviewers of journals, or to organizers of open conferences or other open gatherings, with the understanding that the papers will be made publicly available if favorably received. (See Questions A(1) and A(3).)

(c) *Information resulting from fundamental research*—(1) *Fundamental research*. Paragraphs (c)(2) through (c)(4) and paragraph (f) of this section provide specific operational rules that will be used to determine whether research in particular institutional contexts qualifies as "fundamental research." The intent behind those operational rules is to identify as "fundamental research" basic and applied research in science and engineering, where the resulting information is ordinarily published and shared broadly within the scientific community. Such research can be distinguished from proprietary research

and from industrial development, design, production, and product utilization, the results of which ordinarily are restricted for proprietary reasons or specific national security reasons as defined in §779.3(f). (See Question D(8).)

(2) *University-based research*. (i) Research conducted by scientists, engineers, or students at a university normally will be considered fundamental research, as described below. ("University" means any accredited institution of higher education located in the United States.)

(ii) Prepublication review by a sponsor of university research solely to ensure that publication would not inadvertently divulge proprietary information that the sponsor has furnished to the researchers does not change the rule described in paragraph (c)(2)(i) of this section. However, General License GTDA does not authorize the release of information from a corporate sponsor to university researchers where the research results are subject to prepublication review. See other sections in this part 779 for provisions that may authorize such releases without a validated license. (See Questions D(7), D(9), and D(10).)

(iii) Prepublication review by a sponsor of university research solely to ensure that publication would not compromise patent rights does not change the rule described in paragraph (c)(2)(i) of this section, so long as the review causes no more than a temporary delay in publication of the research results.

(iv) However, General License GTDA does not authorize the initial transfer of information from an industry sponsor to university researchers where the parties have agreed that the sponsor may withhold from publication some or all of the information so provided. (See Question D(2).)

(v) University based research is not considered "fundamental research" if the university or its researchers accept (at the request, for example, of an industrial sponsor) other restrictions on publication of scientific and technical information resulting from the project or activity. Scientific and technical information resulting from the research will nonetheless become subject to General License GTDA once all such restrictions have expired or have been removed. (See Questions D(7) and D(9).)

(vi) The provisions of paragraph (f) of this section will apply if a university or its researchers accept specific national security controls (as defined in paragraph (f) of this section) on a research project or activity sponsored

by the U.S. Government. (See Questions E(1) and E(2).)

(3) *Research based at Federal agencies or FFRDCs*. Research conducted by scientists or engineers working for a Federal agency or a Federally Funded Research and Development Center (FFRDC) may be designated as "fundamental research" within any appropriate system controlling release of information by such scientists and engineers devised by the agency or the FFRDC. (See Questions D(8) and D(11).)

(4) *Corporate research*. (i) Research conducted by scientists or engineers working for a business entity will be considered "fundamental research" at such time and to the extent that the researchers are free to make scientific and technical information resulting from the research publicly available without restriction or delay based on proprietary concerns or specific national security controls as defined in paragraph (f) of this section.

(ii) Prepublication review by the company solely to ensure that the publication would compromise no proprietary information provided by the company to the researchers is not considered to be a proprietary restriction under paragraph (c)(4)(i) of this section. However General License GTDA does not authorize the release of information to university researchers where the research results are subject to prepublication review. See other sections in this part 779 for provisions that may authorize such releases without a validated license. (See Questions D(8), D(9), and D(10).)

(iii) Prepublication review by the company solely to ensure that prepublication would compromise no patent rights will not be considered a proprietary restriction for this purpose, so long as the review causes no more than a temporary delay in publication of the research results.

(iv) However, General License GTDA does not authorize the initial transfer of information from a business entity to researchers where the parties have agreed that the business entity may withhold from publication some or all of the information so provided.

(5) *Research based elsewhere*. Research conducted by scientists or engineers who are not working for any of the institutions described in paragraphs (c)(2) through (c)(4) of this section will be treated as corporate research, as described in paragraph (c)(4) of this section. (See Question D(8).)

(d) *Educational information*. The release of "educational information"

referred to in paragraph (a)(3) of this section is release by instruction in catalog courses and associated teaching laboratories of academic institutions. Dissertation research is treated in paragraph (c)(2) of this section. (See Question C(1) through C(6).)

(e) *Patent applications.* The information referred to in paragraph (a)(4) of this section is:

(1) Information contained in a patent application prepared wholly from foreign-origin technical data where the application is being sent to the foreign inventor to be executed and returned to the United States for subsequent filing in the U.S. Patent and Trademark office;

(2) Information contained in a patent application, or an amendment, modification, supplement, or division of an application, and authorized for filing in a foreign country in accordance with the regulations of the Patent and Trademark Office, 37 CFR part 5 (see § 770.10(j)); or

(3) Information contained in a patent application when sent to a foreign country before or within six months after the filing of a United States patent application for the purpose of obtaining the signature of an inventor who was in the United States when the invention was made or who is a co-inventor with a person residing in the United States.

(f) *Government-sponsored research covered by contract controls.* (1) If research is funded by the U.S. Government, and specific national security controls are agreed on to protect information resulting from the research, paragraph (a)(2) of this section will not apply to any export of such information in violation of such controls. General License GTDA as described in paragraph (a)(2) of this section is nonetheless available for any export of information resulting from the research that is consistent with the specific controls.

(2) Examples of "specific national security controls" include requirements for prepublication review by the Government, with right to withhold permission for publication; restrictions on prepublication dissemination of information to non-U.S. citizens or other categories of persons; or restrictions on participation of non-U.S. citizens or other categories of persons in the research. A general reference to one or more export control laws or regulations or a general reminder that the Government retains the right to classify is not a "specific national security control" (See Questions E(1) and E(2).)

(g) *Advice concerning uncontrolled information.* Persons may be concerned that an export of uncontrolled information could adversely affect U.S.

national security interests. Exporters who wish advice before exporting such information can contact the appropriate Government scientific or technical personnel by calling the Bureau of Export Administration at (202) 377-4811.

Note: Consulting and training. Technical data can be inadvertently exported in various ways. Consulting and training are especially effective mechanisms of technology transfer. The exporter should be aware that the Department of Commerce maintains controls on exports of technical data that do not qualify for General License GTDA as described in paragraphs (a)(1) through (a)(3) of this section, including application abroad of personal knowledge or technical experience acquired in the United States. (See also paragraph (g) of this section and Question F(1).)

(Approved by the Office of Management and Budget under control number 065-0011)

3. A new supplement No. 5 to part 779 is added to read as follows:

**Supplement No. 5 to Part 779—
Questions and Answers—General
License GTDA**

This supplement No. 5 contains explanatory questions and answers about General License GTDA. This Supplement is divided into six sections according to topic as follows:

Section A: Publication of technical data and exports of technical data that has been or will be published.

Section B: Release of technical data at conferences.

Section C: Educational instruction.

Section D: Research, correspondence, and informal scientific exchanges.

Section E: Federal contract controls.

Section F: Commercial consulting.

Section G: Software.

Section H: Available in a public library.

Section I: Miscellaneous.

Section A: Publication

Question A(1): I plan to publish in a foreign journal a scientific paper describing the results of my research, which is in an area listed in § 779.4(d). Do I need a validated license?

Answer: No. General License GTDA permits unrestricted export to any destination not only of technical data that are already publicly available, but of technical data that are made public by the transaction in question (§ 779.3(a)(1)). Your research results would be made public by the planned publication. You would not need a validated license.

Question A(2): Would the answer differ depending on where I work or where I performed the research?

Answer: No. Of course, the General License would not relieve you from any restrictions on publications that your employer or another sponsor of your research may have imposed.

Question A(3): Would it make any difference if I published in a foreign journal? Would I need a validated license to send the paper to the editors for review?

Answer: No to both questions. General license GTDA authorizes submission of papers to editors or reviewers of journals, including foreign journals, if the intention is that the papers will be published if favorably received § 779.3(b), last paragraph).

Question A(4): The research on which I will be reporting in my paper is supported by a grant from the Department of Energy. The grant requires prepublication clearance by DOE. Does that make any difference under the Export Administration Regulations?

Answer: No; GTDA would still apply. But if you publish in violation of the controls you have accepted in the grant, you will be subject to appropriate administrative, civil, and possible criminal sanctions under other laws.

Question A(5): We provide consulting services on the design, layout, and construction of integrated circuit plants and production lines. A major part of our business is the publication for sale to clients of detailed handbooks and reference manuals on key aspects of the design and manufacturing processes. A typical cost of publishing such a handbook and manual might be \$500; the typical sales price is around \$15,000. Does general license GTDA cover publication and sale of such handbooks or manuals?

Answer: No. The price is above the cost of reproduction and distribution (§ 779.3(b)(1)). Thus, you would need some other form of license before you could export any of these handbooks or manuals.

Question A(6): My Ph.D. thesis on a subject listed in § 779.4(d) has never been published for general distribution. However, it is available at the institution from which I took the degree. Do I need a validated license to send another copy to a colleague overseas?

Answer: That may depend on where in the institution it is available. If it is not readily available in the university library (e.g., by filing in open stacks with a reference in the catalog), it is not "publicly available" and the GTDA license would not be available on that ground. The GTDA license would still be applicable if your Ph.D. research qualified as "fundamental research" under § 779.3(c). If not, however, you will need some other form of license before you can send a copy out of the country.

Question A(7): We sell electronically recorded information, including software and databases, at wholesale and retail. Our products are available by mail order to any member of the public, though intended for specialists in various fields. They are priced to maximize sales to persons in those fields. Do we need validated licenses to sell our products to foreign customers?

Answer: You would not need a validated license for otherwise controlled technical data or software if the technical data and software are made publicly available at a price that does not exceed the cost of production and distribution to the technical community. Even if priced at a higher level, General License GTDA authorizes the export if the technical data or software source code is in a library accessible to the public. (§ 779.3(b)(1).)

Section B. Conferences

Question B(1): I have been invited to give a paper at a prestigious international scientific conference on a subject listed in § 779.4(d). Scientists in the field are given an opportunity to submit applications to attend. Invitations are given to those judged by a panel of scientific peers to be the leading researchers in the field, and attendance is by invitation only. Attendees will be free to take notes, but not make electronic or verbatim recordings of the presentations or discussions. Some of the attendees will be foreigners. Do I need a validated license to give my paper?

Answer: No. General license GTDA is available for release of information at an open conference. The conference you describe fits the definition of an open conference (§ 779.3(a)(1) and (b)(4)).

Question B(2): Would it make any difference if there were a prohibition on making any notes or other personal record of what transpires at the conference?

Answer: Yes. To qualify as an "open" conference, attendees must be permitted to take notes or otherwise make a personal record (although not necessarily a recording). If note taking or the making of personal records as altogether prohibited, the conference would not be considered "open."

Question B(3): Would it make any difference if there were also a registration fee?

Answer: That would depend on whether the fee is reasonably related to costs and reflects an intention that all interested and technically qualified persons should be able to attend (§ 779.3(b)(4)(ii)(A)).

Question B(4): Would it make any difference if the conference were to take place in another country?

Answer: No.

Question B(5): Must I have a validated license to send the paper I propose to present at such a foreign conference to the conference organizer for review?

Answer: No. General license GTDA authorizes submission of papers to foreign organizers of open conferences or other open gatherings with the intention that the papers will be delivered at the conference, and so made publicly available, if favorably received (§ 779.3(b), last paragraph).

Question B(6): Would the answers to any of the foregoing questions be different if my work were supported by the Federal Government?

Answer: No. You may use GTDA to export the papers, even if the release of the paper violates any agreements you have made with your government sponsor. However, nothing in the Export Administration Regulations relieves you of responsibility for conforming to any controls you have agreed to in your Federal grant or contract.

Section C: Educational Instruction

Question C(1): I teach a university graduate course on design and manufacture of very high-speed integrated circuitry. Many of the students are foreigners. Do I need a validated license to teach this course?

Answer: No. Release of information by instruction in catalog courses and associated teaching laboratories of academic institutions

is licensed under general license GTDA (§ 779.3(d)).

Question C(2): Would it make any difference if some of the students were from Communist Bloc countries?

Answer: No.

Question C(3): Would it make any difference if I talk about recent and as yet unpublished results from my laboratory research?

Answer: No.

Question C(4): Even if that research is funded by the Government?

Answer: Even then the general license would apply, but the export Administration Regulations would not release you from any separate obligations you have accepted in your grant or contract.

Question C(5): Would it make any difference if I were teaching at a foreign university?

Answer: No.

Question C(6): We teach proprietary courses on design and manufacture of high-performance aircraft and missiles. Is the instruction in our classes covered by the GTDA license?

Answer: That instruction would not qualify as "release of educational information" under § 779.3(a)(3) because your proprietary business does not qualify as an "academic institution" within the meaning of § 779.3(d). Conceivably, however, the instruction might qualify as "release at an open seminar, or other open gathering" under § 779.3(b)(4). The conditions for qualification of such a seminar or gathering as "open, including a fee "reasonably related to costs (of the conference, not of producing the data) and reflecting an intention that all interested and technically qualified persons be able to attend, would have to be satisfied.

Section D: Research, Correspondence, and Informal Scientific Exchanges

Question D(1): Do I need a validated license in order for a foreign graduate student to work in my laboratory?

Answer: Not if the research on which the foreign student is working qualifies as "fundamental research" under § 779.3(c). In that case, the GTDA general license is available.

Question D(2): Our company has entered into a cooperative research arrangement with a research group at a university. One of the researchers in that group is a Polish national. We would like to share some of our proprietary information with the university research group. We have no way of guaranteeing that this information will not get into the hands of the Polish scientist. Do we need to obtain a validated license to protect against that possibility?

Answer: No. General License GTDA authorizes the disclosure of information to any scientists, engineers, or students at a U.S. university in the course of industry-university research collaboration under specific arrangements between a firm and the university, provided these arrangements do not permit the sponsor to withhold from publication any of the information that he provides to the researchers. However, if your company and the researchers have agreed to a prohibition on publication, then you must

qualify for another general license or obtain a validated license before transferring the information to the university. It is important that you as the corporate sponsor and the university get together to discuss whether foreign nationals will have access to the information, so that you may obtain any necessary export authorization prior to transferring the information to the research team.

Question D(3): My university will host a prominent scientist from the Soviet Union who is an expert on research in engineered ceramics and composite materials. Do I require a validated license before telling our visitor about my latest, as yet unpublished, research results in those fields?

Answer: Probably not. If you performed your research at the university, and you were subject to no contract controls on release of research results agreed to with a sponsor of the research, your research would qualify as "fundamental research" (§ 779.3(c)(2)). Unrestricted export of information arising during or resulting from such research is covered by general license GTDA (779.3(a)(2)). You should probably assume, however, that your visitor will be debriefed later about anything of potential military value he learns from you. If you are concerned that giving such information to him, even though licensed, could jeopardize U.S. security interests, the Commerce Department can put you in touch with appropriate Government scientists who can advise you. Write to Department of Commerce, Bureau of Export Administration, Office of Technology and Policy Analysis, P.O. Box 273, Washington, DC 20044.

Question D(4): Would it make any difference if I were proposing to talk with a Soviet expert in the Soviet Union?

Answer: No, if the information in question arose during or resulted from the same "fundamental research."

Question D(5): Could I properly do some work with him in his research laboratory inside the Soviet Union?

Answer: Application abroad of personal knowledge or technical experience acquired in the United States constitutes an export of that knowledge and experience, and such an export is subject to the Export Administration Regulations (§ 779.1(b)(1)(iii) and (2)(iii) and § 779.2). Such an export must be licensed. If any of the knowledge or experience you export in this way is not covered by general license, you would need a validated license.

Question D(6): I would like to correspond and share research results with a Soviet-Bloc expert in my field, which is listed in § 779.4(d). Do I require a validated license to do so?

Answer: Not as long as we are still talking about information that arose during or resulted from research that qualifies as "fundamental" under the rules spelled out in § 779.3(c).

Question D(7): Suppose the research in question were funded by a corporate sponsor and I had agreed to prepublication review of any paper arising from the research?

Answer: Whether your research would still qualify as "fundamental" would depend on the nature and purpose of the prepublication

review. If the review is intended solely to ensure that your publications will neither compromise patent rights nor inadvertently divulge proprietary information that the sponsor has furnished to you, the research could still qualify as "fundamental. But if the sponsor will consider as part of its prepublication review whether it wants to hold your new research results as trade secrets or otherwise proprietary information (even if your voluntary cooperation would be needed for it to do so), your research would no longer qualify as "fundamental. As used in these regulations it is the actual and intended openness of research results that primarily determines whether the research counts as "fundamental" and so comes under general license GTDA.

Question D(8): In determining whether research is thus open and therefore counts as "fundamental, does it matter where or in what sort of institution the research is performed?

Answer: In principle, no. "Fundamental research" is performed in industry, Federal laboratories, or other types of institutions, as well as in universities. The regulations introduce some operational presumptions and procedures that can be used both by those subject to the regulations and by those who administer them to determine with some precision whether a particular research activity is covered. Recognizing that common and predictable norms operate in different types of institutions, the regulations use the institutional locus of the research as a starting point for these presumptions and procedures. Nonetheless, it remains the type of research, and particularly the intent and freedom to publish, that identifies "fundamental research"—not the institutional locus (§ 779.3(c)).

Question D(9): I am doing research on high-powered lasers in the central basic-research laboratory of an industrial corporation. I am required to submit the results of my research for prepublication review before I can publish them or otherwise make them public. I would like to compare research results with a scientific colleague from an East Bloc country and discuss the results of the research with her when she visits the United States. Do I need a validated license to do so?

Answer: You probably do need a validated license (§ 779.3(c)(4)). However, if the only restriction on your publishing any of that information is a prepublication review solely to ensure that publication would compromise no patent rights or proprietary information provided by the company to the researcher your research may be considered "fundamental research, in which case you may be able to share information under the GTDA general license. Note that GTDA will not be available if the prepublication review is intended to withhold the results of the research from publication.

Question D(10): Suppose I have already cleared my company's review process and am free to publish all the information I intend to share with my colleague, though I have not yet published?

Answer: If the clearance from your company means that you are free to make all the information publicly available without restriction or delay, the GTDA license will

apply and you will not need a validated license for this exchange (§ 779.3(c)(4)).

Question D(11): I work as a researcher at a Government-owned, contractor-operated research center. May I share the results of my unpublished research with foreign nationals without concern for export controls under the Export Administration Regulations?

Answer: That is up to the sponsoring agency and the center's management. If your research is designated "fundamental research" within any appropriate system devised by them to control release of information by scientists and engineers at the center, it will be treated as such by the Commerce Department, and the GTDA license will apply. Otherwise, you would need some other form of license, except to publish or otherwise make the information public (§ 779.3(c)(3)).

Section E: Federal Contract Controls

Question E(1): In a contract for performance of research entered into with the Department of Defense, we have agreed to certain national security controls. DOD is to have ninety days to review any papers we proposed before they are published and must approve assignment of any foreign nationals to the project. The work in question would otherwise qualify as "fundamental research" under § 779.3(c). Does the GTDA license cover information arising during or resulting from this sponsored research?

Answer: Any "export" inconsistent with the controls you have agreed to will not qualify for export under GTDA as "fundamental research. Any "export" consistent with the controls will qualify for export under GTDA as "fundamental research." Thus, if you abide by the specific controls you have agreed to, you need not be concerned about violating the Export Administration Regulations. If you violate those controls and export information as "fundamental research" under § 779.3(c), you may subject yourself to the sanctions provided for under the Export Administration Regulations, including criminal sanctions, in addition to administrative and civil remedies for breach of contract.

Question E(2): Do the Export Administration Regulations restrict my ability to publish the results of my research?

Answer: The Export Administration Regulations are not the means for enforcing the national security controls you have agreed to. If such a publication violates the contract, you would be subject to administrative, civil, and possible criminal penalties under other law.

Section F: Commercial Consulting

Question F(1): I am a professor at a U.S. university, with expertise in design and creation of submicron devices. I have been asked to be a consultant for a "third-world" company that wishes to manufacture such devices. Do I need a validated license to do so?

Answer: Quite possibly you do. Application abroad of personal knowledge or technical experience acquired in the United States constitutes an export of that knowledge and experience that is subject to the Export Administration Regulations (§ 779.1(b) (1)(iii)

and (2)(iii), and § 779.2). Such an export must be licensed. If any part of the knowledge or experience you export in this way is not covered by general license, you would need a validated license.

Section G: Software

Question G(1): Does General License GTDA authorize the export of software in machine readable code when the source code for such software is publicly available?

Answer: If the source code of a software program is publicly available, then the machine readable code compiled from the source code is software that is publicly available and therefore eligible for General License GTDA.

Question G(2): Does General License GTDA authorize the export of software sold at a price that does not exceed the cost of reproduction and distribution?

Answer: Software in machine readable code is publicly available if it is available to a community at a price that does not exceed the cost of reproduction and distribution. Such reproduction and distribution costs may include variable and fixed allocations of overhead and normal profit for the reproduction and distribution functions either in your company or in a third party distribution system. In your company, such costs may not include recovery for development, design, or acquisition. In this case, the provider of the software does not receive a fee for the inherent value of the software.

Question G(3): Does General License GTDA authorize the export of software sold at a price BXA concludes in a classification letter to be sufficiently low to qualify the particular software for General License GTDA?

Answer: In response to classification requests, BXA may choose to classify certain software as eligible for General License GTDA even though it is sold at a price above the costs of reproduction and distribution as long as the price is nonetheless sufficiently low to qualify for such a classification in the judgment of BXA.

Section H: Available in a Public Library

Question H(1): Does General License GTDA authorize the export of information available in a library and sold through an electronic or print service?

Answer: Electronic and print services for the distribution of information may be relatively expensive in the marketplace because of the value vendors add in retrieving and organizing information in a useful way. If such information is also available in a library—itsself accessible to the public—or has been published in any way, that information is "publicly available" for those reasons, and the information itself remains eligible for General License GTDA even though you access the information through an electronic or print service for which you or your employer pay a substantial fee.

Question H(2): Does General License GTDA authorize the export of information available in an electronic form in a library at no charge to the library patron?

Answer: Information available in an electronic form at no charge to the library patron in a library accessible to the public is information publicly available even though the library pays a substantial subscription fee for the electronic retrieval service.

Question H(3): Does General License GTDA authorize the export of information available in a library and sold for more than the cost of reproduction and distribution?

Answer: Information from books, magazines, dissertations, papers, electronic data bases, and other information available in a library that is accessible to the public qualifies for General License GTDA. This is true even if you purchase such a book at more than the cost of reproduction and distribution. In other words, such information is "publicly available" even though the author makes a profit on your particular purchase for the inherent value of the information.

Section I: Miscellaneous

Question I(1): The manufacturing plant that I work at is planning to begin admitting groups of the general public to tour the plant facilities. We are concerned that an export license might be required if the tour groups include foreign nationals. Would such a tour constitute an export? If so, does General License GTDA authorize this type of export?

Answer: EAR § 779.1(b) defines exports of technical data to include release through visual inspection by foreign nationals of U.S. origin equipment and facilities. Consequently, you must obtain export authorization prior to permitting foreign nationals to tour your facilities. Such an export qualifies under the "publicly available" provision of General License GTDA so long as the tour is truly open to all members of the public, including your competitors, and you do not charge a fee that is not reasonably related to the cost of conducting the tours (§ 779.3(a)(1)).

Question I(2): Does General License GTDA authorize the export of information not in a library or published, but sold at a price that does not exceed the cost of reproduction and distribution?

Answer: Information that is not in a library accessible to the public and that has not been published in any way, may nonetheless become "publicly available" if you make it both available to a community of persons and if you sell it at no more than the cost of reproduction and distribution. Such reproduction and distribution costs may include variable and fixed cost allocations of overhead and normal profit for the reproduction and distribution functions either in your company or in a third party distribution system. In your company, such costs may not include recovery for development, design, or acquisition of the technical data or software. The reason for this conclusion is that the provider of the information receives nothing for the inherent value of the information.

Question I(3): Does General License GTDA authorize the export of information contributed to an electronic bulletin board?

Answer: Assume each of the following:

1. Information is uploaded to an electronic bulletin board by a person that is the owner or originator of the information;

2. That person does not charge a fee to the bulletin board administrator or the subscribers of the bulletin board; and

3. The bulletin board is available for subscription to any subscriber in a given community regardless of the cost of subscription.

Such information is "publicly available" and therefore eligible for General License GTDA even if it is not elsewhere published and is not in a library. The reason for this conclusion is that the bulletin board subscription charges or line charges are for distribution exclusively, and the provider of the information receives nothing for the inherent value of the information.

Question I(4): Does General License GTDA authorize the export of patented information fully disclosed on the public record?

Answer: Information to the extent it is disclosed on the patent record open to the public is eligible for General License GTDA even though you may use such information only after paying a fee in excess of the costs of reproduction and distribution. In this case the seller does receive a fee for the inherent value of the technical data; however, General License GTDA is nonetheless available because any person can obtain the technical data from the public record and further disclose or publish the information. For that reason, it is impossible to impose export controls that deny access to the information.

Dated: September 25, 1989.

James M. LeMunyon,
Deputy Assistant Secretary for Export
Administration.

[FR Doc. 89-23046 Filed 10-2-89; 8:45 am]

BILLING CODE 3510-DT-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 442

[Docket No. 89N-0323]

Antibiotic Drugs; Ceftazidime Sodium Injection

AGENCY: Food and Drug Administration.
ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the antibiotic drug regulations to provide for the inclusion of accepted standards for a new dosage form of ceftazidime, ceftazidime sodium injection. The manufacturer has supplied sufficient data and information to establish its safety and efficacy.

DATES: Effective November 2, 1989; written comments, notice of participation, and request for hearing by November 2, 1989; data, information, and analyses to justify a hearing by December 4, 1989.

ADDRESSES: Written comments to the Dockets Management Branch (HFA-

305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857

FOR FURTHER INFORMATION CONTACT: Peter A. Dionne, Center for Drug Evaluation and Research (HFD-520), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857 301-443-4290.

SUPPLEMENTARY INFORMATION: FDA has evaluated data submitted in accordance with regulations promulgated under section 507 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 357), as amended, with respect to a request for approval of a new dosage form of ceftazidime, ceftazidime sodium injection. The agency has concluded that the data supplied by the manufacturer concerning this antibiotic drug are adequate to establish its safety and efficacy when used as directed in the labeling and that the regulations should be amended in part 442 (21 CFR part 442) to provide for the inclusion of accepted standards for this product by adding new § 442.16 and by redesignating § 442.216 as § 442.216a and adding new §§ 442.216 and 442.216b.

Environmental Impact

The agency has determined under 21 CFR 25.24(c)(6) 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.

Submitting Comments and Filing Objections

This final rule announces standards that FDA has accepted in a request for approval of an antibiotic drug. Because this final rule is not controversial and because when effective it provides notice of accepted standards, FDA finds that notice and comment procedure is unnecessary and not in the public interest. This final rule, therefore, becomes effective November 2, 1989. However, interested persons may, on or before November 2, 1989, submit comments to the Dockets Management Branch (address above). Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Any person who will be adversely affected by this final rule may file

objections to it and request a hearing. Reasonable grounds for the hearing must be shown. Any person who decides to seek a hearing must file: (1) On or before November 2, 1989, a written notice of participation and request for hearing, and (2) on or before December 4, 1989, the data, information, and analyses on which the person relies to justify a hearing, as specified in 21 CFR 314.300. A request for a hearing may not rest upon mere allegations or denials, but must set forth specific facts showing that there is a genuine and substantial issue of fact that requires a hearing. If it conclusively appears from the face of the data, information, and factual analyses in the request for hearing that no genuine and substantial issue of fact precludes the action taken by this order, or if a request for hearing is not made in the required format or with the required analyses, the Commissioner of Food and Drugs will enter summary judgment against the person(s) who request(s) the hearing, making findings and conclusions and denying a hearing. All submissions must be filed in three copies, identified with the docket number appearing in the heading of this order and filed with the Dockets Management Branch.

The procedures and requirements governing this order, a notice of participation and request for hearing, a submission of data, information, and analyses to justify a hearing, other comments, and grant or denial of a hearing are contained in 21 CFR 314.300.

All submissions under this order, except for data and information prohibited from public disclosure under 21 U.S.C. 331(j) or 18 U.S.C. 1905, may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects in 21 CFR Part 442

Antibiotics.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 442 is amended as follows:

PART 442—CEPHA ANTIBIOTIC DRUGS

1. The authority citation for 21 CFR part 442 continues to read as follows:

Authority: Sec. 507 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 357).

2. New § 442.16 is added to subpart A to read as follows:

§ 442.16 Cefazidime pentahydrate.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity.* Cefazidime pentahydrate is

pyridinium, 1-[[7-[[[2-amino-4-thiazolyl] [1-carboxy-1-methylethoxy]imino]-acetyl]amino]-2-carboxy-8-oxo-5-thia-1-azabicyclo[4.2.0]oct-2-en-3-yl)methyl]-hydroxide, inner salt, [6*R*-[6*α*,7*β*(*Z*)]]-pentahydrate. It is so purified and dried that:

(i) Its potency is not less than 950 micrograms and not more than 1,020 micrograms of cefazidime activity per milligram on an anhydrous basis.

(ii) Its loss on drying is not less than 13.0 percent and not more than 15.0 percent.

(iii) The pH of an aqueous solution containing 5 milligrams of cefazidime per milliliter is not less than 3.0 and not more than 4.0.

(iv) It is crystalline.

(v) It gives a positive identity test for cefazidime.

(vi) Its high molecular weight polymer content is not more than 0.05 percent.

(2) *Labeling.* It shall be labeled in accordance with the requirements of § 432.5 of this chapter.

(3) *Requests for certification; samples.* In addition to complying with the requirements of § 431.1 of this chapter, each such request shall contain:

(i) Results of tests and assays on the batch for potency, loss on drying, pH, crystallinity, identity, and high molecular weight polymer content.

(ii) Samples, if required by the Director, Center for Drug Evaluation and Research: 10 packages, each containing approximately 500 milligrams.

(b) *Tests and methods of assay*—(1) *Potency.* Proceed as directed in § 442.16a(b)(1).

(2) *Loss on drying.* Proceed as directed in § 436.200(a) of this chapter.

(3) *pH.* Proceed as directed in § 436.202 of this chapter, using an aqueous solution containing 5 milligrams of cefazidime per milliliter.

(4) *Crystallinity.* Proceed as directed in § 436.203(a) of this chapter.

(5) *Identity.* The high performance liquid chromatogram of the sample determined as directed in paragraph (b)(1) of this section compares qualitatively to that of the cefazidime working standard.

(6) *High molecular weight polymer content.* Proceed as directed in § 442.16a(b)(8).

§ 442.216a [Redesignated from § 442.216]

3. Section 442.216 is redesignated as § 442.216a and new §§ 442.216 and 442.216b are added to subpart C to read as follows:

§ 442.216 Cefazidime injectable dosage forms.

§ 442.216b Cefazidime sodium injection.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity.* Cefazidime sodium injection is a frozen, aqueous, iso-osmotic solution of cefazidime sodium which may contain one or more suitable and harmless buffer substances and a tonicity adjusting agent. Each milliliter contains cefazidime sodium equivalent to 10, 20, or 40 milligrams of cefazidime per milliliter. Its cefazidime content is satisfactory if it is not less than 90 percent and not more than 120 percent of the number of milligrams of cefazidime that it is represented to contain. It is sterile. It is nonpyrogenic. Its pH is not less than 5.0 and not more than 7.5. It passes the identity test. The cefazidime pentahydrate conforms to the standards prescribed by § 442.16(a)(1).

(2) *Labeling.* It shall be labeled in accordance with the requirements of § 432.5 of this chapter.

(3) *Requests for certification; samples.* In addition to complying with the requirements of § 431.1 of this chapter, each such request shall contain:

(i) Results of tests and assays on:

(A) The cefazidime pentahydrate used in making the batch for potency, loss on drying, pH, crystallinity, identity, and high molecular weight polymer content.

(B) The batch for cefazidime content, sterility, pyrogens, pH, and identity.

(ii) Samples, if required by the Director, Center for Drug Evaluation and Research:

(A) The cefazidime pentahydrate used in making the batch: 10 packages, each containing 500 milligrams.

(B) The batch:

(1) For all tests except sterility: A minimum of 10 immediate containers.

(2) For sterility testing: 20 immediate containers, collected at regular intervals throughout each filling operation.

(b) *Tests and methods of assay.* Thaw the sample as directed in the labeling. The sample solution used for testing must be at room temperature.

(1) *Cefazidime content.* Proceed as directed in § 442.216(b)(1), except prepare the sample solution and calculate the cefazidime content as follows:

(i) *Preparation of sample solution.* Remove an accurately measured representative portion from each container immediately after thawing and reaching room temperature and dilute with mobile phase to obtain a solution containing 100 micrograms of

ceftazidime per milliliter (estimated). Prepare the sample solution just prior to its introduction into the chromatograph.

(ii) *Calculation.* Calculate the milligrams of ceftazidime per milliliter of sample as follows:

$$\text{Milligrams of ceftazidime per milliliter} = \frac{A_u \times P_s \times d}{A_s \times 1,000}$$

where:

A_u = Area of the ceftazidime peak in the chromatogram of the sample (at a retention time equal to that observed for the standard);

A_s = Area of the ceftazidime peak in the chromatogram of the ceftazidime working standard;

P_s = Ceftazidime activity in the ceftazidime working standard solution in micrograms per milliliter; and

d = Dilution factor of the sample.

(2) *Sterility.* Proceed as directed in § 436.20 of this chapter, using the method described in paragraph (e)(1) of that section.

(3) *Pyrogens.* Proceed as directed in § 436.32(b) of this chapter, except inject a sufficient volume of the diluted solution to deliver 80 milligrams of ceftazidime per kilogram.

(4) *pH.* Proceed as directed in § 436.202 of this chapter, using the undiluted solution.

(5) *Identify.* The high performance liquid chromatogram of the sample determined as directed in paragraph (b)(1) of this section compares qualitatively to that of the ceftazidime working standard.

Dated: September 22, 1989.

Albert Rothschild,

Acting Director, Office of Compliance, Center for Drug Evaluation and Research.

[FR Doc. 89-23212 Filed 10-2-89; 8:45 am]

BILLING CODE 4160-01-M

21 CFR Part 442

[Docket No. 89N-0326]

Antibiotic Drugs; Cefuroxime Sodium Injection

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the antibiotic drug regulations to provide for the inclusion of accepted standards for a new dosage form of cefuroxime, cefuroxime sodium injection. The manufacturer has supplied sufficient data and information to establish its safety and efficacy.

DATES: Effective November 2, 1989; comments, notice of participation, and

request for hearing by November 2, 1989; data, information, and analyses to justify a hearing by December 4, 1989.

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

FOR FURTHER INFORMATION CONTACT: Peter A. Dionne, Center for Drug Evaluation and Research (HFD-520), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857 301-443-4290.

SUPPLEMENTARY INFORMATION: FDA has evaluated data submitted in accordance with regulations promulgated under section 507 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 357), as amended, with respect to a request for approval of a new dosage form of cefuroxime, cefuroxime sodium injection. The agency has concluded that the data supplied by the manufacturer concerning this antibiotic drug are adequate to establish its safety and efficacy when used as directed in the labeling and that the regulations should be amended in part 442 (21 CFR part 442) by adding new § 442.18, redesignating § 442.218 as § 442.218a, and adding new §§ 442.218 and 442.218b to provide for the inclusion of accepted standards for this product.

Environmental Impact

The agency has determined under 21 CFR 25.24(c)(6) 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.

Submitting Comments and Filing Objections

This final rule announces standards that FDA has accepted in a request for approval of an antibiotic drug. Because this final rule is not controversial and because when effective it provides notice of accepted standards, FDA finds that notice and comment procedure is unnecessary and not in the public interest. This final rule, therefore, is effective November 2, 1989. However, interested persons may, on or before November 2, 1989, submit comments to the Dockets Management Branch (address above). Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Dockets

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

Any person who will be adversely affected by this final rule may file objections to it and request a hearing. Reasonable grounds for the hearing must be shown. Any person who decides to seek a hearing must file: (1) On or before November 2, 1989, a written notice of participation and request for hearing, and (2) on or before December 4, 1989, the data, information, and analyses on which the person relies to justify a hearing, as specified in 21 CFR 314.300. A request for a hearing may not rest upon mere allegations or denials, but must set forth specific facts showing that there is a genuine and substantial issue of fact that requires a hearing. If it conclusively appears from the face of the data, information, and factual analyses in the request for a hearing that no genuine and substantial issue of fact precludes the action taken by this order, or if a request for a hearing is not made in the required format or with the required analyses, the Commissioner of Food and Drugs will enter summary judgment against the person(s) who request(s) the hearing, making findings and conclusions and denying a hearing. All submissions must be filed in three copies, identified with the docket number appearing in the heading of this order and filed with the Dockets Management Branch.

The procedures and requirements governing this order, a notice of participation and request for hearing, a submission of data, information, and analyses to justify a hearing, other comments, and grant or denial of a hearing are contained in 21 CFR 314.300.

All submissions under this order, except for data and information prohibited from public disclosure under 21 U.S.C. 331(j) or 18 U.S.C. 1905, may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects in 21 CFR Part 442

Antibiotics.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 442 is amended as follows:

PART 442—CEPHA ANTIBIOTIC DRUGS

1. The authority citation for 21 CFR part 442 continues to read as follows:

Authority: Sec. 507 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 357).

2. New § 442.18 is added to subpart A to read as follows:

§ 442.18 **Cefuroxime sodium.**

(a) *Requirements for certification—(1) Standards of identity, strength, quality, and purity.* Cefuroxime sodium is the sodium salt of (6R, 7R)-3-carbamoyloxy-methyl-7-[(2Z)-2-(2-furyl)-2-methoxyiminoacetamido]cepha-3-em-4-carboxylic acid. It is so purified and dried that:

(i) Its potency is not less than 855 micrograms and not more than 1,000 micrograms of cefuroxime activity per milligram on an anhydrous basis.

(ii) Its moisture content is not more than 3.5 percent.

(iii) The pH of an aqueous solution containing 100 milligrams of cefuroxime per milliliter is not less than 6.0 and not more than 8.5.

(iv) It gives a positive identity test for cefuroxime.

(2) *Labeling.* It shall be labeled in accordance with the requirements of § 432.5 of this chapter.

(3) *Requests for certification; samples.* In addition to complying with the requirements of § 431.1 of this chapter, each such request shall contain:

(i) Results of tests and assays on the batch for potency, moisture, pH, and identity.

(ii) Samples, if required by the Director, Center for Drug Evaluation and Research: 10 packages, each containing approximately 1 gram.

(b) *Tests and methods of assay—(1) Potency.* Proceed as directed in § 442.343.

(2) *Moisture.* Proceed as directed in § 436.18a(b)(4) of this chapter.

(3) *pH.* Proceed as directed in § 436.202 of this chapter, using an aqueous solution containing 100 milligrams of cefuroxime per milliliter.

(4) *Identity.* Proceed as directed in § 442.18a(b)(6).

§ 442.218a [Redesignated from § 442.218]

3. Section 442.218 is redesignated as § 442.218a and new §§ 442.218 and 442.218b are added to read as follows:

§ 442.218 **Cefuroxime injectable dosage forms.**

§ 442.218b **Cefuroxime sodium injection.**

(a) *Requirements for certification—(1) Standards of identity, strength, quality, and purity.* Cefuroxime sodium injection is a frozen, aqueous, iso-osmotic solution of cefuroxime sodium which may contain one or more suitable and harmless buffer substances and a tonicity adjusting agent. Each milliliter contains cefuroxime sodium equivalent to 15 or 30 milligrams of cefuroxime per milliliter. Its cefuroxime content is

satisfactory if it is not less than 90 percent and not more than 120 percent of the number of milligrams of cefuroxime that it is represented to contain. It is sterile. It is nonpyrogenic. Its pH is not less than 5.0 and not more than 7.5. It passes the identity test. The cefuroxime sodium used conforms to the standards prescribed by § 442.18(a)(1).

(2) *Labeling.* It shall be labeled in accordance with the requirements of § 432.5 of this chapter.

(3) *Requests for certification; samples.* In addition to complying with the requirements of § 431.1 of this chapter, each such request shall contain:

(i) Results of tests and assays on:

(A) The cefuroxime sodium used in making the batch for potency, moisture, pH, and identity.

(B) The batch for cefuroxime content, sterility, pyrogens, pH, and identity.

(ii) Samples, if required by the Director, Center for Drug Evaluation and Research:

(A) The cefuroxime sodium used in making the batch: 10 packages, each containing 1 gram.

(B) The batch:

(1) For all tests except sterility: A minimum of 10 immediate containers.

(2) For sterility testing: 20 immediate containers, collected at regular intervals throughout each filling operation.

(b) *Tests and methods of assay—*Thaw the sample as directed in the labeling. The sample solution used for testing must be at room temperature.

(1) *Cefuroxime content.* Proceed as directed in § 436.343 of this chapter, except prepare the sample solution and calculate the cefuroxime content as follows:

(i) *Preparation of sample solution.* Remove an accurately measured representative portion from each container immediately after thawing and reaching room temperature and dilute with water to obtain a solution containing 50 micrograms of cefuroxime per milliliter (estimated). Prepare the sample solution just prior to its introduction in the chromatograph.

(ii) *Calculation.* Calculate the milligrams of cefuroxime per milliliter of sample as follows:

$$\text{Milligrams of cefuroxime per milliliter} = \frac{A_u X P_s X d}{A_s X 1,000}$$

where:

A_u = Area of the cefuroxime peak in the chromatogram of the sample (at a retention time equal to that observed for the standard);

A_s = Area of the cefuroxime peak in the chromatogram of the cefuroxime working standard;

P_s = Cefuroxime activity in the cefuroxime working standard solution in micrograms per milliliter; and

d = Dilution factor of the sample.

(2) *Sterility.* Proceed as directed in § 436.20 of this chapter, using the method described in paragraph (e)(1) of that section.

(3) *Pyrogens.* Proceed as directed in § 436.32(b) this chapter, except inject a sufficient volume of the undiluted solution to deliver 50 milligrams of cefuroxime per kilogram.

(4) *pH.* Proceed as directed in § 436.202 of this chapter, using the undiluted solution.

(5) *Identity.* The high performance liquid chromatogram of the sample determined as directed in paragraph (b)(1) of this section compares qualitatively to that of the cefuroxime working standard.

Dated: September 22, 1989.

Albert Rothschild,

Acting Director, Office of Compliance, Center for Drug Evaluation and Research.

[FR Doc. 89-23214 Filed 10-2-89; 8:45 am]

BILLING CODE 4160-01-M

21 CFR Part 453

[Docket No. 89N-0324]

Antibiotic Drugs; Clindamycin Phosphate Lotion

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the antibiotic drug regulations to provide for the inclusion of accepted standards for a new dosage form of clindamycin phosphate, clindamycin phosphate lotion. The manufacturer has supplied sufficient data and information to establish its safety and efficacy.

DATES: Effective November 2, 1989; written comments, notices of participation, and request for hearing by November 2, 1989; data, information, and analyses to justify a hearing by December 4, 1989.

ADDRESSES: Written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20875.

FOR FURTHER INFORMATION CONTACT: Peter A. Dionne, Center for Drug Evaluation and Research (HFD-520), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857 301-443-4290.

SUPPLEMENTARY INFORMATION: FDA has evaluated data submitted in accordance

with regulations promulgated under section 507 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 357), as amended, with respect to a request for approval of a new dosage form of clindamycin phosphate, clindamycin phosphate lotion. The agency has concluded that the data supplied by the manufacturer concerning this antibiotic drug are adequate to establish its safety and efficacy when used as directed in the labeling and that the regulations should be amended by adding new 21 CFR 453.522c to provide for the inclusion of accepted standards for this product.

Environmental Impact

The agency has determined under 21 CFR 25.24(c)(6) 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.

Submitting Comments and Filing Objections

This final rule announces standards that FDA has accepted in a request for approval of an antibiotic drug. Because this final rule is not controversial and because when effective it provides notice of accepted standards, FDA finds that notice and comment procedure is unnecessary and not in the public interest. This final rule, therefore, becomes effective November 2, 1989. However, interested persons may, on or before November 2, 1989, submit comments to the Dockets Management Branch (address above). Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Any person who will be adversely affected by this final rule may file objections to it and request a hearing. Reasonable grounds for the hearing must be shown. Any person who decides to seek a hearing must file: (1) On or before November 2, 1989, a written notice of participation and request for hearing, and (2) on or before December 4, 1989, the data, information, and analyses on which the person relies to justify a hearing, as specified in 21 CFR 314.300. A request for hearing may not rest upon mere allegations or denials, but must set forth specific facts showing that there is a genuine and substantial issue of fact that requires a

hearing. If it conclusively appears from the face of the data, information, and factual analyses in the request for hearing that no genuine and substantial issue of fact precludes the action taken by this order, or if a request for hearing is not made in the required format or with the required analyses, the Commissioner of Food and Drugs will enter summary judgment against the person(s) who request(s) the hearing, making findings and conclusions and denying a hearing. All submissions must be filed in three copies, identified with the docket number appearing in the heading of this order and filed with the Dockets Management Branch.

The procedures and requirements governing this order, a notice of participation, and request for hearing, a submission of data, information, and analyses to justify a hearing, other comments, and grant or denial of a hearing are contained in 21 CFR 314.300.

All submissions under this order, except for data and information prohibited from public disclosure under 21 U.S.C. 331(j) or 18 U.S.C. 1950, may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects in 21 CFR Part 453

Antibiotics.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 453 is amended as follows:

PART 453—LINCOMYCIN ANTIBIOTIC DRUGS

1. The authority citation for 21 CFR part 453 continues to read as follows:

Authority: Sec. 507 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 357).

2. New § 453.522c is added to subpart F to read as follows:

§ 453.522c Clindamycin phosphate lotion.

(a) *Requirements for certification*—(1) *Standards for identity, strength, quality, and purity.* Clindamycin phosphate lotion contains clindamycin phosphate in a suitable and harmless lotion vehicle, with one or more suitable and harmless emollients, buffers, and dispersants. Each milliliter contains clindamycin phosphate equivalent to 10 milligrams of clindamycin. Its clindamycin content is satisfactory if it is not less than 90 percent and not more than 110 percent of the number of milligrams of clindamycin that it is represented to contain. Its pH is not less than 4.5 and not more than 6.5. It passes the identity test. The clindamycin

phosphate used conforms to the standards prescribed by § 453.22(a)(1).

(2) *Labeling.* It shall be labeled in accordance with the requirements of § 432.5 of this chapter.

(3) *Requests for certification; samples.* In addition to complying with the requirements of § 431.1 of this chapter, each such request shall contain:

(i) Results of tests and assays on:

(A) The clindamycin phosphate used in making the batch for clindamycin content, microbiological activity, moisture, pH, crystallinity, and identity.

(B) The batch for clindamycin content, pH, and identity.

(ii) Samples, if required by the Director, Center for Drug Evaluation and Research:

(A) The clindamycin phosphate used in making the batch: 10 packages, each containing approximately 300 milligrams.

(B) The batch: A minimum of six immediate containers.

(b) *Tests and methods of assay*—(1) *Clindamycin content (high performance liquid chromatographic assay).* Proceed as directed in § 436.216 of this chapter, using ambient temperature, an ultraviolet detection system operating at a wavelength of 210 nanometers, a 25-centimeter long x 4.6 millimeter ID column packed with microparticulate (5 to 10 micrometers in diameter) reversed phase octylsilane hydrocarbon bonded silica packing material, a flow rate of about 1.08 milliliter per minute, and a known injection volume of between 10 and 20 microliters. The retention time of clindamycin phosphate and clindamycin are approximately 6 and 9 minutes, respectively. Reagents, working standard and sample solutions, resolution test solution, system suitability requirements, and calculations are as follows:

(i) *Reagents*—(A) *0.1M Potassium phosphate monobasic buffer.* Dissolve 13.61 grams of potassium phosphate monobasic in 775 milliliters of water. Adjust the pH to 2.5 with phosphoric acid. Further dilute with water to a volume of 1,000 milliliters.

(B) *Mobile phase.* Mix 225 milliliters of acetonitrile and 775 milliliters of 0.1M potassium phosphate, pH 2.5 buffer (225:775). Filter through a suitable filter capable of removing particulate matter greater than 0.5 micron in diameter. Degas the mobile phase just prior to its introduction into the chromatograph.

(ii) *Preparation of working standard, sample, and resolution test solutions*—(A) *Working standard solution.* Dissolve an accurately weighted portion of the clindamycin phosphate working standard with sufficient mobile phase

(prepared as directed in paragraph (b)(1)(i)(B) of this section) to obtain a solution containing 200 micrograms of clindamycin activity per milliliter.

(B) *Sample solution.* Using a suitable hypodermic needle and syringe, remove an accurately measured representative portion from each container and dilute with sufficient mobile phase (prepared as directed in paragraph (b)(1)(i)(B) of this section) to obtain a solution containing 200 micrograms of clindamycin per milliliter (estimated).

(C) *Resolution test solution.* Dissolve 30 milligrams of clindamycin phosphate in 25 milliliters of mobile phase. Dissolve 30 milligrams of clindamycin hydrochloride in 25 milliliters of mobile phase. Combine both solutions in a 50-milliliter volumetric flask and shake or use a vortex shaker to assure mixture of both solutions. Use this solution to determine the resolution factor.

(iii) *System suitability requirements—*(A) *Asymmetry factor.* Calculate the asymmetry factor (A_s), measured at a point 5 percent of the peak height from the baseline as follows:

$$A_s = \frac{a+b}{2a}$$

where:

a = Horizontal distance from point of ascent to point of maximum peak height; and
 b = Horizontal distance from the point of maximum peak height to point of descent.

The asymmetry factor (A_s) is satisfactory if it is not more than 1.3.

(B) *Efficiency of the column.* From the number of theoretical plates (n) calculated as described in § 436.216(c)(2) of this chapter, calculate the reduced plate height (h_r) as follows:

$$h_r = \frac{(L) (10,000)}{(n) (d_p)}$$

where:

L = Length of the column in centimeters;
 n = Number of theoretical plates; and
 d_p = Average diameter of the particles in the analytical column packing in micrometers.

The absolute efficiency (h_r) is satisfactory if it is not more than 15.

(C) *Resolution factor.* The resolution factor (R) between the peak for clindamycin phosphate and the peak for clindamycin (hydrochloride) in the chromatogram of the resolution test solution is satisfactory if it is not less than 6.0.

(D) *Coefficient of variation (relative standard deviation).* The coefficient of

variation (S_R in percent) of 5 replicate injections of the working standard solution (prepared as directed in paragraph (b)(1)(ii)(A) of this section) is satisfactory if it is not more than 2.5 percent.

If the system suitability parameters have been met, then proceed as described in § 436.216(b) of this chapter.

(iv) *Calculations.* Calculate the clindamycin content as follows:

$$\text{Milligrams of clindamycin per milliliter} = \frac{A_u X P_s X d}{A_s X 1000}$$

where:

A_u = Area of the clindamycin phosphate peak in the chromatogram of the sample (at a retention time equal to that observed for the standard);

A_s = Area of the clindamycin phosphate peak in the chromatogram of the clindamycin phosphate working standard;

P_s = Clindamycin activity in the clindamycin phosphate working standard solution in micrograms per milliliter; and

d = Dilution factor of the sample.

(2) *pH.* Proceed as directed in § 436.202 of this chapter, using the undiluted lotion.

(3) *Identity.* The high-performance liquid chromatogram of the sample determined in paragraph (b)(1) of this section compares qualitatively to that of the clindamycin phosphate working standard.

Dated: September 22, 1989.

Albert Rothschild,
Acting Director, Office of Compliance, Center for Drug Evaluation and Research.

[FR Doc. 89-23213 Filed 10-2-89; 8:45 am]

BILLING CODE 4180-01-M

21 CFR Parts 510 and 522

Animal Drugs, Feeds, and Related Products; Yohimbine Injectable

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect a change in sponsor and approval of a new animal drug application (NADA) filed by Vet-A-Mix, Inc. The NADA provides for use of yohimbine injectable solution in dogs as a xylazine reversing agent and antidote.

EFFECTIVE DATE: October 3, 1989.

FOR FURTHER INFORMATION CONTACT: Marcia K. Larkins, Center for Veterinary Medicine (HFV-112), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857 301-443-3430.

SUPPLEMENTARY INFORMATION: Vet-A-Mix Laboratories, Inc., P.O. Box 86, Shenandoah, IA 51601, has informed FDA of a change in sponsor name and address to Vet-A-Mix, Inc., P.O. Box A, Shenandoah, IA 51601. Vet-A-Mix, Inc., has filed NADA 140-866 which provides for use of Yobine™ (yohimbine hydrochloride, 2 milligrams per milliliter) Injectable Solution for dogs to reverse the effects of xylazine. The NADA is approved and new 21 CFR 522.2670 is added to reflect the approval. The basis for approval is discussed in the freedom of information summary.

In addition, the list of sponsors of approved NADA's in the table in 21 CFR 510.600(c) (1) and (2) is amended to reflect the new sponsor name and address.

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. 4-62, 5600 Fishers Lane, Rockville, MD 20857 from 9 a.m. to 4 p.m., Monday through Friday.

The agency has carefully considered the potential environmental effects of this action. FDA 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, contained in an environmental assessment, may be seen in the Dockets Management Branch (address above), between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects

21 CFR part 510

Administrative practice and procedure, Animal drugs, Labeling, Reporting and recordkeeping requirements.

21 CFR part 522

Animal drugs.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR parts 510 and 522 are amended as follows:

PART 510—NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 510 continues to read as follows:

Authority: Secs. 201, 301, 501, 502, 503, 512, 701, 706 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 351, 352, 353, 360b, 371, 376).

2. Section 510.600 is amended in the table of paragraph (c)(1) by revising the entry for "VET-A-MIX Laboratories, Inc., and in the table of paragraph (c)(2) in the entry for "032998" by revising the sponsor name and address to read as follows:

§ 510.600 Names, addresses, and drug labeler codes of sponsors of approved applications.

(c) (1)	
Firm name and address	Drug labeler code
Vet-A-Mix, Inc., P.O. Box A, Shenandoah, IA 51601	032998
(2)	
Drug labeler code	Firm name and address
032998	Vet-A-Mix, Inc., P.O. Box A, Shenandoah, IA 51601.

PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS NOT SUBJECT TO CERTIFICATION

3. The authority citation for 21 CFR part 522 continues to read as follows:

Authority: Sec. 512 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b).

4. New § 522.2670 is added to read as follows:

§ 522.2670 Yohimbine injectable.

(a) *Specifications.* Each milliliter of sterile aqueous solution contains 2 milligrams of yohimbine (as hydrochloride).

(b) *Sponsor.* See 032998 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs—(1) Amount.* 0.05 milligram per pound (0.11 milligram per kilogram) of body weight.

(2) *Indications for use.* To reverse the effects of xylazine.

(3) *Limitations.* For intravenous use in dogs only. Not for use in food-producing animals. Safety of use in pregnant dogs or in dogs intended for breeding has not been established. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

Dated: September 25, 1989.

Gerald B. Guest,
Director, Center for Veterinary Medicine.
[FR Doc. 89-23215 Filed 10-2-89; 8:45 am]
BILLING CODE 4160-01-M

21 CFR Part 558.

Animal Drugs, Feeds, and Related Products; Monensin; Correction

AGENCY: Food and Drug Administration.
ACTION: Final rule; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a final rule that amended the animal drug regulations to reflect approval of Elanco Products Co.'s supplemental new animal drug application (NADA 95-735) for use of a monensin Type C goat feed (August 9, 1989; 54 FR 32633). In providing for the amended medicated feed application regulation, the document inadvertently omitted turkeys and quail. This document corrects that omission.

EFFECTIVE DATE: August 9, 1989.

FOR FURTHER INFORMATION CONTACT: David L. Gordon, Center for Veterinary Medicine (HFV-238), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857 301-443-6243.

PART 558—[AMENDED]

§ 558.4 [Corrected]

In FR Doc. 89-18589, appearing at page 32633 in the Federal Register of Wednesday, August 9, 1989, the following correction is made: On the same page, in the 3d column, in § 558.4, under amendment "4. 6th line, "Chickens:" is revised to read "Chickens, turkeys, and quail:"

Dated: September 25, 1989.
Gerald B. Guest,
Director, Center for Veterinary Medicine.
[FR Doc. 89-23216 Filed 10-2-89; 8:45 am]
BILLING CODE 4160-01-M

EQUAL EMPLOYMENT OPPORTUNITY COMMISSION

29 CFR Part 1601

706 Agencies; Designation of Anchorage (AK) Equal Rights Commission

AGENCY: Equal Employment Opportunity Commission.

ACTION: Final rule.

SUMMARY: The Equal Employment Opportunity Commission amends its regulations on certified designated 706 agencies. Publication of this amendment

effectuates the designation of the Anchorage (AK) Equal Rights Commission as a certified 706 Agency.
EFFECTIVE DATE: October 3, 1989.

FOR FURTHER INFORMATION CONTACT: Valentina Jackson, Equal Employment Opportunity Commission, Office of Program Operations, Systemic Investigations and Individual Compliance Programs, State and Local Branch, 1801 L Street NW Room 8060, Washington, DC 20507 Telephone 202/663-4892.

SUPPLEMENTARY INFORMATION: The Commission has determined that the Anchorage (AK) Equal Rights Commission meets the eligibility criteria for certification of a designated 706 agency as established in 29 CFR 1601.75(b). In accordance with 29 CFR 1601.75(c), the Commission hereby amends the list of certified designated 706 agencies to include the Anchorage Commission. Publication of this amendment to § 1601.80 effectuates the designation of the following agency as a certified 706 agency: Anchorage (AK) Equal Rights Commission.

List of Subjects in 29 CFR Part 1601

Administrative practice and procedure, Equal employment opportunity, Intergovernmental relations.

Accordingly, 29 CFR part 1601 is amended as follows:

PART 1601—[AMENDED]

1. The authority citation for part 1601 continues to read as follows:

Authority: 42 U.S.C. 2000e to 2000e-17

§ 1601.60 [Amended]

2. Section 1601.60 is amended by adding, in alphabetical order, the Anchorage (AK) Equal Rights Commission.

Signed at Washington, DC this 27th day of September 1989, for the Commission.

James H. Troy,
Director, Office of Program Operations.
[FR Doc. 89-23219 Filed 10-2-89; 8:45 am]
BILLING CODE 6570-06-M

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[FRL-3653-8]

Approval and Promulgation of Implementation Plans; Michigan

AGENCY: U.S. Environmental Protection Agency (USEPA).

ACTION: Final rule.

SUMMARY: The purpose of this notice is to announce final rulemaking action on a Stipulation of Entry of Consent Order and Final Order, State Implementation Plan (SIP) No. 14-1987 for Continental Fiber Drum, Inc. (Continental) in Midland, Michigan. The order concerns the volatile organic compounds (VOC) emissions from surface coating operations. This action approves Consent Order No. 14-1987 as a revision to the Michigan SIP

DATES: This action is effective December 4, 1989, unless notice is received within 30 days that someone wishes to submit comments. If the effective date is delayed, timely notice will be published in the Federal Register.

ADDRESSES: Copies of the SIP revision are available at the following addresses for review: (It is recommended that you telephone Ms. Toni Lesser, at (312) 886-6037 before visiting the Region V office.)

U.S. Environmental Protection Agency, Region V Air and Radiation Branch (5AR-26), 230 South Dearborn Street, Chicago, Illinois 60604

Michigan Department of Natural Resources, Air Quality Division, Stevens T. Mason Building, 530 West Allegan, Lansing, Michigan 48909

U.S. Environmental Protection Agency, Public Information Reference Unit, 401 M Street SW Washington, DC 20460.

Comments on these proposed rules should be addressed to: (Please submit an original and three copies, if possible.) Gary Gulezian, Chief, Regulatory Analysis Section, U.S. Environmental Protection Agency, Air and Radiation Branch (5AR-26), 230 South Dearborn Street, Chicago, Illinois 60604.

FOR FURTHER INFORMATION CONTACT: Ms. Toni Lesser, Michigan Regulatory Specialist, U.S. Environmental Protection Agency, Air and Radiation Branch (5AR-26), 230 South Dearborn Street, Chicago, Illinois 60604. (312) 886-6037

SUPPLEMENTARY INFORMATION: On December 17 1987 the State of Michigan submitted to USEPA a revision in the form of Stipulation for Entry of Consent Order and Final Order, SIP No. 14-1987 for Continental. The order concerns volatile organic compounds (VOC) emissions from the surface coating operations at the facility located in Midland, Michigan.

Continental is a metal drum coating facility located in Midland County, which is classified as rural nonattainment for ozone. Continental operations involve applying interior and exterior coatings to shells and heads of

metal drums which are subject to Michigan's Rule 336.1621. Rule 336.1621 limits the VOC content of extreme performance coating applied to miscellaneous metal parts and products to 3.5 pounds per gallon coating.

Michigan's Consent Order No. 14-1987 proposed the following requirements as an alternative to the requirements contained in Rule 336.1621:

1. The emission of VOCs from the coating line operations conducted at Continental meet the following limits:

(a) 3.0 pounds of VOC per gallon of coating, minus water, as applied, for each exterior drum coating; and

(b) 4.3 pounds of VOC per gallon of coating, minus water, as applied, for each interior drum coating.

2. The total annual emission of VOCs from the coating line operations conducted at the Continental shall not exceed 80 tons per year. Continental shall not operate the coating line for more than 3,000 hours per year.

3. Continental shall employ heat application to all coatings for which such application is determined to be technically feasible.

USEPA's guidance recommends that a "presumptive norm of 4.3 pounds of VOC per gallon of coating less water is a reasonably available control technology (RACT) for coatings used in pail and drum interior protective linings" Therefore, USEPA is today approving the Stipulation for Entry of Consent Order and Final Order, SIP No. 14-1987 for Continental as a revision to the Michigan SIP because it represents a site-specific RACT determination which limits the interior coating used by Continental to the presumptive norm of 4.3 pounds of VOC per gallon of coating less water.

USEPA believes it is not necessary for Michigan to provide an up-to-date attainment demonstration for Midland County in this case, because the revision will not cause an increase in actual emissions and Midland County is a rural nonattainment area that was never required to have an ozone attainment demonstration. USEPA believes today's action to be noncontroversial and routine, therefore, it is being approved without prior proposal. This action will become effective December 4, 1989. However, if we receive notice by November 2, 1989, that someone wishes to submit comments, then USEPA will publish: (1) A notice that withdraws the action, and (2) a notice that begins a new rulemaking by proposing the action and establishing a comment period.

The Office of Management and Budget has exempted this rule from the requirements of section 3 of Executive Order 12291.

Under 5 U.S.C. 605(b), I certify that this SIP approval action will not have a significant economic impact on a substantial number of small entities.

Under section 307(b)(1) of the CAA, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by (60 days from date of publication). This action may not be challenged later in proceedings to enforce its requirements (See section 307(b)(2)).

List of Subjects in 40 CFR Part 52

Air pollution control, Ozone, Incorporation by reference, Intergovernmental relations.

Note: Incorporation by reference of the State Implementation Plan for the State of Michigan was approved by the Director of the Federal Register on July 1, 1982.

Dated: September 22, 1989.

F Henry Habicht,
Acting Administrator.

PART 52—APPROVAL AND PROMULGATION OF IMPLEMENTATION PLANS**Subpart X—Michigan**

Title 40 of the Code of Federal Regulations, chapter 1, part 52, is amended as follows:

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

Authority: 42 U.S.C. 7401-7642.

2. Section 52.1170 is amended by adding paragraph (c)(90) to read as follows:

§ 52.1170 Identification of plan.

(c)

(90) On December 17 1987 the State of Michigan submitted to USEPA a revision to the Michigan State Implementation Plan for the Continental Fiber Drum, Inc., which limits volatile organic compound emissions from the surface coating operations at the facility.

(i) Incorporation by reference.

(A) State of Michigan, Air Pollution Control Commission, Stipulation for Entry of Consent Order and Final Order No. 14-1987 which was adopted by the State on December 9, 1987

(B) Letter of December 17 1987 from the State of Michigan, Department of Natural Resources to USEPA.

[FR Doc. 89-23240 Filed 10-2-89; 8:45 am]

BILLING CODE 6560-50-M

40 CFR Part 52

[SC-012; FRL-3655-2]

Approval and Promulgation of Implementation Plans, South Carolina: Approval of Plan Revisions**AGENCY:** Environmental Protection Agency (EPA).**ACTION:** Final rule.

SUMMARY: EPA is approving revisions to the South Carolina State Implementation Plan (SIP) which were submitted by the South Carolina Department of Health and Environmental Control (SCDHEC) on June 5, 1985. EPA is deferring action on the revisions to Regulation 62.1, section II (Permit Requirements). The entire section has been reorganized affecting each of the parts in this section collectively including part B (Operating Permit). EPA does not currently have regulations for evaluating operating permit programs and consequently does not recognize such operating permit programs as being part of a SIP. Since the revisions to this section affect each of the parts including part B, EPA is deferring action on the entire Section II until such time that the operating permit program issue is decided. EPA at this time is not taking action on the revisions to Regulations 62.5, Standard No. 6 (Alternative Emission Limitation Options) since EPA is presently evaluating this regulation for agreement with the new Emissions Trading Policy (ETP) published on December 4, 1986 (51 FR 43814). The changes and additions to the regulatory and nonregulatory parts of the South Carolina plan involved: requirements concerning prohibition of open burning; emissions from fuel burning operations; emissions from process industries; requirements concerning air pollution episodes; control of fugitive particulate matter; requirements concerning the prevention of significant deterioration of air quality in South Carolina; and the requirements concerning source evaluation contained in chapter 7 of the narrative portion of the SIP.

DATES: This action will be effective November 2, 1989.

ADDRESSES: Written comments should be addressed to Beverly T. Hudson of EPA Region IV (address below). Copies of the materials submitted by South Carolina may be examined during normal business hours at the following locations:

Public Information Reference Unit,
Library System Branch,
Environmental Protection Agency, 401
M Street, SW Washington, DC 20460.

Environmental Protection Agency,
Region IV Air Programs Branch, 345
Courtland Street, NE., Atlanta,
Georgia 30365.

Bureau of Air Quality Control, South
Carolina Department of Health and
Environmental Control, 2600 Bull
Street, Columbia, South Carolina
29201.

FOR FURTHER INFORMATION CONTACT:
Beverly T. Hudson of the EPA Region IV
Air Programs Branch at the address
given above, telephone (404) 347-2864
(FTS 257-2864).

SUPPLEMENTARY INFORMATION: On June 5, 1985, the South Carolina Department of Health and Environmental Control submitted to EPA for approval revisions to the South Carolina State Implementation Plan, and EPA is today approving a number of them. This submittal contained certification that the revisions were preceded by adequate notice and public hearing. The revisions submitted by South Carolina on June 5, 1985, were discussed in detail in the December 15, 1988, proposal notice (53 FR 50425). For simplicity, only those portions of the submittal which EPA is not taking action on will be discussed again here. They are as follows:

Regulation 62.1, section II (Permit Requirements) was amended by reorganizing and adding to the existing regulation. The regulation is split into six parts. Part A stipulates requirements for construction permits. Part B stipulates requirements for operating permits. The remaining parts pertain to permit applications, special permit conditions, permit exemptions, and permit inspections. The entire section has been reorganized affecting each of the parts in this section collectively including part B (Operating Permit). EPA currently has no regulations or guidance which specify the requirements for an approvable operating permit program and consequently does not recognize such operating permit programs as part of a SIP. Since the revisions affect each of the parts in this section including Part B, EPA is deferring action on the entire section II. EPA is planning on proposing operating permit regulations in the near future as a result of the Chemical Manufacturers Association (CMA) rulemaking pursuant to the out of court settlement. If and when EPA promulgates the operating permit regulations, EPA will take action to approve or disapprove the revisions to section II at that time.

Regulation 62.5, Standard No. 6 (Alternative Emission Limitation Options) was revised to provide better clarity within the regulation. EPA is not

taking action at this time on the revisions to this regulation since EPA is presently evaluating this regulation for agreement with the new Emissions Trading Policy (ETP) published on December 4, 1986 (51 FR 43814). These revisions will be acted upon in a separate notice.

For a detailed discussion of the revisions EPA is acting on, please refer to the December 15, 1988, proposal notice.

On December 15, 1988 (53 FR 50425), EPA proposed to approve the revisions which South Carolina submitted on June 5, 1985. At that time, the public was invited to submit written comments on the proposed action. However, no comments were received.

Final Action: EPA is approving the regulation changes which were submitted on June 5, 1985, as detailed in December 15, 1988, proposal notice. EPA is taking no action on revisions to Regulations 62.1, section II B (Operating Permit) since EPA does not recognize that this section is part of the SIP. EPA is also not taking action on the revisions to Regulations 62.5, Standard No. 6 (Alternative Emission Limitation Options) since EPA is presently evaluating this regulation for agreement with the new Emissions Trading Policy (ETP) published on December 4, 1986 (51 FR 43814).

The Office of Management and Budget has exempted this rule from the requirements of section 3 of Executive Order 12291.

Under section 307(b)(1) of the Act, petitions for judicial review of this action must be filed in the United States Court of appeals for the appropriate circuit by December 4, 1989. This action may not be challenged later in proceedings to enforce its requirements (See section 307(b)(2).)

List of Subjects in 40 CFR Part 52

Air pollution control, Carbon monoxide, Incorporation by reference, Intergovernmental relations, Particulate matter, Sulfur oxides.

Note: Incorporation by reference of the State Implementation Plan for the State of South Carolina was approved by the Director of the Federal Register on July 1, 1982.

Dated: March 3, 1989.

Lee A. DeHihns, III,
Acting Regional Administrator.

Editorial Note: This document was received at the Office of the Federal Register September 28, 1989.

PART 52—[AMENDED]

Part 52 of chapter 1, Title 40 of the Code of Federal Regulations is amended as follows:

Subpart PP—South Carolina

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

Authority: 42 U.S.C. 7401-7642.

2. Section 52.2120 is amended by adding paragraph (c)(31) to read as follows:

§ 52.2120 Identification of plan.

(c)

(31) Changes in South Carolina's SIP submitted to EPA on June 5, 1985, by the South Carolina Department of Health and Environmental Control.

(i) Incorporation by reference.

(A) Changes in South Carolina's Regulations which were adopted May 24, 1985:

(1) Regulations 62.1, Section I (Definitions) No. 1 and Section III (Emission Inventory)

(2) Regulation 62.2 (Prohibition of Open Burning)

(3) Regulation 62.3 (Air Pollution Episodes); except for Section I and Section II Introductory paragraph

(4) Regulation 62.5, Standard No. 1 (Emissions From Fuel Burning Operations), Section IV Part B, Section V and Section VII

(5) Regulation 62.5, Standard No. 4 (Emissions from Process Industries), Except for Section III, Section VIII(A), and Section XI Introductory paragraph

(6) Regulation 62.5, Standard No. 7 (Prevention of Significant Deterioration), Section I, Parts B(1), E, F and Q(2).

(7) Regulation 62.6 (Control of Fugitive Particulate Matter), Section I (b) and (c) and Section III (c) and (d)

(ii) Other material.

Quality State Implementation Plan (SIP) for particulate matter. On July 1, 1987 EPA promulgated new ambient air quality standards for particulate matter which are based upon the measurement of particles having an aerodynamic diameter of 10 microns or less (PM₁₀). Consequently, states are required to develop plans which provide for attainment and maintenance of these new standards. The South Carolina statewide SIP revision demonstrates that the existing SIP for total suspended particulates (TSP) is adequate to provide for attainment and maintenance of the PM₁₀ standards.

DATES: This action will become effective on December 4, 1989 unless notice is received within 30 days that someone wishes to submit adverse or critical comments. If the effective date is delayed, timely notice will be published in the Federal Register.

ADDRESSES: Written comments should be addressed to Beverly T. Hudson of EPA Region IV's Air Programs Branch (see EPA region IV address below). Copies of the documents relevant to this action are available for public inspection during normal business hours at the following locations:

Public Information Reference Unit,
Library System Branch,
Environmental Protection Agency, 401
M. Street, SW Washington, DC
20460.

EPA Region IV Air Programs Branch,
345 Courtland Street, N.E., Atlanta,
Georgia 30365.

Bureau of Air Quality Control, South
Carolina Department of Health and
Environmental Control, 2600 Bull
Street, Columbia, South Carolina
29201.

FOR FURTHER INFORMATION CONTACT:
Beverly T. Hudson, Air Programs
Branch, EPA Region IV at the above
address and telephone number (404)
347-2864 or FTS 257-2864.

SUPPLEMENTARY INFORMATION: The 1977 amendments to the Clean Air Act require the Environmental Protection Agency (EPA) to review periodically and, if appropriate, revise the criteria on which each National Ambient Air Quality Standard (NAAQS) is based, along with the standard itself. In response to these requirements, EPA, on July 1, 1987 (52 FR 24634), promulgated revised primary and secondary NAAQS by replacing the total suspended particulate matter standard with a standard that included only those particles with an aerodynamic diameter less than or equal to a nominal 10 micrometers. These particles are referred to as "PM₁₀". The PM₁₀ standard covers a size range of particles

different than the range of particles covered by the former particulate standard, total suspended particulate (TSP). This means the states have to develop and implement PM₁₀ control programs. This process will follow the basic approach used in the development and implementation of TSP control programs. First, the air quality across the state is examined and areas where improvement is needed are delineated. Then, the degree of improvement needed is determined. Next, the sources contributing to the problem are inventoried and a strategy is developed to reduce emissions from those sources to bring about attainment of the NAAQS. Finally the strategy is implemented and steps are taken to ensure that the NAAQS will not be violated.

EPA, in conjunction with the states, have completed the first two steps in the development and implementation of control programs. Areas have been categorized into three groups. They are:

Group I—Areas for which the existing particulate matter SIP may need substantial revision to be adequate for attaining and maintaining PM₁₀ standards.

Group II—Areas for which the existing particulate matter SIP may be adequate or need only minor adjustment.

Group III—Areas for which the existing particulate matter SIP's are believed adequate to attain and maintain the PM₁₀ standards.

EPA evaluated the probabilities of PM₁₀ air quality levels predicted from actual TSP data and concluded that South Carolina is a Group III area; therefore, the South Carolina State Implementation Plan had to be revised to address the PM₁₀ NAAQS in the following ways:

a. To include State ambient air quality standards for PM₁₀ at least as stringent as the NAAQS;

b. To trigger preconstruction review for new or modified sources which would emit significant amounts of either PM or PM₁₀ emissions;

c. To invoke the emergency episode plan to prevent PM₁₀ concentrations from reaching the significant harm level of 600 µg/m³

d. To meet ambient PM₁₀ monitoring requirements of 40 CFR Part 58; and

e. To meet the requirements of 40 CFR 51.322 and 51.323 to report actual annual emissions of PM₁₀ (beginning with emissions for 1988) for point sources emitting 100 tons per year or more.

On April 29, 1988, the State of South Carolina submitted to EPA several

[FR Doc. 89-23330 Filed 10-2-89; 8:45 am]

BILLING CODE 6560-50-M

40 CFR Part 52

[SC-020; FRL-3655-3]

Approval and Promulgation of Implementation Plans South Carolina: Revisions for PM₁₀

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA) is today announcing the approval of the South Carolina State Air

revisions to the State Implementation Plan (SIP). Subsequent to the April 29 submittal, by letters of June 16 and August 1, 1988, EPA noted deficiencies in the revision. As a result of the noted deficiencies, the State's rulemaking process was reinitiated, culminating in a public hearing on November 28, 1988. All of EPA's comments and revisions are reflected in the following regulations which South Carolina resubmitted on April 4, 1989.

Regulation 62.1, Definitions, Permit

Requirements, and Emissions Inventory

Regulation 62.3, Air Pollution Episodes

Regulation 62.5, Standard No. 1—Emissions from Fuel Burning Operations

Regulation 62.5, Standard No. 2—Ambient Air Quality Standards

Regulation 62.5, Standard No. 4—Emissions from Process Industries

Regulation 62.5, Standard No. 6—Alternative Emission Limitation Options

Regulation 62.5, Standard No. 7—Prevention of Significant Deterioration

SIP Narrative Section 8—New Source Review and Source Permit System and Offset Policy

SIP Amendments

Regulation 62.1, Definitions, Permit Requirements, and Emissions Inventory, was revised to include definitions of "PM₁₀," "particulate emissions," and "particulate matter emissions." The definition of "suspended particulate" was amended to "total suspended particulate." The regulation also revised references to "particulate" and includes permit conditions presently stated in the State's Pollution Control Act. EPA currently has no regulations or guidance which specify the requirements for an approvable operating permit program and consequently does not recognize such operating permit programs as part of a SIP. Regulation 62.1, section II was previously revised in a June 5, 1985, submittal. EPA has deferred action on the June 5, 1985, revision and is deferring action on this revision. EPA is planning on proposing operating permit regulations in the near future as a result of the Chemical Manufacturers Association rulemaking pursuant to the out of court settlement. If and when EPA promulgates the operating permit regulations, EPA will take action to approve or disapprove the revisions to section II at that time.

Regulation 62.3, Air Pollution Episodes, is revised by adding PM₁₀ Watch, Alert, and Emergency levels. It specifies the conditions justifying the proclamation of an air pollution episode. The revision deletes levels for "Particulate," "SO₂ and Particulate combined," and revises references to "Particulate."

Regulation 62.5, Standard No. 1, Emissions from Fuel Burning Operations, is revised in its references to "Particulate."

Regulation 62.5, Standard No. 2, Ambient Air Quality Standards, is revised to incorporate the PM₁₀ ambient air quality standards, to revise the "suspended particulates" standard, and to include methods used to determine attainment of the PM₁₀ standard which are the same as the standards and methods in the July 1, 1987 Federal Register notice.

Regulation 62.5, Standard No. 4, Emissions from Process Industries, is amended to revise references to "Particulate."

Regulation 62.5, Standard No. 6, Alternative Emission Limitation Options, was amended to revise references to "Particulate." The state submitted a revision to 62.5, Standard No. 6, on June 5, 1985. EPA is evaluating this regulation, as revised in both submittals for agreement with the new Emissions Trading Policy published on December 4, 1986 (51 FR 43814). EPA will act on both revisions to Standard No. 6 at the same time.

Regulation No. 62.5, Standard No. 7 is revised to add clarifying references to "particulate matter" and "governing standard," to delete the "24-hour" averaging time reference, to add a requirement for EPA's concurrence, to change the referenced standard from federal to State, to replace "particulate matter" in the Class I variance table with "TSP" to add PM₁₀ emission rates, to add a "Grandfather rule," to add a PM₁₀ impact level, to add PM₁₀ monitoring transition requirements, and to include allowable increases of PM₁₀.

In addition to the revisions to the Regulations and Standards, clarifying language was added to the narrative portion of the South Carolina Air Quality Implementation Plan to maintain consistency with the regulatory and federal requirements. The narrative portion includes section 8, New Source Review and Source Permit System, and the offset policy. EPA will approve these revisions in a separate notice.

In order to complete South Carolina's PM₁₀ SIP submittal, the Bureau of Air Quality Control submitted a list of the regulations relied upon to maintain the PM₁₀ National Ambient Air Quality Standards along with the corresponding Federal Register approval dates.

Final Action. EPA has reviewed the submitted material and found it to meet the requirements of 40 CFR part 51. Therefore, EPA approves the South Carolina PM₁₀ revisions. However, the revisions for the nonattainment new

source review and source permit system, and offset policy will be dealt with in a forthcoming notice.

This action is being taken without prior proposal because the changes are noncontroversial and EPA anticipates no significant comments on them. The public should be advised that this action will be effective 60 days from date of this Federal Register notice. However, if notice is received within 30 days that someone wishes to submit adverse or critical comments, this action will be withdrawn and two subsequent notices will be published before the effective date. One notice will withdraw the final action and another will begin a new rulemaking by announcing a proposal of the action and establishing a comment period.

Under 5 U.S.C. 605(b), I certify that these revisions will not have a significant economic impact on a substantial number of small entities. (See 46 FR 8709.)

This action has been classified as a Table 3 action by the Regional Administrator under the procedures published in the Federal Register on January 19, 1989 (54 FR 2214-2225). On January 6, 1989, the Office of Management and Budget waived Table 2 and 3 SIP revisions (54 FR 2222) from the requirements of Section 3 of Executive Order 12291 for a period of two years.

Under section 307(b)(1) of the Act, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by [60 days from date of publication]. This action may not be challenged later in proceedings to enforce its requirements. (See 307(b)(2).)

List of Subjects in 40 CFR Part 52:

Air pollution control; Incorporation by reference; Intergovernmental relations; Particulate matter.

Note: Incorporation by reference of the State Implementation Plan for the State of South Carolina was approved by the Director of the Federal Register on July 1, 1982.

Dated: June 22, 1989.

Joe R. Franzmathes,

Acting Regional Administrator.

Part 52 of chapter I, title 40, Code of Federal Regulations, is amended as follows:

PART 52—[AMENDED]

Subpart PP—South Carolina

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

Authority: 42 U.S.C. 7401-7642.

2. Section 52.2120 is amended by adding paragraph (c)(32) to read as follows:

§ 52.2120 Identification of plan.

(c)

(32) Provisions for PM₁₀ submitted on April 29, 1988 and April 4, 1989, by the South Carolina Department of Health and Environmental Control. The April 29, 1988, submittal contained revisions that were effective on April 22, 1988. The April 4, 1989, submittal contained revisions that were effective on March 24, 1989.

(i) Incorporation by reference.

(A) Regulation 62.1, Definitions, Permit Requirements, and Emissions Inventory as revised by the addition on April 22, 1988, of Section I, Nos. 22, 23, 25, and 42.

(B) The following portions of Regulation 62.3, Air Pollution Episodes were revised April 22, 1988.

(1) Section I.

(2) Section II, Introductory paragraph.

(C) The following portions of Regulation 62.5, Standard No. 1—Emissions from Fuel Burning Operations were revised April 22, 1988:

(1) Section II, Title.

(2) Section VI, Introductory paragraph

(D) Regulation 62.5, Standard No. 2—Ambient Air Quality Standards revised April 22, 1988.

(E) The following portions of Regulation 62.5, Standard No. 4—Emissions from Process Industries were revised April 22, 1988.

(1) Section III

(2) Section VIII (A)

(3) Section XI, Introductory paragraph

(F) The following portions of Regulation 62.5, Standard No. 7—Prevention of Significant Deterioration were revised April 22, 1988.

(1) Section I, Part V(1)

(2) Section II, Part A

(3) Section III Part H(1)

(4) Section IV Part E(4)

(G) The following portions of Regulation 62.5, Standard No. 7—Prevention of Significant Deterioration were revised March 24, 1989.

(1) Section III, Part D, (6) and (7)

(2) Section III Part (J)(3), (4), and (5)

(3) Section IV Part (H)(4)

(ii) Other materials.

(A) Letters of April 29, 1988, and April 4, 1989, from the South Carolina Department of Health and Environmental Control which address PM₁₀ revisions.

(B) Revised narrative on particulate matter.

[FR Doc. 89-23329 Filed 10-2-89; 8:45 am]

BILLING CODE 6560-50-M

40 CFR Parts 60 and 61

[FRL-3651-1; Docket No. AMO705]

Standards of Performance for New Stationary Sources and National Emission Standards for Hazardous Air Pollutants; Delegation of Authority to the State of Delaware

AGENCY: U.S. Environmental Protection Agency.

ACTION: Final rule.

SUMMARY: Sections 111(c) and 112(d) of the Clean Air Act (CAA) permits EPA to delegate to the States the authority to implement and enforce the standards set out in 40 CFR parts 60 and 61, Standards of Performance for New Stationary Sources (NSPS) and National Emission Standards for Hazardous Air Pollutants (NESHAP). On December 21, 1988, the State of Delaware requested EPA to delegate to it the authority for additional NSPS and NESHAP source categories.

EFFECTIVE DATE: April 26, 1989.

ADDRESSES: Applications and reports required under NSPS and NESHAP source categories which EPA has delegated Delaware authority to implement and enforce should be addressed to: Mr. Robert French, Delaware Department of Natural Resource and Environmental Control, 89 Kings Highway, P.O. Box 1401, Dover, Delaware 19901, rather than to EPA Region III.

FOR FURTHER INFORMATION CONTACT: Terry Yost at (215) 597-2746.

SUPPLEMENTARY INFORMATION: On December 21, 1988, the State of Delaware requested additional NSPS and NESHAP source categories. Delaware requested these delegations to supplement the delegations for other source categories which the State had already received and which EPA had published notifications at 43 FR 66771 (1978), 44 FR 70465 (1979), 46 FR 28402 (1981), 48 FR 41764 (1983), 47 FR 17989 (1982), 51 FR 12144 (1986).

The following letter was sent to Delaware on delegating authority for additional source categories:

Dear Secretary Clark:

On December 21, 1988, Mr. Wilson, former Secretary, requested that EPA delegate to the State of Delaware the authority to implement and enforce additional New Source Performance Standards (NSPS) and National Emission Standards for Hazardous Air Pollutants (NESHAP) for various NSPS and NESHAP source categories. These additional source categories are as follows:

1. Standards of Performance for Petroleum Liquids for which Construction, Reconstruction, or Modification commenced after June 11, 1973, and prior to May 19, 1978. This action would replace the previous

delegation with EPA revised version of 6/16/87

2. Standards of Performance for Storage Vessels for Petroleum Liquids for which Construction, Reconstruction, or Modification commenced after May 18, 1978, and prior to July 23, 1984. This amends the previous delegation, EPA's revised version, to incorporate the 40 CFR part 60, Subpart Ka (4/8/87).

3. Standards of Performance for Equipment Leaks of VOC in Synthetic Organic Chemical Manufacturing Industry. This action will replace the previous delegation to incorporate EPA revised version of 1/21/86.

4. Standards of Performance for Industrial-Commercial-Industrial Steam Generating Units. This is an additional adoption by reference of the Federal NSPS, subpart D which was promulgated on 11/25/86.

5. Standards of Performance for Volatile Organic Liquid Storage Vessels (including Petroleum Liquid Storage Vessels), for which Construction, Reconstruction, or Modification commenced after July 23, 1984. This is an additional adoption by reference of the Federal NSPS subpart Kb, which was promulgated on 6/16/87

6. National Emission Standards for Mercury. This action will replace the 2/15/78 delegation with EPA revised version of 3/19/87

7. National Emission Standards for Vinyl Chloride. This action will replace the 4/27/82 delegation with EPA revised version of 9/30/86.

8. National Emission Standards for Equipment Leaks (Fugitive Emission Sources). This action will replace the delegation with EPA revised version of 7/1/86.

Also requested was EPA's approval of Delaware's adoption by reference of the following Test Methods for the determination of compliance with applicable New Source Performance Standards and National Emission Standards for Hazardous Air Pollutants:

1. 40 CFR, part 60, Standards of Performance for New Stationary Sources: Appendix A, Reference Methods, Miscellaneous Clarifications and Additions of Concentration Calculation Equations to Method 19, 1987 pp. 5106-5112, and the corrections as they appear in 40 CFR, part 60, Vol. 52, No. 64, Friday, April 3, 1987 p. 10852.

2. 40 CFR, part 60, Standards of Performance for New Stationary Sources: Addition of Alternative Procedures (Critical Orifice as Calibration Standards) to Method 5, Appendix A, published in the Federal Register Vol. 52, No. 58, Thursday, March 26, 1987 pp. 9658-9662, and the corrections as they appear in 40 CFR, Part 60, Vol. 52, No. 115, Thursday, June 16, 1987 p. 22888.

3. 40 CFR, part 60, Standards of Performance for New Stationary Sources; Reference Methods; Method 15A for the Determination of Total Reduced Sulfur Emissions from Sulfur Recovery Plants in Petroleum Refineries, published in the Federal Register, Vol. 51, No. 107 Wednesday, June 4, 1986, p. 20288.

4. 40 CFR, part 60, Standards of Performance for New Stationary Sources;

Addition of Alternative Procedure to Method 1 of Appendix A; Measurement Location, published in the *Federal Register*, Vol. 51, No. 107 Wednesday, June 4, 1986, p. 20288.

5. 40 CFR, part 60, Standards of Performance for New Stationary Sources, subparts D and Da, Appendix A, published in the *Federal Register*, Vol. 51, No. 112, Wednesday, June 11, 1986, pp. 21164-21172, and the corrections as they appear in 40 CFR, part 60, Vol. 52, No. 101, Wednesday, May 27 1987 p. 198797

6. 40 CFR, part 60, Appendix B, Alternative Procedure to Performance Specification 2, for SO₂ and NO_x Continuous Emission Monitoring Systems, published in the *Federal Register*, Vol. 51, No. 115, Monday, June 16, 1986.

7. 40 CFR, part 60, Appendix F Procedure 1, Quality Assurance Requirements for Gaseous Continuous Emission Monitoring Systems Used for Compliance Determination, Published in the *Federal Register*, Vol. 52, No. 107 Thursday, June 4, 1987 pp. 21007-21010.

8. 40 CFR, part 61, Test Method 107 for National Emission Standards for Hazardous Air Pollutants, published in the *Federal Register*, Vol. 52, No. 104, dated Monday, June 1, 1987

We have reviewed the pertinent laws, rules, and regulations of the State of Delaware and have determined that they continue to provide adequate and effective procedures for implementing and enforcing the NSPS and NESHAP regulations. Therefore, we hereby delegate our authority for the implementation and enforcement of the NSPS and NESHAP regulations listed above to the State of Delaware for all sources located or to be located in Delaware that fall under the requirements of these regulations. We also approve Delaware's adoption by reference of the above test methods and test method revisions.

This NSPS and NESHAP delegation is based upon the following conditions:

1. Quarterly reports which may be combined with other reporting information are to be submitted to EPA Region III, Air Enforcement Section (3AM20) by the Delaware Department of Natural Resources and Environmental Control (DNREC) and should include the following:

- (i) Source determined to be applicable during that quarter.
- (ii) Applicable sources which started operating during that quarter or which have not been previously reported;
- (iii) The compliance status of the above, including the summary sheet from the compliance test(s); and
- (iv) Any legal actions which pertain to these sources.

2. Enforcement of the NSPS and NESHAP regulations in the State of Delaware will be the primary responsibility of the DNREC. Where DNREC determines that such enforcement is not feasible and so notifies EPA, or where DNREC acts in a manner inconsistent with the terms of this delegation, EPA will exercise its concurrent enforcement authority pursuant to section 113 of the Clean Air Act, as amended, with respect to sources within the State of Delaware subject to NSPS regulations.

3. Acceptance of this delegation of regulations for the source categories listed

above does not commit the State of Delaware to request or accept delegation of other present or future standards and requirements. A new request for delegation will be required for any additional standards or amendments to previously delegated standards.

4. DNREC will not grant a variance from compliance with the applicable NSPS and NESHAP regulations if such variances delay compliance with the Federal Standards. Should DNREC grant such a variance EPA will consider the source receiving the variance to be in violation of the applicable Federal regulation and may initiate enforcement action against the source pursuant to section 113 of the Clean Air Act. The grant of such variance by the Agency shall also constitute grounds for revocation of delegation by EPA.

5. DNREC and EPA will develop a system of communication sufficient to guarantee that each office is always fully informed regarding the interpretation of applicable regulations. In instances where there is a conflict between DNREC's interpretation and a Federal interpretation of applicable regulations, the Federal interpretation must be applied if it is more stringent than that of DNREC.

6. If at any time there is a conflict between DNREC and the Federal regulation found at 40 CFR part 60, the federal regulation must be applied if it is more stringent than that of DNREC. If DNREC does not have to enforce the more stringent Federal regulation, this portion of the delegation may be revoked.

7. DNREC will utilize the methods specified in 40 CFR part 60 in performing source tests pursuant to these regulations. However, alternatives to continuous monitoring procedures and requirements may be acceptable upon concurrence by EPA as stipulated in 40 CFR 60.13.

8. If the Director of the Air Management Division determines that DNREC's program for enforcing or implementing the NSPS and NESHAP regulations is inadequate, or is not being effectively carried out this delegation may be revoked in whole or in part. Any such revocation shall be effective as of the date specified in a Notice or Revocation to DNREC.

EPA procedures permit delegation of all the Administrator's authorities under 40 CFR parts 60 and 61 except for any which require rulemaking in the *Federal Register* to implement or where Federal overview is the only way to ensure national consistency in the application of standards. Accordingly, the following authorities are not delegable under section 111 of the Clean Air Act, as amended.

1. Performance Tests, §§ 60.8(b)(2) and 60.8(b)(3). In order to ensure uniformity and technical quality in the test methods used for enforcement of national standards, EPA will retain the authority to approve alternative and equivalent methods which effectively replace a reference method. This restriction on delegation does not apply to 60.8(b)(1), which allows for approval of minor modifications to reference methods on a case-by-case basis.

Some subparts include general references to the authority in § 60.8(b) to approve alternative or equivalent standards. Examples include, but are not necessarily

limited to §§ 60.11(b), 60.274(d), 60.396(a)(1), 60.396(a)(2), and 60.393(c)(1)(i). These references are reminders of the provisions of paragraphs 60.8 and are not separate authorities which can be delegated.

2. Compliance with Standards and Maintenance Requirements § 60.195(e). The granting of an alternative opacity standard requires a site-specific capacity limit to be adopted under 40 CFR part 60.

3. Subpart S, § 60.195(b). Development of alternative compliance testing schedules for primary aluminum plants is done by adopting site-specific amendments to Subpart S.

4. Subpart Da § 60.45a. Commercial demonstration permits allow an alternative emission standard for a limited number of utility steam generators.

5. Subpart GG, §§ 60.332(a)(3) and 60.335(a)(ii). These sections pertain to approval of customized factors (fuel nitrogen content and ambient air conditions, respectively), for use by gas turbine manufacturers in assembly-line compliance testing. Since each approval potentially could affect emissions from equipment installed in a number of States, the decisionmaking must be maintained at the Federal level to ensure national consistency. Notice of approval must be published in the *Federal Register*.

6. Equivalency Determinations, section 111(h)(3) of the Clean Air Act. Approval of alternative to any design, equipment, work practice, or operational standard, e.g., §§ 60.114(a) and 60.302(d)(3) is accomplished through the rulemaking process and is adopted as a change to the individual subpart.

7. Innovative Technology Waiver, section 111(i) of the Clean Air Act. Innovative Technology waivers must be adopted as site-specific amendments to the individual subpart. Any questions pertaining to such waivers should be sent to the Director of the Air Management Division, Region III. (States may be delegated the authority to enforce waivers provisions if the State has been delegated the authority to enforce NSPS.)

8. Determination of Construction or Modification (Applicability), § 60.5. In order to ensure uniformity in making applicability determinations pertaining to sources, EPA will retain this authority. The delegated agency may exercise judgment based upon the Compendium of Applicability Determinations issued by EPA annually, and updated quarterly. Any applicability determinations made by the State agency based on the Compendium must be sent to EPA for informational purposes in order for EPA to maintain national consistency.

9. Determination of whether actions intended to be taken constitute construction or modification of source subject to a standard (40 CFR 61.06).

10. Allowance of alternative means of compliance (40 CFR 61.12(d)).

11. Approval of specified or alternative emission testing (40 CFR 61.13(h)).

12. Approval of specified or alternative monitoring requirements (40 CFR 61.14(g)).

13. Determination of public availability of information (40 CFR 61.16).

14. Allowance of use of alternative means of emission limitation (40 CFR 61.244).

A Notice announcing this delegation will be published in the Federal Register in the near future. The Notice will state, among other things, that effective immediately, all reports required pursuant to the above-enumerated Federal NSPS and NESHAP regulations by sources located in the State of Delaware should be submitted to the Delaware Department of Natural Resources and Environmental Control, 89 Kings Highway, Dover, Delaware 19901. In addition to EPA Region III, any original reports which are received by EPA region III will be promptly transmitted to DNREC.

Since this delegation is effective immediately, there is no requirement that DNREC notify EPA of its acceptance. Unless EPA receives from DNREC written notice of objections within ten (10) days of receipt of this letter, DNREC will be deemed to have accepted all of the terms of the delegation.

Sincerely,

Edwin B. Erickson,

Regional Administrator.

The Office of Management and Budget has exempted this delegation of authority from the requirements of section 3 of the Executive Order 12291.

Authority: Secs. 11(c) and 112(d), the Clean Air Act, 42 U.S.C. 7412(d).

Edwin B. Erickson,

Regional Administrator.

Title 40, chapter I of the Code of Federal Regulations is amended as follows:

PART 60—[AMENDED]

1. The authority citation for part 60 continues to read as follows:

Authority: 52 U.S.C. 7401, 7411, 7414, 7416, and 7601.

§ 60.4 [Amended]

2. Section 60.4(b)(I) is amended by removing the parenthetical statement.

PART 61—[AMENDED]

3. The authority citation for part 61 continues to read as follows:

Authority: Secs. 101, 112, 114, 116, and 301 of the Clean Air Act, as amended (42 U.S.C. 7401, 7412, 7414, 7416, and 7601).

§ 61.04 [Amended]

4. Section 61.04(b)(I) is amended by removing the parenthetical statement.

[FR Doc. 89-22694 Filed 10-2-89; 8:45 am]

BILLING CODE 6560-50-M

40 CFR Parts 123 and 403

[FRL 3652-2]

Approval of California's Revisions to the State National Pollution Discharge Elimination System Program

AGENCY: Environmental Protection Agency.

ACTION: Notice of approval of the National Pollutant Discharge Elimination System (NPDES) Pretreatment Program, approval to issue NPDES general permits and approval of revisions to the existing NPDES permit regulations of the State of California.

SUMMARY: On September 22, 1989, the Environmental Protection Agency, Region IX approved the State of California NPDES Pretreatment Program which authorizes the State of California to administer the National Pretreatment Program as it applies to municipalities and industries within the State. EPA, Region IX also approved authority of the State of California to issue NPDES general permits and approved revisions to the State's existing NPDES permit regulations.

EFFECTIVE DATE: September 22, 1989.

FOR FURTHER INFORMATION CONTACT: William H. Pierce, Chief, Permits Branch, Water Management Division, 215 Fremont Street, San Francisco, CA 94105 (415-974-8110).

SUPPLEMENTARY INFORMATION: Section 402 of the Clean Water Act (CWA) (33 U.S.C. 1251 *et seq.*) requires EPA to administer the NPDES permit program under which the Agency may issue permits for the discharge of pollutants into waters of the United States in accordance with conditions required by the Act. Section 402(b) of the CWA provides for States to assume NPDES permitting responsibilities upon approval by EPA. States also may request authority to issue general permits for similar dischargers with the same effluent limitations. (See 40 CFR 122.28.) In addition, under section 54 of the 1977 amendments to the CWA, States requesting NPDES permitting authority, as well as States already approved to administer the NPDES permit program, must also request permitting authority over dischargers from federal facilities located within the State and authority to administer the federal pretreatment program governing the introduction of non-domestic pollutants into publicly owned treatment works (POTWs). (Cf. CWA section 402(n) 33 U.S.C. 1342(n).) After EPA approves a State's request for NPDES permit and/or pretreatment authority, the State must thereafter submit any proposed program revisions to EPA for reapproval pursuant to 40 CFR 123.62(b).

On May 14, 1973, California became the first State to be approved by EPA to administer the NPDES permit program. On May 5, 1978, it also became the first

State to receive EPA approval to regulate discharges from federal facilities.

On June 8, 1989, California submitted an application to EPA for approval of revisions to its approved NPDES program in accordance with 40 CFR 123.62 and 403.10. This application included a request to add pretreatment and general permit authority to its approved program. It also included a request for EPA approval of revisions to the State's existing NPDES permit regulations. (California does not have, and has not requested, EPA approval to administer the NPDES and pretreatment programs on Indian lands.) Pursuant to 40 CFR 123.62(b) and 403.10(g), California submitted in support of its application an Attorney General's Statement (including copies of all applicable State statutes and regulations) certifying that the State has adequate authority to administer the NPDES program being sought, a program description describing how the State intends to carry out its responsibilities, and a proposed EPA/California Memorandum of Agreement. These documents were revisions of the original copies submitted to EPA when California sought approval of its existing NPDES permit program.

With respect to California's request for approval of revisions to the State's existing NPDES permit regulations, EPA has approved the State's request to implement the State permit program under State law, which, according to the California Attorney General, incorporates by reference all existing and future federal NPDES law and regulations. Specifically, the Attorney General has certified that the Porter-Cologne Water Quality Control Act (Porter-Cologne Act), which implements the California NPDES program, incorporates federal NPDES and pretreatment law and regulations prospectively, meaning that future amendments to federal law and regulations are automatically incorporated into State law without the need for amendment of State statutes and regulations. (In support of this authority for prospective incorporation by reference, the California Attorney General has cited the Porter-Cologne Act, Water Code sections 13160, 13170, 13177, 13385, 13386, and 13387.) The California Attorney General also has certified that regulations adopted by the California State Water Resources Control Board, the Statewide NPDES permitting agency, prospectively

incorporate EPA regulations applicable to the processing of NPDES applications and issuance of NPDES permits. [The cited State regulations in the Attorney General's Statement are 23 Cal. Admin. Code sections 2235.1(c), 2235.2, and 2235.4] Such prospective incorporation of federal law and regulations is, according to the California Attorney General, authorized under California law and the State's Constitution.

As discussed above, California also has requested authority to issue NPDES general permits and administer the pretreatment program. With respect to general permit authority, EPA regulations at 40 CFR 122.28 provide for the issuance of general permits to regulate discharges of waste water which result from similar operations, are of the same type of wastes, require the same effluent limitations, require similar monitoring, and are more appropriately controlled under a general permit rather than by individual permits. EPA is approving California's request for general permit authority. Each general permit proposed by the State will be subject to EPA review and approval as provided by 40 CFR 123.44(a)(2). Public notice and opportunity to request a hearing also must be provided for each general permit.

EPA is also approving California's request for pretreatment authority. California has demonstrated that there is appropriate legal authority, procedures, available funding, and qualified personnel to implement the program as specified in 40 CFR 403.10. The State will implement its pretreatment program under the Porter-Cologne Act provisions which prospectively incorporate federal law and regulations. Under the CWA and EPA regulations at 40 CFR part 403, the primary objectives of the pretreatment program are to: (1) Prevent the introduction of pollutants into POTWs which will interfere with plant operations and/or disposal or use of municipal sludge; (2) prevent the introduction of pollutants into POTWs which will pass through treatment works in unacceptable amounts to receiving waters; and (3) improve the feasibility of recycling and reclaiming municipal and industrial wastewater and sludge. Local pretreatment programs will be the primary vehicle for administering, applying, and enforcing California's pretreatment requirements. Currently, 102 such programs have been approved by EPA. Where local programs have not yet been required or developed in California, the State must apply and enforce the pretreatment requirements

directly against industries that discharge to POTWs (e.g., 40 CFR 403.10(f)(2)(i)).¹

The Regional Administrator's decision to approve California's proposed program revisions, including its request for pretreatment and general permit authority, is based on a determination that the program meets the requirements of the Clean Water Act and 40 CFR parts 122, 123, 124, and 403. The public was notified in the July 20, 1989 Federal Register (54 FR 30405) of the submittal, public comment period and opportunity to request a public hearing, and EPA's proposal to approve all requested program revisions. In addition, notice was provided in four major newspapers in the State on July 20, 1989 and notice was provided to all POTWs with approved pretreatment programs. No comments were received by EPA during the public comment period which ended September 5, 1989.

California's pretreatment program, as well as its revised NPDES permit program, is administered by the California State Water Resources Control Board and nine Regional Water Quality Control Boards.

Review Under Executive Order 12291 and the Regulatory Flexibility Act

The Office of Management and Budget has exempted this rule from the review requirements of Executive Order 12291 pursuant to section 8(b) of that Order.

Under the Regulatory Flexibility Act, EPA is required to prepare a Regulatory Flexibility Analysis for all rules which may have a significant impact on a substantial number of small entities. Approval of California's NPDES program revisions, including the addition of pretreatment and general permit authority, does not alter the regulatory control over any municipal or industrial category. No new substantive requirements are established by this action. Therefore, since this notice does not have a significant impact on a substantial number of small entities, a Regulatory Flexibility Analysis is not necessary.

Dated: September 22, 1989.

John Wise,

Acting Regional Administrator for Region IX.
[FR Doc. 89-23163 Filed 10-2-89; 8:45 am]

BILLING CODE 6560-50-M

According to the California Attorney General, the requirements of the CWA and implementing regulations incorporated by reference by the Porter-Cologne Act, include but are not limited to the pretreatment standards and reporting requirements for IUs of POTWs (for example 40 CFR 403.5, 403.6 and 403.12).

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

49 CFR Part 531

[Docket No. LVM 89-01; Notice 1]

Passenger Automobile Average Fuel Economy Standards; Denial of Petitions for Exemption by Low Volume Petitioners

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

ACTION: Denial of petitions for exemption from average fuel economy standards and for establishment of alternative standards.

SUMMARY: This consolidated notice responds to individual petitions filed by four low volume manufacturers, Bitter, Ferrari, Lotus, and Maserati, each requesting exemption from the generally applicable passenger automobile average fuel economy standards, and that lower alternative standards be established for each model year (MY) from which they seek exemption. This notice denies each petition as follows:

Bitter Automobile of America, Inc. (Bitter) petitioned to be exempted for MYs 1983 through 1987. This notice denies Bitter's request because the Bitter petition and its amendment were not timely filed for those years and good cause was not shown for the late filing.

Ferrari S.p.A. (Ferrari) petitioned to be exempted for MYs 1986 through 1988. A separate notice published on December 10, 1986 (51 FR 44492) proposed to grant Ferrari's petition for MY 1986, establishing an alternative standard of 16.0 miles per gallon (mpg) and for MY 1988, establishing an alternative standard of 16.6 mpg. For MY 1987 this notice denies Ferrari's request because Ferrari was not eligible for an exemption as a low volume manufacturer for that model year.

Lotus Cars Ltd. (Lotus) petitioned to be exempted for MYs 1983 through 1987. This notice denies Lotus' request because the Lotus petition was not timely filed for MYs 1983 through 1985 and good cause was not shown for the late filing. This notice also denies Lotus' request for MYs 1986 and 1987. The agency concludes that Lotus was ineligible in those years for exemption as a low volume manufacturer.

Officine Alfieri Maserati S.p.A. (Maserati) petitioned to be exempted for MYs 1982 through 1985. This notice denies Maserati's request for MYs 1982 through 1983 because the Maserati petition was not timely filed for those

years and good cause was not shown for the late filing. A separate notice proposes to grant the requested exemption for MYs 1984 and 1985, and to establish alternative standards for Maserati of 17.3 mpg for MY 1984 and 16.6 mpg for MY 1985.

ADDRESS: Comments on this notice must refer to Docket No. LVM 89-01; Notice 1 and should be submitted to: Docket Section, NHTSA, Room 5109, 400 Seventh Street SW Washington, DC 20590. Docket hours are from 8:00 a.m. to 4:00 p.m. Monday through Friday.

FOR FURTHER INFORMATION CONTACT: Mr. Orron Kee, Office of Market Incentives, NHTSA, 400 Seventh Street SW Washington, DC 20590. Mr. Kee's telephone number is (202) 366-0846.

SUPPLEMENTARY INFORMATION:

Background

Statute

Title V of the Motor Vehicle Information and Cost Savings Act (Cost Savings Act), which is codified at 15 U.S.C. 2001-2002, provides for an automotive fuel economy regulatory program under which standards are established for the corporate average fuel economy (CAFE) of the annual production fleets of passenger automobiles and light trucks. The standards for passenger automobiles for MY's 1982-1988, the years covered by the petitions for exemption, are: 24 miles per gallon (mpg) for MY 1982; 26 mpg for MY 1983; 27 mpg for MY 1984; 27.5 mpg for MY 1985; and 26 mpg for MY's 1986-88.

Section 502(c) of the Cost Savings Act provides that a low volume manufacturer of passenger automobiles may be exempted from the generally applicable average fuel economy standards for passenger automobiles if those standards are more stringent than the maximum feasible average fuel economy for that manufacturer and if the NHTSA establishes an alternative standard for the manufacturer at its maximum level. Under the Act, a low volume manufacturer is one that manufactures (worldwide) fewer than 10,000 passenger automobiles in the model year for which the exemption is sought (the affected model year) and that manufactured fewer than 10,000 passenger automobiles in the second model year before the affected model year. In determining maximum feasible average fuel economy, the agency is required by section 502(e) of the Act to consider:

- (1) Technological feasibility;
- (2) Economic practicability;

- (3) The effect of other Federal motor vehicle standards on fuel economy; and
- (4) The need of the Nation to conserve energy.

Regulation: Timing of Petitions

Title 49 CFR part 525 sets forth the required contents of and procedures for processing petitions for exemption from the generally applicable passenger automobile average fuel economy standards. Section 525.6(b) specifies that each petition for exemption must be filed "not later than 24 months before the beginning of the affected model year, unless good cause for later submission is shown; * * * The stated reasons for including this provision in § 525.6 were to facilitate the low volume manufacturers' planning to comply with the alternative standards, and to ensure that the NHTSA's analysis of those manufacturers' maximum feasible average fuel economy would not be simply a "rubber stamping" of the individual manufacturer's planned fuel economy, caused by insufficient leadtime for the manufacturer to make changes. See 41 FR 53827 at 53828; December 9, 1976.

However, the agency recognized that there would be situations when good cause existed for not filing 24 months before the start of the model year. NHTSA has recognized two circumstances as establishing good cause for failure to submit a timely petition. First, there are situations in which the necessary supporting data for the petition were unavailable until after the due date has passed. For example, a recently incorporated manufacturer would not have adequate time to file an exemption petition 24 months prior to the model year. Second, there are situations in which a legitimately unexpected noncompliance occurs. An example is if a company providing a low volume manufacturer with its engines goes out of business, and the manufacturer is forced to make an unanticipated engine switch, resulting in lower than expected fuel economy. See 44 FR 21051 at 21055, April 9, 1979.

Agency Response to Petitions

Bitter

By letter dated November 22, 1985, Bitter petitioned NHTSA for an alternate fuel economy standard for Bitter passenger automobiles for MYs 1983 through 1986. NHTSA requested that additional information be provided to justify the reason for late filing of the petition and to more fully describe the models and quantities that will be or have been imported. Bitter was reminded of the need to submit future

petitions at least two years before the start of the model year. By letter dated May 16, 1986, Bitter amended the original petition to cover MY 1987. The amendment also provided additional information on Bitter's product offerings but did not include any reason for late filing of the petition.

Since the Bitter petition and its amendment were not filed in a timely manner to qualify for an alternate corporate average fuel economy standard and Bitter has not furnished any justification for the late filing, the agency denies Bitter's petition for an alternate fuel economy standard for Bitter passenger cars for MYs 1983 through 1987.

Ferrari

By letter dated January 2, 1986, Ferrari requested an exemption from the generally applicable corporate average fuel economy standards and requested alternate standards for MYs 1986-88. On December 10, 1986 (51 FR 44492), NHTSA issued a proposed decision to grant an exemption for Ferrari from the average fuel economy standards and to establish alternative standards for MYs 1986 through 1988. The notice proposed to grant the requested exemptions for all three years, and to establish alternative standards for Ferrari of 16.0 mpg for MY 1986, 16.2 mpg for MY 1987 and 16.6 mpg for MY 1988. No comments were received on the proposed decision.

As of the time of that proposal, Ferrari was eligible for exemptions for all of those years despite Fiat's ownership of 50 percent of Ferrari. Section 502(c) allows NHTSA to exempt manufacturers from the generally applicable standards only if the manufacturer produces fewer than 10,000 passenger automobiles in the model years for which exemption is sought. By itself, Ferrari would qualify as a low volume manufacturer under section 502(c) since it manufactures about 3,500 cars annually worldwide. Section 503(c)(1) of the Act specifies that any reference in Title V to automobiles manufactured by a manufacturer "shall be deemed to include all automobiles manufactured by persons who control, are controlled by, or are under common control with, such manufacturer. NHTSA found that Fiat controls Ferrari for purposes of section 503(c). Nevertheless, Fiat's production was not added to Ferrari's for the purpose of determining Ferrari's eligibility for an exemption. In a July 26, 1978 interpretation letter to Howard E. Chase, of Singer, Hutner, Levine & Seeman, NHTSA determined that, for purposes of section 502(c) of the Cost Savings Act, the term "manufacture

means "to produce or assemble in the customs territory of the United States, or to import. Since for MY 1987 Fiat neither assembled its car in the United States nor imported its cars into the United States, it did not manufacture any automobiles for the purposes of section 503(c). Accordingly, although Ferrari was controlled by Fiat, for purposes of determining Ferrari's low volume manufacturer status, none of Fiat's automobiles would be added to Ferrari's total.

Ferrari's eligibility for MY 1987 changed on January 1, 1987 when Fiat acquired 100 percent ownership of Alfa Romeo. That acquisition rendered Ferrari ineligible under Title V for a exemption for that year. Section 503(c) requires all of the automobiles imported by Alfa Romeo to be added to those manufactured by Ferrari to determine whether Ferrari is eligible for a low volume exemption for MY 1987 and thereafter. Since Alfa Romeo imported 8,930 cars into the United States for MY 1987 Alfa Romeo would be considered a "manufacturer" for purposes of section 502(c). Further, because Alfa Romeo and Ferrari are under the common control of Fiat, Alfa Romeo's, 8,930 import cars would be added to Ferrari's annual world wide production in order to determine Ferrari's low volume manufacturer status. The resulting total exceeds the 10,000 vehicle limitation on eligibility. Accordingly, Ferrari is statutorily ineligible for a low volume exemption for MY 1987.

However, in MY 1988, Alfa Romeo imported only 4,166 cars into the United States. This figure, even when combined with Ferrari's worldwide production in 1988 of 3,996, would not exceed the 10,000 vehicle limitation. Accordingly, Ferrari remains eligible for an exemption for MY 1988.

Lotus

MYs 1983-1985: Timeliness of Petition

Lotus filed its original exemption petition on February 14, 1985 and later filed a number of addenda. Under part 525, Lotus' petition was untimely filed with respect to MYs 1983 through 1985. In defense of this later filing, the company essentially argues that its history since 1982 has been tumultuous. However, during its corporate distress, the company continued to sell its products in the United States. Nothing in its petition suggests an unanticipated event that made compliance with this deadline impossible. The fact that the company continued to operate and sell products during this period indicates that Lotus retained control of data necessary to file the exemption petition.

Under the circumstances, NHTSA concludes that Lotus has not made a showing of good cause for having filed its petition late. Therefore, the Agency denies Lotus' petition for exemption and alternative standards for MYs 1983-1985.

MYs 1986 and 1987: Timeliness of an Eligibility for Exemption

According to Lotus's petition, in July 1986, General Motors (GM) acquired at least 93% of Lotus' shares. Section 503(c)(1) of the Act states that any reference in Title V to automobiles manufactured by a manufacturer includes "all automobiles manufactured by persons who control the manufacturer. NHTSA concludes that General Motors' 93% interest in Lotus is a controlling interest under section 503(c) of the Act, and that its production must be added to that of Lotus. GM manufactured over 10,000 passenger automobiles in both the second model year preceding the model years for which the application for exemption was made and in those model years. The agency therefore finds Lotus ineligible for consideration as a low volume manufacturer for MYs 1986 and 1987. Further, Lotus did not provide a showing of good cause to explain the lateness of its petition for those years.

Maserati

Background Information About Maserati

Maserati's automobiles have traditionally been expensive high performance vehicles. According to its petition, Maserati's reputation is based on a combination of performance and luxury. The company experienced an extended period of financial instability in the late 1970's and early 1980's. In 1974, Citroen, the owner of Maserati, put Maserati into voluntary bankruptcy. This action resulted in Maserati's totally ceasing all production for more than a year during 1975 and 1976. The company produced very few cars through MY 1981, and the models it did produce were simply continuations of its older models. However, a loan from the Italian government permitted Maserati to develop and introduce a new model, the Biturbo, in Europe in 1982. This new model helped return Maserati to profitability. In fact, Maserati had projected sales of 4,100 vehicles in the United States in MY 1985, up from sales of 52 vehicles in MY 1983.

Maserati produced two models during MYs 1982-1985. One of these models, the Quattroporte, was the first "new" vehicle produced by Maserati after the company was reorganized in bankruptcy. However, this vehicle was

designed on very short notice, using as many components in Maserati's inventory as possible. The company's management determined that they needed to generate revenue quickly to reverse the significant operating losses Maserati had accumulated. The Quattroporte, according to Maserati's petition, "cannot play a leading role in the company's future.

The other model is the Biturbo, which is primarily responsible for the company's improved financial status. The Biturbo was introduced in Europe in 1982 and in the United States for MY 1984. It was a completely new design by Maserati that was not required to use components in the company's inventory. The Biturbo is much lighter and more aerodynamic than the Quattroporte. Further, the Biturbo is powered by a 152 cubic inch displacement (CID) V-6 engine with two turbochargers and 3 valves per cylinder, while the Quattroporte is powered by a 301 CID V-8 engine with only 2 valves per cylinder.

Denial of Maserati's Petition for MYs 1982-1983

Maserati filed a petition asking for an exemption from the average fuel economy standards for MYs 1982 through 1985 on May 3, 1983. Its petition was clarified and updated in a June 1985 submission. In the original petition, Maserati stated that it was unable to file the petition in a timely manner because its "future viability was in serious doubt" through the middle of 1982. The petition also stated, "Maserati's return to profitability in 1982 only now enables it to project the realistic prospect of continued and profitable operations, without which it would be impossible, as a practical matter, to provide the appropriate information (required to be included in petitions filed under part 525).

The financial difficulties experienced by Maserati during the late 1970's and early 1980's were serious. The company's financial ability to design and introduce its new Biturbo model, much less its ability to produce and export a U.S. version of the model, was not foreseeable 24 months in advance of MY 1984. Accordingly, NHTSA tentatively concludes that Maserati showed good cause for the late filing of its petition for MYs 1984 and 1985.

However, NHTSA does not believe that financial difficulties constituted good cause for the late filing of Maserati's petition for MYs 1982 and 1983. The company had full knowledge 24 months in advance of those model years that it would be selling only the

Quattroporte in the United States, and knew all the required technical information for that vehicle. Since Maserati knew that it would be only selling the Quattroporte, and there was no issue of model mix, the company knew that its CAFE would be the same as the fuel economy figure for that model. Further, Maserati knew that its total production would be well under 10,000, and that it would therefore be eligible for a low volume exemption. After considering these factors, NHTSA has concluded that Maserati has not shown good cause for the late filing of its petitions for MYs 1982 and 1983. Accordingly, Maserati's request for exemptions for MYs 1982 and 1983 is denied.

(Sec. 9, Pub. L. 89-670, 80 Stat. 981 (49 U.S.C. 1657); Sec. 301, Pub. L. 94-163, 89 Stat. 901 (15 U.S.C. 2002); delegations of authority at 49 CFR 1.50 and 49 CFR 501.8.)

Issued on September 26, 1989.

Barry Felrice,

Associate Administrator for Rulemaking.

[FR Doc. 89-23087 Filed 10-2-89; 8:45 am]

BILLING CODE 4910-59-M

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 380

[Docket No. 90923-9223]

Antarctic Marine Living Resources Convention Act of 1984

AGENCY: National Marine Fisheries Service (NMFS), NOAA, Commerce.

ACTION: Final rule.

SUMMARY: The Secretary of Commerce (Secretary) promulgates this rule to implement further the Antarctic Marine Living Resources Convention Act of 1984 (the Act), which provides the legislative authority for United States implementation of the provisions of the Convention on the Conservation of Antarctic Marine Living Resources (Convention). The Convention establishes international mechanisms and creates legal obligations necessary for the protection and conservation of Antarctic marine living resources. This rule gives effect, for vessels of the United States and persons subject to the jurisdiction of the United States, to the Commission for the Conservation of Antarctic Marine Living Resources (CCAMLR) System of Observation Inspection (the system). The system applies to all vessels of Contracting Parties to the Convention harvesting marine living resources (including those

vessels engaged in scientific research) in the Convention area. It will operate through the use of inspectors designated by Contracting Parties to the Convention and through information transmitted to the Department of State by scientists, fishermen, and others in the Convention area not designated as inspectors. All Contracting Parties, whether or not they designate inspectors, have agreed to transmit to CCAMLR information about violations of conservation and management measures observed by scientists, fishermen, and other non-inspectors under their jurisdiction.

EFFECTIVE DATE: October 3, 1989.

ADDRESSES: A copy of the framework environmental assessment may be obtained from the Assistant Administrator for Fisheries, NOAA, 1335 East-West Highway, Silver Spring, MD 20910.

FOR FURTHER INFORMATION CONTACT:

Robin Tuttle, International Science, Development and Polar Affairs Division, NMFS, NOAA, Room 7240, 1335 East-West Highway, Silver Spring, MD 20910 (301-427-2282).

SUPPLEMENTARY INFORMATION: The United States, at the seventh meeting of the Commission for the Conservation of Antarctic Marine Living Resources, agreed to and is obligated by the framework of the CCAMLR System of Observation and Inspection. As approved, each member of CCAMLR may designate inspectors who will be allowed to board vessels engaged in scientific research or harvesting in the Convention area in order to verify compliance with measures in effect under the Convention.

CCAMLR has not elaborated provisions for scientific observation under the system. Once elaborated and adopted, members of CCAMLR may place individuals on board vessels to observe the harvesting of marine living resources in the Convention area. Observation will facilitate the acquisition of information needed to better understand and more effectively model and manage the harvesting of Antarctic marine living resources.

These regulations implement for the United States the inspection provisions of the system. Additional regulations implementing observation provisions will be promulgated by the Department of Commerce once CCAMLR has adopted an observation scheme.

The inspection provisions of the system require that inspectors be familiar with the fishing and scientific research activities to be inspected, the provisions of the Convention, and measures adopted under it. A Contracting Party (Party) must certify

the qualifications of its designated inspectors to CCAMLR. Designated inspectors must be nationals of the designating Party and while carrying out inspection activities, will be subject solely to the jurisdiction of the designating Party. Inspectors must be able to communicate in the language of the flag State of the vessels on which they carry out their activities and must be accorded the status of ship's officer while on board such vessels.

Inspection will be carried out by U.S. designated inspectors from U.S. vessels and by any foreign inspectors that may be designated by members of CCAMLR. Vessels carrying inspectors will fly a special flag or pennant approved by CCAMLR to indicate that the inspectors on board are carrying out their duties in accordance with the system. U.S. inspectors may also board the vessels of other Party States.

Any U.S. vessel present in the Convention area for the purpose of harvesting marine living resources (including vessels engaged in scientific research) must, when given the appropriate signal in the International Code of Signals by a ship carrying an inspector (as signified by flying the CCAMLR-approved flag or pennant), stop or take such other actions as necessary to facilitate the safe and prompt transfer of the inspector to the vessel, unless the vessel is actively engaged in scientific research or other harvesting operations, in which case it shall do so as soon as practicable.

The master of the U.S. vessel must permit the inspector, who may be accompanied by appropriate assistants, to board the vessel. Inspectors will have the authority to inspect catch, nets, and other fishing gear, as well as fishing and scientific research activities, and must be given access to records and reports of catch and location data insofar as necessary to carry out their functions. However, in order to protect scientific research that could be compromised by an inspection, CCAMLR inspectors will not disturb areas in which the operator of a harvesting vessel asserts that specific, sensitive scientific research is in progress. Research requiring a controlled environment (e.g., light, temperature) and areas restricted for safety reasons (e.g., isotope vans) qualify as sensitive research or conditions. Vessel operators asserting such special circumstances must produce an Individual Permit covering the specific research. "Individual permit" is defined by 50 CFR 380.2 as a National Science Foundation (NSF) permit issued under 45 CFR part 670; or an NSF award letter (demonstrating that

the individual has received an award from NSF to do research in the Antarctic); or a marine mammal permit issued under 50 CFR 216.31; or an endangered species permit issued under 50 CFR 222.21. CCAMLR inspectors will record information pertaining to the denial of access or inspection in these circumstances.

Each inspector will carry an identity document issued by the designating State in a form approved or provided by CCAMLR stating that the inspector has been designated to carry out inspection. On boarding a vessel, the inspector will present the identity document.

Inspection will be carried out so that the vessel is subject to minimum interference and inconvenience. Inquiries will be limited to the ascertainment of facts in relation to compliance with CCAMLR measures in effect. Inspectors are permitted to take photographs as necessary to document alleged violations of CCAMLR measures in effect. If photographs are taken, a duplicate will be attached to the notice of alleged violations provided to the vessel master. Inspectors will affix an identification mark approved by CCAMLR to any net or other fishing gear which appears to have been used in contravention of conservation measures in effect and shall record the fact in all reports and notifications.

Inspectors must be provided appropriate assistance by the master of the U.S. vessel in carrying out their duties, including access as necessary to communications equipment. If a U.S. vessel refuses to stop or otherwise facilitate transfer of an inspector, or if the master or crew of a vessel interferes with the authorized activities of an inspector, the inspector involved will prepare a detailed report, including a full description of all the circumstances, and provide the report to the United States. Such refusal or interference is prohibited.

U.S. inspectors will prepare detailed reports on their inspection activities. These reports will be provided to the Department of State, which shall in turn report to CCAMLR. Before leaving vessels that have been inspected, the inspector shall give the master of the vessel a Certification of Inspection and a written notification of any alleged violations of CCAMLR measures in effect and will afford the master opportunity to comment in writing on any such notification. The ship's master must sign the notification to acknowledge receipt and the opportunity to comment on it.

U.S. scientists, fishermen, and other non-inspectors present in the Convention area are encouraged to

report violations of CCAMLR conservation and management measures observed in the Convention area to the Office of Ocean Affairs, Department of State. The U.S. Government will transmit the information contained in these reports to the Chairman of CCAMLR for forwarding to the State named in the report. The Chairman will circulate the information and any comment upon it to all CCAMLR Members prior to the next meeting of the Commission.

Reports of inspection of U.S. activities will be provided to the United States and the United States will have the opportunity to comment on them prior to their consideration by CCAMLR. If, as a result of inspection activities carried out in accordance with these provisions, there is evidence of violation by U.S. vessels of measures adopted under the Convention, the United States will take steps to prosecute and, if necessary, impose sanctions.

Classification

The Secretary has determined that this rule is necessary to implement the Antarctic Marine Living Resources Convention Act of 1984 and to give effect to the conservation and management measures adopted by CCAMLR and agreed to by the United States.

The Assistant Administrator for Fisheries, NOAA (Assistant Administrator) prepared a framework environmental assessment (EA) for the implementation of the Antarctic Marine Living Resources Convention Act of 1984 in 1987. NMFS has reviewed this rule and determined that the actions it requires were generally summarized in the framework EA and are thus excluded from further National Environmental Policy Act analysis.

This action is exempt from Executive Order 12291 and section 553 of the Administrative Procedure Act because it involves a foreign affairs function of the United States. Because notice and comment rulemaking is not required for this rule, the Regulatory Flexibility Act does not apply; therefore, a regulatory flexibility analysis has not been prepared.

At present there are no U.S. vessels or vessels subject to the jurisdiction of the United States harvesting Antarctic marine living resources within the area to which these regulations apply, except for research purposes. Presently, the only Antarctic resources affected are scientific specimens taken under NSF permits and by the U.S. Antarctic Marine Living Resources directed research program. Accordingly, these regulations should not have an

incremental impact on U.S. vessels harvesting or performing associated activities in the Convention area.

This rule does not impose a collection-of-information requirement and therefore is not subject to the Paperwork Reduction Act. The rule restates at § 380.8(a)(2)(3) a requirement previously approved by the Office of Management and Budget under Control Number 06480194 to provide vessel positions.

This rule does not contain policies with federalism implications sufficient to warrant preparation of a federalism assessment under Executive Order 12612.

List of Subjects in 50 CFR Part 380

Antarctic, Fish and wildlife, Reporting and recordkeeping requirements.

Dated: September 26, 1989.

James E. Douglas, Jr.,

Deputy Assistant Administrator for Fisheries, National Marine Fisheries Service.

For the reasons set out in the preamble, 50 CFR part 380 is amended as follows:

PART 380—ANTARCTIC MARINE LIVING RESOURCES CONVENTION ACT OF 1984

1. The authority citation for part 380 continues to read as follows:

Authority: 16 U.S.C. 2431 *et seq.*

2. Section 380.2 is amended by adding the definitions "CCAMLR inspector" and "Inspection vessel" in alphabetical order to read as follows:

§ 380.2 Definitions.

CCAMLR inspector means a person designated by a member of the Commission as an inspector under Article XXIV of the Convention to verify compliance with measures in effect under the Convention.

Inspection vessel means a vessel carrying a CCAMLR inspector and displaying the pennant approved by the Commission to identify such vessel.

§ 380.4 [Amended]

3. Section 380.4 paragraph (g) is amended by adding the words "or CCAMLR inspector" to the end of the first sentence.

§ 380.6 [Amended]

4. Section 380.6 paragraph (b) is amended by adding the words "or CCAMLR inspector" before the semicolon at the end of the paragraph.

§ 380.7 [Amended]

5. In § 380.7 in paragraphs (a) and (d)(2) the words "or inspection" are added between "enforcement" and "vessel" and in paragraph (c)(3) the words "or CCAMLR inspector" are added at the end of the paragraph.

6. Section 380.8 is revised to read as follows:

§ 380.8 Facilitation of enforcement and inspection.

(a) *General.* (1) The owner, operator, or any person aboard any harvesting vessel subject to this part must immediately comply with instructions and signals issued by an authorized officer to stop the harvesting vessel; to move the harvesting vessel to a specified location; or to take any other action to facilitate safe boarding and inspection of the vessel, its gear, equipment, records, and harvested resources.

(2) The owner, operator, or any person aboard any harvesting vessel subject to this part must immediately comply with instructions and signals issued by a CCAMLR inspector, unless the vessel is actively engaged in scientific research or other harvesting operations, in which case it shall do so as soon as practicable. The vessel must comply with any instructions and signals to stop the vessel, move the vessel to a specified location, or to take any other action to facilitate safe boarding and inspection of the vessel, its gear, equipment, records, or harvested resources.

(3) The operator of each harvesting vessel subject to this part must provide vessel position or other information when requested by NMFS, the Coast Guard, an authorized officer or CCAMLR inspector within the time specified in the request.

(4) CCAMLR inspectors must be provided appropriate assistance by the master of the vessel in carrying out their duties, including access as necessary to communications equipment.

(b) *Communications equipment.* (1) Each harvesting vessel must be equipped with a VHF-FM radiotelephone station located so that it may be operated from the wheelhouse. Each operator must maintain a continuous listening watch on channel 16 (156.8 MHz).

(2) Each harvesting vessel must be equipped with a radiotelegraph station capable of communicating via 500 kHz radiotelegraphy and at least one working frequency between 405 kHz and 535 Khz, and a radiotelephone station capable of communicating via 2182 kHz radiotelephony. Each operator must be ready to communicate via 500 kHz

radiotelegraph and 2182 kHz radiotelephone each day from 0800 GMT to 0830 GMT and 2000 to 2030 GMT, and in preparation for boarding.

(3) Harvesting vessels that are not equipped with processing facilities and that deliver all catches to a processing vessel on the harvesting grounds are exempt from the requirements of paragraph (b)(2) of this section.

(4) Harvesting vessels with no IRCS which do not catch fish and are used as auxiliary vessels to handle codends, nets, equipment, or passengers for a processing vessel are exempt from the requirements of paragraphs (b)(1) and (b)(2) of this section.

(5) The Assistant Administrator, with the agreement of the appropriate Coast Guard commander, may, upon request by the owner or operator, accept alternatives to the communications equipment requirements of paragraphs (b)(1) and (b)(2) of this section for certain harvesting vessels or types of harvesting vessels, provided they are adequate for communications needs.

(c) *Communications procedures.* (1) Upon being approached by a Coast Guard vessel or aircraft or other vessel or aircraft with an authorized officer or CCAMLR inspector aboard, the operator of any harvesting vessel subject to the jurisdiction of the United States must be alert for communications conveying enforcement or inspection instructions. The enforcement or inspection unit may communicate by channel 16 VHF-FM radiotelephone, 2182 kHz radiotelephone, 500 kHz radiotelegraph, message block from an aircraft, flashing light or flag signals from the International Code of Signals, hand signal, placard, loudhailer, or other appropriate means. The following signals extracted from the International Code of Signals are among those which may be used.

(i) AA, AA, AA, etc. which is the call for an unknown station. the signaled vessel should respond by identifying itself or by illuminating the vessel identification required by § 380.6 of this part:

(ii) "RY-CY" meaning "You should proceed at a slow speed; a boat is coming to you"

(iii) "SQ3" meaning "You should stop or heave to: I am going to board you"

(iv) "L" meaning "You should stop your vessel instantly.

(2) The operator of, or any person aboard, a harvesting vessel who does not understand a signal from an enforcement unit or inspection vessel and who is unable to obtain clarification by radiotelephone or other means must consider the signal to be a command to stop the vessel instantly.

(d) Boarding equipment and procedures. The operator of a harvesting vessel signaled for boarding must:

(1) Stop immediately or lay to or maneuver in such a way as to maintain the safety of the harvesting vessel and facilitate boarding by an authorized officer of CCAMLR inspector and the boarding party;

(2) Provide the authorized officer or CCAMLR inspector and boarding party a safe pilot ladder. The operator must ensure the pilot ladder is securely attached to the harvesting vessel and meets the construction requirements of Regulation 17 Chapter V of the International Convention for the Safety of Life at Sea, 1974 (TIAS 9700 and 1978 Protocol, TIAS 10009), or a substantially equivalent standard approved by letter from the Assistant Administrator, with the agreement of the Coast Guard. A summary of safe pilot ladder standards follows:

(i) The ladder must be of a single length of not more than 9 meters (30 feet), capable of reaching the water from the point of access to the harvesting vessel, accounting for all conditions of loading and trim of the harvesting vessel and for an adverse list of 15 degrees. Whenever the distance from sea level to the point of access to the ship is more than 9 meters (30 feet), access must be by means of an accommodation ladder or other safe and convenient means.

(ii) The steps of the pilot ladder must be:

(A) Of hardwood, or other material or equivalent properties, made in one piece free of knots, having an efficient non-slip surface; the four lowest steps made of rubber of sufficient strength and stiffness or of other suitable material of equivalent characteristics;

(B) Not less than 480 millimeters (19 inches) long, 115 millimeters (4½ inches) wide, and 25 millimeters (1 inch) in depth, excluding any non-slip device; and

(C) Equally spaced not less than 300 millimeters (12 inches) nor more than 380 millimeters (15 inches) apart and secured in such a manner that they will remain horizontal.

(iii) No pilot ladder may have more than two replacement steps which are secured in position by a method different from that used in the original construction of the ladder.

(iv) The sides ropes of the ladder must consist of two uncovered manila rope not less than 60 millimeters (2¼ inches) in circumference on each side (or synthetic ropes of equivalent size and equivalent or greater strength). Each rope must be continuous with no joint below the top step.

(v) Battens made of hardwood, or other material of equivalent properties in one piece and not less than 1.8 meters (5 feet 10 inches) long must be provided at such intervals as will prevent the pilot ladder from twisting. The lowest batten must be on the fifth step from the bottom of the ladder and the interval between any batten and the next must not exceed nine steps.

(vi) Where passage onto or off the ship is by means of a bulwark ladder, two handhold stanchions must be fitted at the point of boarding or leaving the harvesting vessel not less than 0.7 meters (2 feet 3 inches) nor more than 0.8 meters (2 feet 7 inches) apart, not less than 40 millimeters (2½ inches) in diameter, must extend not less than 1.2 meters (3 feet 11 inches) above the top of the bulwark.

(3) When necessary to facilitate the boarding or when requested by an authorized officer or CCAMLR inspector, provide a manrope, a safety line, and illumination for the ladder; and

(4) Take such other actions as necessary to ensure the safety of the authorized officer, CCAMLR inspector, and the boarding party and to facilitate the boarding and inspection.

(e) *Access and records.* (1) The owners and operator of each harvesting vessel must provide authorized officers and CCAMLR inspectors access to all spaces where work is conducted or business papers and records are prepared or stored, including but not limited to personal quarters and areas within personal quarters. If inspection of a particular area would interfere with specific on-going scientific research, and if the operator of the harvesting vessel makes such assertion and produces an Individual Permit that covers that specific research, the authorized officer or CCAMLR inspector will not disturb

the area, but will record the information pertaining to the denial of access.

(2) The owner and operator of each harvesting vessel must provide to authorized officers and CCAMLR inspectors all records and documents pertaining to the harvesting activities of the vessel, including but not limited to production records, fishing logs, navigation logs, transfer records, product receipts, cargo stowage plans or records, draft or displacement calculations, customs documents or records, and an accurate hold plan reflecting the current structure of the vessel's storage and factory spaces.

(3) Before leaving vessels that have been inspected, the CCAMLR inspector will give the master of the vessel a Certificate of Inspection and a written notification of any alleged violations of Commission measures in effect and will afford the master the opportunity to comment on it. The ship's master must sign the notification to acknowledge receipt and the opportunity to comment on it.

(f) *Reports by non-inspectors.* All scientists, fishermen and other non-inspectors present in the Convention area and subject to the jurisdiction of the United States are encouraged to report any violation of Commission conservation and management measures observed in the Convention area to the Office of Ocean Affairs (CCAMLR Violations), Department of State, Room 5801, Washington, DC 20520.

(g) *Storage of Antarctic marine living resources.* The operator of each harvesting vessel storing Antarctic marine living resources in a storage space on board the vessel must ensure that non-resource items are neither stowed beneath nor covered by resource items, unless required to maintain the stability and safety of the vessel. Non-

resource items include, but are not limited to, portable conveyors, exhaust fans, ladders, nets, fuel bladders, extra bin boards, or other moveable non-resource items. These non-resource items may be in a resource storage space when necessary for the safety of the vessel or crew or for the storage of the items. Lumber, bin boards, or other dunnage may be used for shoring or bracing of product to ensure the safety of crew and to prevent shifting of cargo within the space.

7 In § 380.10, paragraph (f) is redesignated (i), paragraphs (g) through (q) are redesignated (k) through (u), and new paragraphs (f), (g), (h), and (j) are added to read as follows:

§ 380.10 Prohibitions.

(f) Refuse to allow any CCAMLR inspector to board a vessel of the United States or a vessel subject to the jurisdiction of the United States for the purpose of conducting an inspection authorized by the Act, this part, or any permit issued under the Act.

(g) Refuse to provide appropriate assistance, including access as necessary to communications equipment, to CCAMLR inspectors.

(h) Refuse to sign a written notification of alleged violations of Commission measures in effect prepared by a CCAMLR inspector.

(i)

(j) Assault, resist, oppose, impede, intimidate or interfere with a CCAMLR inspector in the conduct of any boarding or inspection authorized by the Act, this part, or any permit issued under the Act.

[FR Doc. 89-23224 Filed 10-2-89; 8:45 am]

BILLING CODE 3510-22-M

Proposed Rules

Federal Register

Vol. 54, No. 190

Tuesday, October 3, 1989

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 Ch. I

[Summary Notice No. PR-89-16]

Petitions for Rulemaking; Summary and Disposition

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of petitions for rulemaking received and of dispositions of prior petitions.

SUMMARY: Pursuant to FAA's rulemaking provisions governing the application, processing, and disposition of petitions for rulemaking (14 CFR part 11), this notice contains a summary of certain petitions requesting the initiation of rulemaking procedures for the amendment of specified provisions of the Federal Aviation Regulations and of denials or withdrawals of certain petitions previously received. The purpose of this notice is to improve the public's awareness of, and participation in, this aspect of FAA's regulatory activities. Neither publication of this notice nor the inclusion or omission of information in the summary is intended to affect the legal status of any petition or its final disposition.

DATE: Comments on petitions received must identify the petition docket number involved and must be received on or before:

ADDRESS: Send comments on any petition in triplicate to: Federal Aviation Administration, Office of the Chief Counsel, Attn: Rules Docket (AGC-10), Petition Docket No. 25700, 800 Independence Avenue SW Washington, DC 20591.

FOR FURTHER INFORMATION: The petition, any comments received, and a copy of any final disposition are filed in the assigned regulatory docket and are available for examination in the Rules Docket (AGC-10), Room 915G, FAA Headquarters Building (FOB 10A), 800

Independence Avenue SW
Washington, DC 20591; telephone (202) 267-3132.

This notice is published pursuant to paragraphs (b) and (f) of § 11.27 of part 11 of the Federal Aviation Regulations (14 CFR part 11).

Issued in Washington, DC, on September 20, 1989.

Denise Donohue Hall,
Manager, Program Management Staff, Office of the Chief Counsel.

Petitions for Rulemaking

Docket No. 25700.

Petitioner: David W Galvin.

Regulations Affected: 14 CFR 121.599 and 121.601.

Description of Petition/Disposition: The petition, if granted, would require all domestic carriers and supplemental air carriers to provide its dispatchers access to professional meteorological advice by having a meteorological department or office in the flight dispatch center and that all meteorologists used as advisory aviation meteorologists must have graduated from an accredited university or college with a degree in meteorology. Denied September 6, 1989.

[FR Doc. 89-23286 Filed 10-2-89; 8:45 am]

BILLING CODE 4910-13-M

14 CFR Part 39

[Docket No. 89-NM-193-AD]

Airworthiness Directives; Avions Marcel Dassault-Breguet Aviation (AMD-BA) Model Mystere Falcon 50 and 900 Series Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This notice proposes to adopt a new airworthiness directive (AD), applicable to certain Avions Marcel Dassault-Breguet Aviation (AMD-BA) Model Mystere Falcon 50 and 900 series airplanes, which would require a one-time functional test of the main landing gear (MLG) door manual release system, and replacement of the MLG door manual release system control bell crank. This proposal is prompted by a report that the main gear door manual release system may not properly release when needed due to rigging interference.

This condition, if not corrected, could prevent manual extension of the main landing gear.

DATES: Comments must be received no later than November 24, 1989.

ADDRESSES: Send comments on the proposal in duplicate to the Federal Aviation Administration, Northwest Mountain Region, Transport Airplane Directorate, ANM-103, Attention: Airworthiness Rules Docket No. 89-NM-193-AD, 17900 Pacific Highway South, C-68966, Seattle, Washington, 98168. The applicable service information may be obtained from Falcon Jet Corporation, Customer Support Department, Teterboro Airport, Teterboro, New Jersey 07608.

This information may be examined at the FAA, Northwest Mountain Region, Transport Airplane Directorate, 17900 Pacific Highway South, Seattle, Washington, or the Standardization Branch, 9010 East Marginal Way South, Seattle, Washington.

FOR FURTHER INFORMATION CONTACT:

Mr. Robert C. McCracken, Standardization Branch, ANM-113; telephone (206) 431-1979. Mailing address: FAA, Northwest Mountain Region, 17900 Pacific Highway South, C-68966, Seattle, Washington 98168.

SUPPLEMENTARY INFORMATION:

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 should identify the regulatory docket number and be submitted in duplicate to the address specified above. All communications received on or before the closing date for comments specified above will be considered by the Administrator before taking action on the proposed rule. The proposals contained in this Notice may be changed in light of the comments received.

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 Notice must submit a self-addressed, stamped postcard on which the following statement is made: "Comments to Docket Number 89-NM-193-AD. The postcard will be date/time stamped and returned to the commenter."

Discussion

The FAA has determined that an unsafe condition exists in AMD-BA Model Falcon 50 and 900 series airplanes. There has been a recent report that the main landing gear (MLG) door manual release system may not properly release when needed, due to rigging interference. This condition, if not corrected, could prevent manual extension of the MLG.

AMD-BA has issued Alert Service Bulletins F50-A212 (F50-A32-19), and F900-A65 (F900-A32-6), both dated July 25, 1989, which describe procedures for performing a functional test of the MLG door manual release system, and replacement of the MLG door manual release system control bell crank with a new adjustable bell crank. The Direction Generale de L Aviation Civile, which is the airworthiness authority of France, has approved these service bulletins, but has not classified them as mandatory.

This airplane model is manufactured in France and type certificated in the United States under the provisions of § 21.29 of the Federal Aviation Regulations and the applicable bilateral airworthiness agreement.

Since this condition is likely to exist or develop on other airplanes of the same type design registered in the United States, an AD is proposed which would require a one-time functional test and replacement of the MLG door manual release system control bell crank, in accordance with the service bulletins previously described.

It is estimated that 171 airplanes of U.S. registry would be affected by this AD, that it would take approximately 2 manhours per airplane to accomplish the required actions, and that the average labor cost would be \$40 per manhour. The required parts would be provided by the manufacturer at no cost to the operator. Based on these figures, the total cost impact of the AD on U.S. operators is estimated to be \$13,680.

The regulations proposed herein 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. Therefore, in accordance with Executive Order 12612, it is determined that this proposal

would not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

For the reason discussed above, I certify that this proposed regulation (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) if promulgated, will not have a significant economic impact, positive or negative, or a substantial number of small entities under the criteria of the Regulatory Flexibility Act. A copy of the draft evaluation prepared for this action is contained in the regulatory docket. A copy of it may be obtained from the Rules Docket.

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 as follows:

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.

§ 39.13 [Amended]

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

Avions Merce! Dassault-Breguet Aviation (AMD-BA): Applies to all Model Mystere Falcon 50 and 900 series airplanes, as listed in AMD-BA Alert Service Bulletins F50-A212 (F50-A32-19) and F900-A65 (F900-A32-6), both dated July 25, 1989, certificated in any category. Compliance is required as indicated, unless previously accomplished.

To prevent inability to manually open the main landing gear (MLG) door for MLG emergency extension, accomplish the following:

A. Within 30 days after the effective date of this AD, verify the integrity of the MLG emergency release mechanism by performing a functional test of the emergency release system, in accordance with AMD-BA Alert Service Bulletin F50-A212 or F900-A65 (as applicable), both dated July 25, 1989. If door release does not occur, prior to further flight, replace the MLG door manual release system control bell crank with an adjustable bell crank, in accordance with the appropriate service bulletin. If door releases normally, the bell crank may remain in service until the requirements of paragraph B., below, are accomplished.

B. Within 180 days after the effective date of this AD, replace the MLG door manual release system control bell crank with an adjustable bell crank, in accordance with AMD-BA Alert Service Bulletin F50-A212 or F900-A65 (as applicable), both dated July 25, 1989.

C. An alternate means of compliance or adjustment of the compliance time, which provides an acceptable level of safety, may be used when approved by the Manager, Standardization Branch, ANM-113, FAA, Northwest Mountain Region.

Note: The request should be forwarded through an FAA Principal Maintenance Inspector (PMI), who will either concur or comment and then send it to the Manager, Standardization Branch, ANM-113.

D. Special flight permits may be issued in accordance with FAR 21.197 and 21.199 to operate airplanes to a base in order to comply with the requirements of this AD.

All persons affected by this directive who have not already received the appropriate service documents from the manufacturer may obtain copies upon request to Falcon Jet Corporation, Customer Support Department, Teterboro Airport, Teterboro, New Jersey 07608. These documents may be examined at the FAA, Northwest Mountain Region, Transport Airplane Directorate, 17900 Pacific Highway South, Seattle, Washington, or the Standardization Branch, 9010 East Marginal Way South, Seattle, Washington.

Issued in Seattle, Washington, on September 22, 1989.

Darrell M. Pederson,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.
[FR Doc. 89-23276 Filed 10-2-89; 8:45 am]

BILLING CODE 4910-13-M

14 CFR Part 39

[Docket No. 89-NM-180-AD]

Airworthiness Directives; Boeing Model 747 Series Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This notice proposes to adopt a new airworthiness directive (AD), applicable to certain Boeing Model 747 series airplanes, which would require installation of control cable block plates. This proposal is prompted by an FAA certification inspection which revealed that, under simulated cable system proof load, there was enough cable slack for the empennage cables to hang up on the cable shroud brackets above the Door 5 crew rest area. This

condition, if not corrected, could lead to the control cables snagging on the cable shroud brackets above Door 5 crew rest area, which could reduce the ability of the pilot to safely control the airplane.

DATES: Comments must be received no later than November 24, 1989.

ADDRESSES: Send comments on the proposal in duplicate to the Federal Aviation Administration, Northwest Mountain Region, Transport Airplane Directorate, ANM-103. Attention: Airworthiness Rules Docket No. 89-NM-180-AD, 17900 Pacific Highway South C-68966, Seattle, Washington 98168. The applicable service information may be obtained from Boeing Commercial Airplanes, P.O. Box 3707 Seattle, Washington 98124. This information may be examined at the FAA, Northwest Mountain Region, Transport Airplane Directorate, 17900 Pacific Highway South, Seattle, Washington, or Seattle Aircraft Certification Office, 9010 East Marginal Way South, Seattle, Washington.

FOR FURTHER INFORMATION CONTACT: Mr. Dan R. Bui, Airframe Branch, ANM-120S; telephone (206) 431-1919. Mailing address: FAA, Northwest Mountain Region, 17900 Pacific Highway South, C-68966, Seattle, Washington 98168.

SUPPLEMENTARY INFORMATION: 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 should identify the regulatory docket number and be submitted in duplicate to the address specified above. All communications received on or before the closing date for comments specified above will be considered by the Administrator before taking action on the proposed rule. The proposals contained in this Notice may be changed in light of the comments received.

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 Rule 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 Notice must submit a self-addressed, stamped post card on which the following statement is made: "Comments to Docket Number 89-NM-180-AD. The

post card will be date/time stamped and returned to the commenter.

Discussion

An FAA certification cable inspection of a Boeing Model 747 series airplane, revealed that, under simulated empennage cable system proof load, enough cable slack developed to hang up the empennage cables on the cable shroud brackets above the Door 5 crew rest area. This condition, if not corrected, could lead to the control cables snagging on the cable shroud brackets above Door 5 crew rest area, which could reduce the ability of the pilot to safely control the airplane.

The FAA has reviewed and approved Boeing Service Bulletin 747-25-2776, dated June 8, 1989, which describes procedures for installation of control cable block plates, which will preclude the possibility of the cable shroud brackets interfering with cable travel.

Since this condition is likely to exist or develop on other airplanes of this same type design, an AD is proposed which would require installation of control cable block plates in accordance with the service bulletin previously described.

There are approximately 13 Model 747 series airplanes of the affected design in the worldwide fleet. Currently, no airplanes of U.S. registry would be affected by this AD; therefore, there is no cost impact of this AD on U.S. operators. However, should an affected airplane be imported and placed on the U.S. Register in the future, approximately 8 manhours would be necessary to accomplish the actions required by this AD, and that the average labor cost would be \$40 per manhour. Based on these figures, the total cost impact of the AD on U.S. operators is estimated to be \$320 per airplane.

The regulations proposed herein 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. Therefore, in accordance with Executive Order 12612, it is determined that this proposal would not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

For the reasons discussed above, I certify that this proposed regulation (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) 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 evaluation prepared for this action is contained in the regulatory docket. A copy of it may be obtained from the Rules Docket.

List of Subject 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 as follows:

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.

§ 39.13 [Amended]

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

Boeing: Applies to Model 748 series airplanes with a Door 5 crew rest area, listed in Boeing Service Bulletin 747-25-2776, dated June 8, 1989, certificated in any category. Compliance required within the next 12 months after the effective date of this AD, unless previously accomplished.

To prevent empennage control cables from snagging on the cable shroud brackets above the Door 5 crew rest area, accomplish the following:

A. Install control cable block plates in accordance with Boeing Service Bulletin 747-25-2776, dated June 8, 1989.

B. An alternate means of compliance or adjustment of the compliance time, which provides an acceptable level of safety, may be used when approved by the Manager, Seattle Aircraft Certification Office, FAA, Northwest Mountain Region.

Note: the request should be forwarded through an FAA Principal Maintenance Inspector (PMI), who will either concur or comment, and then send it to the Manager, Seattle Aircraft Certification Office.

C. Special flight permits may be issued in accordance with FAR 21.197 and 21.199 to operate airplanes to a base in order to comply with the requirements of this AD.

All persons affected by this directive who have not already received the appropriate service documents from the manufacturer may obtain copies upon request to Boeing Commercial Airplanes, P.O. Box 3707 Seattle, Washington 98124. These documents may be examined at the FAA, Northwest Mountain Region, Transport Airplane Directorate, 17900 Pacific Highway South, Seattle, Washington, or

Seattle Aircraft Certification Office,
9010 East Marginal Way South, Seattle,
Washington.

Issued in Seattle, Washington, on
September 22, 1989.

Darrell M. Pederson,

*Acting Manager, Transport Airplane
Directorate, Aircraft Certification Service.*
[FR Doc. 89-23275 Filed 10-2-89; 8:45 am]

BILLING CODE 4910-13-M

14 CFR Part 39

[Docket No. 89-NM-187-AD]

Airworthiness Directives; Boeing Model 767 Series Airplanes

AGENCY: Federal Aviation
Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking
(NPRM).

SUMMARY: This notice proposes to adopt a new airworthiness directive (AD), applicable to certain Boeing Model 767 series airplanes, which would require replacement of the oxygen generator release cable assembly. This proposal is prompted by reports of broken release pins. This condition, if not corrected, could result in failure of the oxygen generator to activate and supply oxygen to the passengers and flight attendants.

DATE: Comments must be received no later than November 24, 1989.

ADDRESSES: Send comments on the proposal in duplicate to the Federal Aviation Administration, Northwest Mountain Region, Transport Airplane Directorate, ANM-103, Attention: Airworthiness Rules Docket No. 89-NM-187-AD, 17900 Pacific Highway South, C-68966, Seattle, Washington 98168. The applicable service information may be obtained from Boeing Commercial Airplanes, P.O. Box 3707 Seattle, Washington 98124. This information may be examined at the FAA, Northwest Mountain Region, Transport Airplane Directorate, 17900 Pacific Highway South, Seattle, Washington, or Seattle Aircraft Certification Office, 9010 East Marginal Way South, Seattle, Washington.

FOR FURTHER INFORMATION CONTACT: David M. Herron, Systems and Equipment Branch, ANM-130S; telephone (206) 431-1949. Mailing address: FAA, Northwest Mountain Region, 17900 Pacific Highway South, C-68966, Seattle, Washington 98168.

SUPPLEMENTARY INFORMATION: 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

should identify the regulatory docket number and be submitted in duplicate to the address specified above. All communications received on or before the closing date for comments specified above will be considered by the Administrator before taking action on the proposed rule. The proposals contained in this Notice may be changed in light of the comments received.

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 Notice must submit a self-addressed, stamped post card on which the following statement is made: "Comments to Docket Number 89-NM-187-AD. The post card will be date/time stamped and returned to the commenter."

Discussion

Two operators of Boeing Model 767 airplanes reported finding broken oxygen generator release pins while inspecting the generator and attempting to replace the 1½-turn lanyard pull rings with 2-turn rings. If the release pin breaks while attempting to activate the oxygen generator, the firing mechanism will not be activated and oxygen will not be produced.

New release cable assembly pins have been correctly drilled to prevent the fractures from occurring and color coded green for easy recognition.

The FAA has reviewed and approved Boeing Alert Service Bulletin 767-35A0015, dated July 13, 1989, which describes the replacement of the release cable assemblies to ensure proposed operation of the oxygen generator. The replacement assembly incorporates the new correctly drilled pins.

Since this condition is likely to exist or develop on other airplanes of this same type design, an AD is proposed which would require replacement of the oxygen generator release cable assemblies in accordance with the service bulletin previously described.

There are approximately 264 Boeing Model 767 series airplanes of the affected design in the worldwide fleet. It is estimated that 111 airplanes of U.S. registry would be affected by this AD, that it would take approximately 48 manhours per airplane to accomplish the

required actions, and that the average labor cost would be \$40 per manhour. Replacement parts are available at no cost. Based on these figures, the total cost impact of the AD on U.S. operators is estimated to be \$213,120.

The regulations proposed herein 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. Therefore, in accordance with Executive Order 12612, it is determined that this proposal would not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

For the reasons discussed above, I certify that this proposed regulation (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) 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 evaluation prepared for this action is contained in the regulatory docket. A copy of it may be obtained from the Rules Docket.

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 as follows:

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.

§ 39.13 [Amended]

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

Boeing: Applies to Model 767 series airplanes, listed in Boeing Alert Service Bulletin 767-35A0015, certificated in any category. Compliance required within 360 days after the effective date of this AD, unless previously accomplished.

To ensure proper operation of the oxygen generator, accomplish the following:

A. Replace the oxygen generator release cable assemblies in accordance with Boeing Alert Service Bulletin 767-35A0015, dated July 13, 1989.

B. An alternate means of compliance or adjustment of the compliance time, which provides an acceptable level of safety, may be used when approved by the Manager, Seattle Aircraft Certification Office, FAA, Northwest Mountain Region.

Note: The request should be forwarded through an FAA Principal Maintenance Inspector (PMI), who will either concur or comment, and then send it to the Manager, Seattle Aircraft Certification Office.

C. Special flight permits may be issued in accordance with FAR 21.197 and 21.199 to operate airplanes to a base in order to comply with the requirements of this AD.

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

Issued in Seattle, Washington, on September 22, 1989.

Darrell M. Pederson,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 89-23274 Filed 10-2-89; 8:45 am]

BILLING CODE 4910-13-M

14 CFR Part 39

[Docket No. 88-NM-115-AD]

Airworthiness Directives; Boeing Model 737-300 Series Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Supplemental notice of proposed rulemaking (NPRM).

SUMMARY: This notice proposes to revise an earlier proposed airworthiness directive (AD), applicable to certain Boeing Model 737 series airplanes, that would have required modification or replacement of the autopilot mode control panel (MCP). That proposal was prompted by reports of uncommanded altitude changes in the MCP. This proposal would delete the proposed requirement to modify or replace the MCP and as an interim, would require a revision to the FAA-approved Airplane Flight Manual to include new procedures related to the use of the autopilot. Failure to detect altitude changes in the MCP could result in the airplane flying at an unassigned altitude.

DATES: Comments must be received no later than November 3, 1989.

ADDRESSES: Send comments on the proposal in duplicate to the Federal

Aviation Administration, Northwest Mountain Region, Transport Airplane Directorate, ANM-103, Attention: Airworthiness Rules Docket No. 88-NM-115-AD, 17900 Pacific Highway South, C-68966, Seattle, Washington 98168. The applicable service information may be obtained from Boeing Commercial Airplanes, P.O. Box 3707 Seattle, Washington 98124; and Honeywell Incorporated, Sperry Commercial Flight Systems Group, P.O. Box 21111, Phoenix, Arizona 85036, ATTN: Customer Services, Air Transport Systems Division. This information may be examined at the FAA, Northwest Mountain Region, Transport Airplane Directorate, 17900 Pacific Highway South, Seattle, Washington, or Seattle Aircraft Certification Office, 9010 East Marginal Way South, Seattle, Washington.

FOR FURTHER INFORMATION CONTACT:

Alvin R. Habbestad, Systems & Equipment Branch, ANM-130S; telephone (206) 431-1942. Mailing address: FAA, Northwest Mountain Region, 17900 Pacific Highway South, C-68966, Seattle, Washington 98168.

SUPPLEMENTARY INFORMATION:

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 should identify the regulatory docket number and be submitted in duplicate to the address above. All communications received on or before the closing date for comments specified above will be considered by the Administrator before taking action on the proposed rule. The proposals contained in this Notice may be changed in light of the comments received.

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 Notice must submit a self-addressed, stamped post card on which the following statement is made: "Comments to Docket Number 88-NM-115-AD. The post card will be date/time stamped and returned to the commenter."

Discussion: A proposal to amend part 39 of the Federal Aviation Regulations

to include an airworthiness directive which requires modification or replacement of the autopilot mode control panel (MCP) on Boeing Model 737-300 series airplanes, was published as a Notice of Proposed Rulemaking (NPRM) in the *Federal Register* on September 20, 1988 (53 FR 36467). That action was prompted by reports of undetected airplane altitude changes caused by uncommanded changes in the altitude select window of the autopilot MCP. This condition, if not corrected, could result in the airplane flying at an unassigned altitude.

Since issuance of the NPRM, Boeing has advised the FAA of several reports received from operators of the altitude window of the MCP continuing to make nonselected changes. These occurred on airplanes on which the proposed modifications to the MCP had already been incorporated.

The FAA has considered this information and has determined that since the proposed corrective action is apparently ineffective in correcting the unsafe condition addressed, the proposal must be amended to delete the requirement to modify or replace the MCP. Accordingly, this supplemental NPRM proposes to require incorporation of certain MCP operating limitations into the Airplane Flight Manual. This is considered interim action. When the manufacturers have developed a modification that will correct the problem, the FAA may consider further rulemaking on this subject. Since this action would expand the scope of the proposed AD, the comment period has been reopened to provide adequate opportunity for public comment.

The regulations proposed herein 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. Therefore, in accordance with Executive Order 12612, it is determined that this proposal would not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

For the reasons discussed above, I certify that this proposed regulation (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) 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 evaluation prepared for this action is contained in the

regulatory docket. A copy of it may be obtained from the Rules Docket.

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 as follows:

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 revising the Notice of Proposed Rulemaking, Docket No. 88-NM-115-AD, published in the *Federal Register* on September 20, 1988 (53 FR 36467), as follows:

Boeing: Applies to Model 737-300 series airplanes, equipped with Sperry Model SP300 autopilot flight control computers (FCC) and mode control panels (MCP), as listed in Boeing Service Bulletin 737-22A1092, dated June 30, 1988, certificated in any category. Compliance required within 15 days after the effective date of this AD unless previously accomplished.

To reduce the potential for nonselected changes in the autopilot mode control panel being undetected, accomplish the following:

A. Incorporate the following procedures into the Airplane Flight Manual (AFM), Limitations Section. This may be accomplished by inserting a copy of this AD in the AFM.

Autopilot Limitations

For airplanes with SP300 autopilot mode control panels (MCP), flightcrews must use the following procedures:

1. Check MCP settings after any electrical power interruptions.
2. Following change in ALT selection in the MCP window, check ALT display to ensure desired altitude is displayed.
3. Closely monitor altitude during all altitude changes to ensure that the autopilot captures and levels off at the desired altitude.
4. Note: Standard "callouts" crew coordination and cross-checking of MCP settings and flight instruments are necessary to detect any nonselected MCP display changes.

B. An alternate means of compliance or adjustment of the compliance time, which provides an acceptable level of safety, may be used when approved by the Manager, Seattle Aircraft Certification Office, FAA, Northwest Mountain Region.

Note: The request should be forwarded through an FAA Principal Operations Inspector (POI), who will either concur or comment, and then send it to the Manager, Seattle Aircraft Certification Office.

C. Special flight permits may be issued in accordance with FAR 21.197 and 21.199 to operate airplanes to a base in order to comply with the requirements of this AD.

All persons affected by this proposal who have not already received the appropriate service documents from the manufacturer may obtain copies upon request to Boeing Commercial Airplanes, P.O. Box 3707 Seattle, Washington 98124. These documents may be examined at the FAA, Northwest Mountain Region, Transport Airplane Directorate, 17900 Pacific Highway South, Seattle, Washington, or Seattle Aircraft Certification Office, 9010 East Marginal Way South, Seattle, Washington.

Issued in Seattle, Washington, on September 22, 1989.

Darrell M. Pederson,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.
[ER Doc. 89-23280 Filed 10-2-89; 8:45 am]

BILLING CODE 4910-13-M

14 CFR Part 39

[Docket No. 88-NM-169-AD]

Airworthiness Directives; British Aerospace Model BAe 146-100A, -200A, and -300A Series Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Supplemental notice of proposed rulemaking (NPRM); reopening of comment period.

SUMMARY: This notice proposes to amend an earlier proposed airworthiness directive (AD), applicable to British Aerospace Model BAe 146-100A, -200A and -300A series airplanes, which would have required inspection and modification of certain aileron disconnect units (ADU's). This proposal would require inspection of additional ADU's and clarify part numbers of certain ADU's that need to be modified.

DATES: Comments must be received no later than November 3, 1989.

ADDRESSES: Send comments on the proposal in duplicate to the Federal Aviation Administration, Northwest Mountain Region, Transport Airplane Directorate, ANM-103, Attention: Airworthiness Rules Docket No. 88-NM-169-AD, 17900 Pacific Highway South, C-68966, Seattle, Washington 98168. The applicable service information may be obtained from British Aerospace, Librarian for Service Bulletins, P.O. Box 17414, Dulles International Airport, Washington, DC 20041. This information may be examined at the FAA, Northwest Mountain Region, Transport

Airplane Directorate, 17900 Pacific Highway South, Seattle, Washington, or the Standardization Branch, 9010 East Marginal Way South, Seattle, Washington.

FOR FURTHER INFORMATION CONTACT:

Mr. William Schroeder, Standardization Branch, ANM-113; telephone (206) 431-1565. Mailing address: FAA, Northwest Mountain Region, 17900 Pacific Highway South, C-68966, Seattle, Washington 98168.

SUPPLEMENTARY INFORMATION:

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 should identify the regulatory docket number and be submitted in duplicate to the address specified above. All communications received on or before the closing date for comments specified above will be considered by the Administrator before taking action on the proposed rule. The proposals contained in this Notice may be changed in light of the comments received.

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 Notice must submit a self-addressed, stamped post card on which the following statement is made: "Comments to Docket Number 88-NM-169-AD. The post card will be date/time stamped and returned to the commenter."

Discussion

A proposal to amend Part 39 of the Federal Aviation Regulations, which would have required inspection and modification of certain aileron disconnect units (ADU) on British Aerospace Model BAe 146-100A, -200A, and -300A series airplanes, was published as a Notice of Proposed Rulemaking (NPRM) in the *Federal Register* on May 25, 1989 (54 FR 22602). That NPRM was prompted by reports of the ADU failing to cock and/or release when tested. This condition, if not corrected, could lead to loss of all roll control should a jam in the aileron flight control system occur. The comment period closed July 14, 1989.

The single commenter to the proposal supported the rule, but noted that British Aerospace Modification Service Bulletin 27-87 dated September 30, 1988, covers three models of ADU's: Normalair Garrett LTD (NGL) Part Numbers 1099R000 and 1244R000, and Fraser Nash Part Number AO-100-902. The commenter also noted that the Fraser Nash model should be included in paragraph A.3., since inspection of this part is necessary, in accordance with the British Aerospace service bulletin. Upon further review of the service bulletins and additional information provided by the manufacturer, the FAA concurs. Accordingly, the NPRM has been revised to clarify the part number of ADU's to be modified, and identify Fraser Nash and NGL part numbers of ADU's to be inspected. Since this additional requirement would expand the scope of the previously proposed rule, the FAA has determined that it is necessary to provide additional time for public comment.

This airplane model is manufactured in the United Kingdom and type certificated in the United States under the provisions of § 21.29 of the Federal Aviation Regulations and the applicable bilateral airworthiness agreement.

It is estimated that 58 airplanes of U.S. registry would be affected by this AD, that it would take approximately 5 manhours per airplane to accomplish the required actions, and that the average labor cost would be \$40 per manhour. The estimated cost for the modifications is \$100. Based on these figures, the total cost impact of the AD on U.S. operators is estimated to be \$17,400.

The regulations proposed herein 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. Therefore, in accordance with Executive Order 12612, it is determined that this proposal would not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

For the reasons discussed above, I certify that this proposed regulation (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) 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 evaluation prepared for this action is contained in the regulatory docket. A copy of it may be obtained from the Rules Docket.

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 as follows:

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.

§ 39.13 [Amended]

2. By revising the Notice of Proposed Rulemaking, Docket 88-NM-169-AD, FR Doc. 89-12501, published in the *Federal Register* on May 25, 1989 (54 FR 22602), as follows:

British Aerospace: Applies to British Aerospace (BAe) Model 146-100A, -200A and -300A series airplanes, certificated in any category. Compliance is required as indicated, unless previously accomplished.

To prevent loss of roll control should a jam in the aileron control system occur, accomplish the following:

A. Within 60 days after the effective date of this AD:

1. Determine if Fraser Nash Part Number AO-100-902 aileron disconnect units (ADU's) or Normalair-Garrett, Ltd., (NGL) Part Number 1099R000, 1224R000, or 1295R000 ADU's are installed. If NGL Part Number 1295R000 ADU's modified to British Aerospace (BAe) Modification HCM70212C (NGL Modification No. 5RM) configuration are installed, no further action is required.

2. Modify NGL Part Number 1295R000 ADU's to BAe modification HCM70212C (NGL modification 5RM) configuration, in accordance with BAe Modification Service Bulletin 27-88-70212C, dated November 10, 1988.

3. Inspect Fraser Nash Part Number AO-100-902 and NGL Part Numbers 1099R000 and 1224R000 ADU's for dormant failure, in accordance with British Aerospace Inspection Service Bulletin 27-87 dated September 30, 1988. Replace any failed units with serviceable units prior to further flight.

B. For all airplanes equipped with NGL Part Numbers 1099R000 and 1224R000 ADU's that have not been previously modified to BAe HCM 70212A&B (NGL Modification 3RM and 4RM) configuration:

1. Within one year after the effective date of this AD, modify NGL Part Numbers 1099R000 and 1224R000 ADU's to BAe HCM70212A&B (NGL Modification 3RM and 4RM) and BAe HCM70212C (NGL Modification 5RM) configuration, in accordance with BAe Modification Service Bulletin 27-75-70212A&B, dated June 16, 1988, and 27-88-70212C, dated November 10, 1988.

Note: British Aerospace Modification Service Bulletin 27-75-70212A&B refers to NGL Service Bulletins 1099R-27-4 and 1224R-27-5. British Aerospace Modification Service Bulletin 27-88-70212C refers to NGL Service Bulletin 1295R-27-6, Revision 1, and NGL Service News Letter, dated September 12, 1988, for specific installation procedures.

C. An alternate means of compliance or adjustment of the compliance time, which provides an acceptable level of safety, may be used when approved by the Manager, Standardization Branch, ANM-113, FAA, Northwest Mountain Region.

Note: The request should be forwarded through an FAA Principal Maintenance Inspector (PMI), who will either concur or comment and then send it to the Manager, Standardization Branch, ANM-113.

D. Special flight permits may be issued in accordance with FAR 21.197 and 21.199 to operate airplanes to a base in order to comply with the requirements of this AD.

All persons affected by this directive who have not already received the appropriate service documents from the manufacturer may obtain copies upon request to British Aerospace, Librarian for Service Bulletins, P.O. Box 17414, Dulles International Airport, Washington, DC 20041. These documents may be examined at the FAA, Northwest Mountain Region, Transport Airplane Directorate, 17900 Pacific Highway South, Seattle, Washington, or the Standardization Branch 9010 East Marginal Way South, Seattle, Washington.

Issued in Seattle, Washington, on September 22, 1989.

Darrell M. Pederson,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 89-23279 Filed 10-2-89; 8:45 am]

BILLING CODE 4910-13-M

14 CFR Part 39

[Docket No. 89-NM-170-AD]

Airworthiness Directives: Lockheed L-1011 Series Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This notice proposes to adopt a new airworthiness directive (AD), applicable to L-1011 series airplanes, which would require inspection and replacement of the flap vane carriage fitting. This proposal is prompted by reports of flap vane separations. This condition, if not corrected, could result in danger to persons and property on the ground.

DATES: Comments must be received no later than November 24, 1989.

ADDRESSES: Send comments on the proposal in duplicate to the Federal Aviation Administration, Northwest Mountain Region, Transport Airplane Directorate, ANM-103, Attention: Airworthiness Rules Docket No. 898-NM-170-AD, 17900 Pacific Highway South, C-68966, Seattle, Washington 98168. The applicable service information may be obtained from Lockheed Aeronautical Systems Company, P. O. Box 551, Burbank, California 91520, Attention: Commercial Order Administration, Dept. 65-33, U-33, B-1. This information may be examined at the FAA, Northwest Mountain Region, Transport Airplane Directorate, 17900 Pacific Highway South, Seattle, Washington, or 3229 East Spring Street, Long Beach, California.

FOR FURTHER INFORMATION CONTACT: Mr. Augusto Coe, Aerospace Engineer, Airframe Branch, ANM-121L, FAA, Northwest Mountain Region, Los Angeles Aircraft Certification Office, 3229 East Spring Street, Long Beach, California 90806-2425; telephone (213) 988-5225.

SUPPLEMENTARY INFORMATION: 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 should identify the regulatory docket number and be submitted in duplicate to the address specified above. All communications received on or before the closing date for comments specified above will be considered by the Administrator before taking action on the proposed rule. The proposals contained in this Notice may be changed in light of the comments received.

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 Notice must submit a self-addressed, stamped post card on which the following statement is made: "Comments to Docket Number 89-NM-170-AD. The post card will be date/time stamped and returned to the commenter.

Discussion

Recently, an operator of a Model L-1011 series airplane experienced separation of the No. 3 flap vane from the airplane on approach for landing. Inspection of the parts revealed signs of an existing fatigue crack in the base of the lower lug of the flap vane outboard carriage link assembly (P/N 1562426-101/-105). Study of previous vane link failures has determined the cause to be inadequate clearance between the spoilers and flap vane causing pressure against the vane during flight cruise mode due to wing deflections. There had been 24 other occurrences. This condition, if not corrected, could result in separation of the flap vane from the airplane, which could endanger persons and property on the ground.

The FAA has reviewed and approved Lockheed Service Bulletin 093-57-209, dated August 10, 1989, which describes procedures for inspection of the No. 3 flap vane outboard link for cracks, and replacement, if necessary.

Since this condition is likely to exist or develop on other airplanes of this same type design, an AD is proposed which would require periodic inspections of the P/N 1562426-101/-105 aluminum link assembly using eddy-current procedures, and if cracks are found, replacement of the aluminum link with a new aluminum link or a P/N 1562426-109 titanium link. Additionally, if the vane installation is not rigged with clearance equal to or greater than the minimum clearance specified in Lockheed Service Bulletin 093-57-209, removal of the outboard spoiler rub strips to increase the vane-to-spoiler clearance would be required.

Finally, this proposal would require operators to eventually replace all aluminum fittings with titanium fittings; this would constitute terminating action for the proposed inspections.

There are approximately 240 Model L-1011 series airplanes of the affected design in the worldwide fleet. It is estimated that 130 airplanes of U.S. registry would be affected by this AD, that it would take approximately 20.0 manhours per airplane to accomplish the required actions, and that the average labor cost would be \$40 per manhour. The cost of the fittings replacement kit would be \$2,000 each (2 kits per airplane). Based on these figures, the total cost impact of the AD on U.S. operators is estimated to be \$624,000.

The regulations proposed herein 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. Therefore,

in accordance with Executive Order 12612, it is determined that this proposal would not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

For the reasons discussed above, I certify that this proposed regulation (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) 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 evaluation prepared for this action is contained in the regulatory docket. A copy of it may be obtained from the Rules Docket.

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 Administration as follows:

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.

§ 39.13 [Amended]

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

Lockheed Aeronautical Systems Company:
Applies to Model L-1011 series airplanes, certificated in any category. Compliance required as indicated, unless previously accomplished.

To prevent the failure of No. 3 flap vane outboard carriage link assembly, accomplish the following:

A. Prior to the accumulation of 6,000 landings or 15,000 flight hours, whichever occurs first, or within 30 days after the effective date of this AD, whichever occurs later, conduct the following in accordance with Section 2, "Accomplishment Instructions," of Lockheed Service Bulletin 093-57-209, dated August 10, 1989:

1. Inspect the left and right No. 3 flap vane outboard carriage link assembly for cracks, using the eddy-current procedure as described in the Service Bulletin.

2. If no cracks are found, conduct repetitive eddy current inspections in accordance with the Service Bulletin at intervals not to exceed 1,000 landings.

3. If a crack is found, replace the link assembly with a new link assembly P/N

1562426-101/-105 or with a titanium No. 3 flap vane outboard carriage link assembly, P/N 1562426-109.

4. If not previously accomplished, remove existing rub strips on lower surface of spoilers No. 3 through No. 6 in accordance with the procedure described in the Service Bulletin. Then conduct an outboard flap vane-to-flap contact check, rigging check, and adjustment in accordance with L-1011 Maintenance Manual, Section 27-51-00. Check the vane-to-spoiler clearance to ensure that a minimum clearance of 0.20 inch is maintained.

5. If rub strips were previously removed, check the vane-to-spoiler clearance as described in the L-1011 Maintenance Manual, Section 27-51-00.

B. Installation of the titanium link assembly, P/N 1562426-109, constitutes terminating action for the repetitive inspections required by Paragraph A.2., above.

C. Within 2½ years after the effective date of this AD, replace all aluminum fittings with titanium fittings.

D. An alternate means of compliance or adjustment of compliance time, which provides an acceptable level of safety, may be used when approved by the Manager, Los Angeles Aircraft Certification Office, FAA, Northwest Mountain Region.

Note: The request with adequate justification should be forwarded through an FAA Principal Maintenance Inspector (PMI), who will either concur or comment and then send it to the Manager, Los Angeles Aircraft Certification Office.

All persons affected by this directive who have not already received the appropriate service documents from the manufacturer may obtain copies upon request to Lockheed Aeronautical Systems Company, P.O. Box 551, Burbank, California 91520, Attention: Commercial Order Administration, Dept. 65-33, U-33, B-1. These documents may be examined at the FAA, Northwest Mountain Region, Transport Airplane Directorate, 1790 Pacific Highway South, Seattle, Washington, or 3229 East Spring Street, Long Beach, California.

Issued in Seattle, Washington, on September 22, 1989.

Darrell M. Pederson,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 89-23277 Filed 10-2-89; 8:45 am]

BILLING CODE 4910-13-M

14 CFR Part 39

[Docket No. 88-NM-214-AD]

Airworthiness Directives: McDonnell Douglas Model DC-10 Series Airplanes Equipped With Lavatories H and J

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Supplemental notice of proposed rulemaking (NPRM); reopening of comment period.

SUMMARY: This notice proposes to revise an earlier proposed airworthiness directive (AD), applicable to McDonnell Douglas Model DC-10 series airplanes equipped with lavatories H and J, which would have required modification of the electrical terminal caps on overhead light assemblies installed in those lavatories to seal the terminals. This proposal was prompted by reports of an electrical short in the light assembly terminal cap. This condition, if not corrected, could result in an in-flight fire in the overhead of a lavatory if an electrical short occurs and the insulation blanket above the light assembly is loose. This action revises the proposed rule by revising the service information for modification of the light assemblies, and by requiring an inspection of the insulation blankets in the area of the H and J lavatories.

DATES: Comments must be received no later than November 3, 1989.

ADDRESSES: Send comments on the proposal in duplicate to the Federal Aviation Administration, Northwest Mountain Region, Transport Airplane Directorate, ANM-103, Attention: Airworthiness Rules Docket No. 88-NM-214-AD, 17900 Pacific Highway South, C-68966, Seattle, Washington 98168. The applicable service information may be obtained from McDonnell Douglas Corporation, 3855 Lakewood Boulevard, Long Beach, California 90846, Attention: Director of Publications, C1-L00 (54-60). This information may be examined at the FAA, Northwest Mountain Region, 17900 Pacific Highway South, Seattle, Washington, or Los Angeles Aircraft Certification Office, 3229 East Spring Street, Long Beach, California.

FOR FURTHER INFORMATION CONTACT: Mr. Richard S. Saul, Aerospace Engineer, Systems and Equipment Branch, ANM-130L, FAA, Northwest Mountain Region, Los Angeles Aircraft Certification Office, 3229 East Spring Street, Long Beach, California 90806-2425; telephone (213) 988-5342.

SUPPLEMENTARY INFORMATION: 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 should identify the regulatory docket number and be submitted in duplicate to the address specified above. All communications received on or before the closing date for comments specified above will be considered by the Administrator before taking action on

the proposed rule. The proposals contained in this Notice may be changed in light of the comments received.

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 Notice must submit a self-addressed, stamped post card on the which the following statement is made: "Comments to Docket Number 88-NM-214-AD. This post card will be date/time stamped and returned to the commenter."

Discussion

A proposal to amend part 39 of the Federal Aviation Regulations to include an airworthiness directive (AD), applicable to McDonnell Douglas Model DC-10 series airplanes equipped with lavatories H and J, which would have required modification of the electrical terminal caps on the overhead light assemblies installed in those lavatories to seal the terminals, was published in the *Federal Register* on February 21, 1989 (54 FR 7445). That proposal was prompted by reports of evidence of electrical arcing in overhead fluorescent light assembly terminals on light assemblies installed in H and J lavatories and flames observed coming from the insulation blanket above the light assemblies. This condition, if not corrected, could result in an in-flight fire in the overhead of a lavatory.

Since issuance of that proposal, a Model DC-10 airplane experienced a fire in Lavatory J while parked at the gate for cleaning and servicing. During tests of insulation blankets from the H and J lavatories on that airplane, a flammable lubricant, used to lubricate the passenger door drive chain, was found on some of the insulation blanket covers. McDonnell Douglas issued All Operator TWX DC-10-COM-35/EHH, dated June 15, 1989, to advise Model DC-10 operators of the lubricant found on the blankets and to recommend they check the blankets at the next practical maintenance period.

It was determined during the investigation that the procedures specified in McDonnell Douglas Service Bulletin 25-350, dated May 5, 1989, which describe sealing the electrical terminal caps on overhead light assemblies installed in lavatories H and

J, may not be completely effective in preventing arcing at the electrical terminals. A new modification to the fluorescent light assemblies has been designed which will preclude the electrical terminals from becoming a fire ignition source. The FAA has reviewed and approved McDonnell Douglas Service Bulletin 25-357 dated September 5, 1989, which describes a newly-developed modification to the H and J overhead fluorescent light assemblies which locates the electrical terminals internally to the light assembly.

The FAA has determined that this NPRM must be revised to require installation of the newly-developed, more effective modification of the fluorescent light assemblies described in McDonnell Douglas Service Bulletin 25-357. In addition, this proposal would require an inspection of the insulation blankets by the H and J lavatories for the presence of lubricant from the passenger door drive chain, and replacement, if necessary.

There are approximately 428 McDonnell Douglas Model DC-10 series airplanes in the worldwide fleet. It is estimated that 58 airplanes of U.S. registry would be affected by this AD, that it would take approximately 5.4 manhours per airplane to accomplish the required actions, and that the average labor cost would be \$40 per manhour. The cost for parts is estimated to be \$400 per airplane. Based on these figures, the total cost impact of the AD on U.S. operators is estimated to be \$35,728.

The regulations proposed herein 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. Therefore, in accordance with Executive Order 12612, it is determined that this proposal would not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

For these reasons discussed above, I certify that this proposed regulation (1) is not a "major rule" under Executive Order 12291; and (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 a draft regulatory evaluation prepared for this action is contained in the regulatory docket. A copy of it may be obtained from the Rules Docket.

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 § 39.13 of part 39 of the Federal Aviation Regulations as follows:

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.

§ 39.13 [Amended]

2. By adding the following new airworthiness directive:

McDonnell Douglas: Applies to McDonnell Douglas Model DC-10 series airplanes equipped with lavatories H and J, as listed in McDonnell Douglas Service Bulletin 25-357 dated September 5, 1989, certificated in any category. Compliance required as indicated, unless previously accomplished.

To prevent fire resulting from an electrical short in the H and J lavatory overhead light assembly terminal caps, accomplish the following:

A. Within 60 days after the effective date of this AD, modify the overhead light assemblies in lavatories H and J, in accordance with the Accomplishment Instructions of McDonnell Douglas Service Bulletin 25-357 dated September 5, 1989.

B. Within 60 days after the effective date of this AD, inspect the insulation blankets and foam insulating material in the areas above lavatories H and J and in the areas outboard of lavatories H and J. Prior to further flight, replace any insulation blankets and/or foam insulating material which has been contaminated by passenger door drive chain lubricant.

C. An alternate means of compliance or adjustment of the compliance time, which provides an acceptable level of safety, may be used when approved by the Manager, Los Angeles Aircraft Certification Office, FAA, Northwest Mountain Region.

Note: The request should be forwarded through an FAA Principal Maintenance Inspector (PMI), who will either concur or comment, and then send it to the Manager of the office indicated above.

D. Special flight permits may be issued in accordance with FAR 21.197 and 21.199 to operate airplanes to a base in order to comply with the requirements of this AD.

All persons affected by this directive who have not already received the appropriate service documents from the manufacturer may obtain copies upon request to McDonnell Douglas Corporation, 3855 Lakewood Boulevard, Long Beach, California 90846, Attention: Director of Publications, C1-LOO (54-

60). These documents may be examined at the FAA, Northwest Mountain Region, 17900 Pacific Highway South, Seattle, Washington, or Los Angeles Aircraft Certification Office, 3229 East Spring Street, Long Beach, California 90846-2425.

Issued in Seattle, Washington, on September 22, 1989.

Darrell M. Pederson,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.
[FR Doc. 89-23278 Filed 10-2-89; 8:45 am]

BILLING CODE 4910-13-M

DEPARTMENT OF COMMERCE

Bureau of Export Administration

15 CFR Parts 771, 772, 773, 774, 786, and 799

[Docket No. 90645-9145]

RIN 0694-AA12

General License G-TEMP- Temporary Exports

AGENCY: Bureau of Export Administration Commerce.

ACTION: Proposed rule, with request for comments.

SUMMARY: General License GTE authorizes temporary exports for certain purposes such as exhibition, demonstration, inspection and testing, and requires prompt return to the country of export. This proposed rule would redesignate that license as General License G-TEMP and amend it by removing the registration requirement and by establishing guidelines for the use of the general license. One effect of removing the registration requirement would be that parties abroad who were not eligible to register under the former General License GTE would be able to use G-TEMP as authorization for a permissive reexport in accordance with the appropriate provisions of the regulations. This proposed rule would permit news media personnel to take their equipment to all destinations and permit shipments of kits consisting of parts that would be eligible for export as one-for-one replacement parts under General License GLR.

DATE: Comments should be received by November 17 1989.

ADDRESSES: Written comment (six copies) should be sent to: Patricia Muldoman, Office of Technology and Policy Analysis, Bureau of Export Administration, Department of

Commerce, P.O. Box 273, Washington, DC 20044.

FOR FURTHER INFORMATION CONTACT: Patricia Muldonian, Office of Technology and Policy Analysis, Bureau of Export Administration, Department of Commerce, Washington, DC 20230, Telephone: (202) 377-2440.

SUPPLEMENTARY INFORMATION:

Rulemaking Requirements

1. This rule is consistent with Executive Orders 12291 and 12661.

2. This rule contains collection of information requirements under the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 *et seq.*). These collections were approved by the Office of Management and Budget (OMB) under Control Numbers 0694-0010 and 0694-0029.

Public reporting for these collections of information is estimated to average 25 minutes per response for 0694-0010 and 15 minutes per response for 0694-0029. This includes the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding these burden estimates or any other aspect of these collections of information, including suggestions for reducing these burdens, to Office of Security and Management, Bureau of Export Administration, U.S. Department of Commerce, Washington, DC, 20230; and to the Office of Management and Budget, Paperwork Reduction Project (0694-0010 and 0694-0029), Washington, DC 20503.

3. Because a notice of proposed rulemaking and an opportunity for public comment are not required to be given for this rule by section 553 of the Administrative Procedure Act (5 U.S.C. 553) or by any other law, under sections 603(a) and 604(a) of the Regulatory Flexibility Act (5 U.S.C. 603(a) and 604(a)) no initial or final Regulatory Flexibility Analysis has to be or will be prepared.

4. Section 13(a) of the Export Administration Act of 1979, as amended (50 U.S.C. app 2412(a)), exempts this rule from all requirements of section 2412(a)), exempts this rule from all requirements of section 553 of the Administrative Procedure Act (APA) (5 U.S.C. 553), including those requiring publication of a notice of proposed rulemaking, an opportunity for public comment, and a delay in effective date. This rule is also exempt from these APA requirements because it involves a foreign affairs function of the United States. Because this rule is being issued in proposed form, this rule complies with section

13(b) of the Export Administration Act. Further, no other law requires that a notice of proposed rulemaking and an opportunity for public comment be given for this rule.

5. This rule does not contain policies with federalism implication sufficient to warrant preparation of a federalism assessment under Executive Order 12612.

Invitation to Comment

Because of the importance of the issues raised by these regulations, this rule is issued in proposed form and comments will be considered in the development of final regulations. Accordingly, the Department encourages interested persons who wish to comment to do so at the earliest possible time to permit the fullest consideration of their views.

The period for submission of comments will close November 17 1989. The Department will consider all comments received before the close of the comment period in developing final regulations. Comments received after the end of the comment period will be considered if possible, but their consideration cannot be assured. The Department will not accept public comments accompanied by a request that part or all of the material be treated confidentially because of its business proprietary nature or for any other reason. The Department will return such comments and will not consider them in the development of final regulations. All public comments on these regulations will be a matter of public record and will be available for public inspection and copying. In the interest of accuracy and completeness, the Department requires comments in written form. Oral comments must be followed by written memoranda, which will also be a matter of public record and will be available for public review and copying. Communications from agencies of the United States Government or foreign governments will not be available for public inspection.

The public record concerning these regulations will be maintained in the Bureau of Export Administration Freedom of Information Records Facility, Room 4086, Department of Commerce, 14th Street and Pennsylvania Avenue, NW Washington, DC 20230. Records in this facility, including written public comments and memoranda summarizing the substance of oral communications, may be inspected and copied in accordance with regulations published in part 4 of title 15 of the Code of Federal Regulations. Information about the inspection and copying of records at

the facility may be obtained from Margaret Cornejo, Bureau of Export Administration Freedom of Information Officer, at the above address or by calling (202) 377-2593.

List of Subjects in 15 CFR Parts 771, 772, 773, 774, 786, and 799

Administrative practice and procedure, Exports, Reporting and recordkeeping requirements.

Accordingly, the Export Administration Regulations (15 CFR parts 730-799) are amended as follows:

PARTS 771, 772, 773, 786 and 799— [AMENDED]

1. The authority citation for 15 CFR parts 771, 772, 773, 786 and 799 continues to read as follows:

Authority: Pub. L. 96-72, 93 Stat. 503 (50 U.S.C. app. 2401 *et seq.*), as amended by Pub. L. 97-145 of Dec. 29, 1981 and by Pub. L. 99-64 of July 12, 1985; E.O. 12525 of July 12, 1985 (50 FR 28757 July 16, 1985) and Pub. L. 100-418 of Aug. 23, 1988; Pub. L. 95-223 of Dec. 28, 1977 (50 U.S.C. 1701 *et seq.*); E.O. 12532 of Sept. 9, 1985 (50 FR 36861, Sept. 10, 1985) as affected by notice of Sept. 4, 1986 (51 FR 31925, Sept. 8, 1986); Pub. L. 99-440 of Oct. 2, 1986 (22 U.S.C. 5001 *et seq.*); E.O. 12571 of Oct. 27 1986 (51 FR 39505, Oct. 29, 1986).

PART 774—[AMENDED]

2. The authority citation for 15 CFR part 774 continues to read as follows:

Authority: Pub. L. 96-72, 93 Stat. 503 (50 U.S.C. app. 2401 *et seq.*), as amended by Pub. L. 97-145 of December 29, 1981 and by Pub. L. 99-64 of July 12, 1985 and Pub. L. 100-418 of August 23, 1988; E.O. 12525 of July 12, 1985 (50 FR 28757 July 16, 1985).

§ 771.1 [Amended]

3. In § 771.1, the second sentence is revised to read: "No written authorization is required for using a general license and no document is issued by Commerce as a precondition to use a general license."

§ 771.22 [Amended]

4. § 771.22 is revised to read as follows:

§ 771.22 General License G-TEMP—temporary exports

(a) *Scope.* A general license designated G-TEMP is established authorizing export of commodities for temporary use abroad (including use in international waters) subject to the conditions and exceptions set forth below. Commodities shipped under this general license must be returned to the country from which exported as soon as practicable but, except in circumstances described below, no later than one year

from the date of export. This requirement does not apply if the commodities are consumed or destroyed in the normal course of authorized temporary use abroad or an extension or other disposition is permitted by the Export Administration Regulations or in writing by the Office of Export Licensing.

(b) *Eligible commodities.* The following commodities are eligible to be shipped under General License G-TEMP:

(1) *Tools of trade.* Usual and reasonable kinds and quantities of commodities and software for use by employees of the exporter in a lawful enterprise or undertaking of the exporter. The commodities and software must remain under the effective control of the exporter or the exporter's employee. The shipment of commodities and software may accompany the individual departing from the United States or may be shipped unaccompanied within one month before or after the individual's departure from the United States. Notwithstanding the restriction in § 771.22(c), personal computers that do not exceed the limits of Advisory Note 9 to 1565A on the Commodity Control List (Supplement No. 1 to § 799.1) may be taken as tools of trade to Country Group Q, W, Y and the People's Republic of China.

(2) *Kits consisting of replacement parts.* Kits consisting of replacement parts may be exported under this provision, provided that:

(i) Such parts would qualify for shipment under General License GLR if exported as one-for-one replacements;

(ii) Such kits remain under effective control of the exporter or an employee of the exporter; and

(iii) All parts in the kit are returned, except that one-for-one replacements may be made in accordance with the requirements of General License GLR and the defective parts returned.

(3) *Exhibition and demonstration Country Groups T and V.* Commodities and software for exhibition or demonstration in Country Groups T or V (excluding the People's Republic of China) may be exported under this provision provided that the exporter maintains ownership of the commodities and software while they are abroad and provided that the exporter, an employee of the exporter, or the exporter's designated sales representative retains effective control over the commodities and software while they are abroad. The commodities and software shall not be exhibited or demonstrated at any one site more than 30 days after installation and debugging, unless authorized by the Office of Export Licensing. However,

prior to or after an exhibition or demonstration, the commodities and software may be placed in a bonded warehouse or a storage facility provided that the exporter retains effective control over disposition of commodities and software, pending movement to another site, return to the U.S., or approval for other disposition. The export documentation for this type of transaction shall show the U.S. exporter as ultimate consignee, in care of the person who will have control over the commodities and software abroad.

(4) *Inspection and calibration.* Commodities to be inspected, tested, calibrated or repaired abroad.

(5) *Containers.* Containers for which another general license is not available and that are necessary for export of commodities. However, General License G-TEMP does not authorize the export of the container's contents, which must be separately authorized for export under either a general or validated license.

(6) *Broadcast material.* (i) Video tape containing program material recorded in the country of export to be publicly broadcast in another country.

(ii) Blank video tape (raw stock) for use in recording program material abroad.

(7) *Assembly in Mexico.* Commodities to be exported to Mexico and returned under HTSUS Nos. 9802.00.60 and 9802.00.80 after processing, assembly, or incorporation into end products by companies, factories, or facilities participating in Mexico's in-bond industrialization program (Maquilladora), provided that all resulting end-products (or the commodities themselves) are returned to the United States. (See § 771.22(c)(3).)

(8) *News media.* (i) Commodities necessary for news-gathering purposes (and software necessary to use such commodities) that accompany "accredited" news media personnel, i.e., persons with credentials from a news gathering or reporting business to Country Groups Q, S, W, Y, or Z, or the People's Republic of China if the commodities:

(A) Are retained under ownership of the exporting news gathering firm;

(B) Remain in the physical possession of the news media personnel; and

(C) Are removed with the news media personnel at the end of the trip.

(ii) Exports under this provision that originate from the U.S. shall be registered with the U.S. Customs Service at the time of both exit and reentry.

(iii) Commodities necessary for news-gathering purposes that accompany news media personnel to all other destinations shall be exported under

and in accordance with paragraph (b)(1), *tools of trade*, of this section if owned by the exporter/company or shall be exported under and in accordance with § 771.6, General License Baggage if they are personal property of the individual news media personnel.

(c) *Special restrictions—(1) Destinations.* (i) No commodity or software may be exported under this general license to Country Group S or Z except as permitted by paragraph (b)(8), *news media*, of this section;

(ii) No commodity or software identified by the code letter A "B" or "M" following the Export Control Commodity Number on the Commodity Control List may be exported under this general license to Country Group Q, W, or Y except:

(A) Commodities and software exported under paragraph (b)(8), *news media*, of this section; and

(B) Note 9 personal computers and necessary software exported under paragraph (b)(1), *tools of trade*, of this section.

(iii) No commodity or software identified by the code letter A" or "M" following the Export Control Number on the Commodity Control List may be exported under this general license to the People's Republic of China except:

(A) Commodities and software exported under paragraph (b)(8), *news media*, of this section; and

(B) Note 9 personal computers and necessary software exported under paragraph (b)(1), *tools of trade*, of this section.

(iv) These destination restrictions apply to any vessel, aircraft or territory under ownership, control, lease, or charter by any country in Country Groups Q, S, W, Y and Z, and the People's Republic of China, or any national thereof.

(2) *Commodities.* (i) The following commodities may not be exported to any destination under this general license:

(A) Supercomputers;

(B) Commodities that will be used outside of the countries listed in Supplement No. 2 to part 773 either directly or indirectly in any sensitive nuclear activity as described in § 778.3.

(C) Electronic, mechanical, or other devices, as described in § 778.13(a), primarily useful for surreptitious interception of wire or oral communications; and

(D) Commodities listed in supplement No. 1 to part 773, except that commodities identified in the footnotes thereto as available for shipment to certain countries under the Distribution License procedure may be shipped to

those same countries under General License G-TEMP

(ii) When warranted, additional eligibility for General License G-TEMP of commodities listed in supplement No. 1 to part 773 will be considered. To request an exception, submit a letter to:

Office of Export Licensing, Room 1099D,
P.O. Box 273, Washington, DC 20044.

describing fully the commodity or software to be exported, its proposed use and disposition, and the reasons eligibility is warranted. The Office of Export Licensing will notify the exporter of its decision on the request for eligibility.

(3) *Use or disposition.* No commodity or software may be exported under this general license if an order to acquire the commodity has been received before shipment or if the exporter has prior knowledge that the commodity will stay abroad beyond the terms of General License G-TEMP

(d) *Return or disposal of commodities.* All commodities and software exported under this General License G-TEMP shall, if not consumed or destroyed in the normal course of authorized temporary use abroad, be returned as soon as practicable but no later than one year after the date of export, to the United States or other country from which the commodities and software were exported under G-TEMP or shall be disposed of or retained by one of the following ways:

(1) *Authorization under Form BXA-699P* If the U.S. exporter wishes to sell or otherwise dispose of the commodities or software abroad or extend the retention of the commodities or software abroad, except as permitted by this general license, he shall request authorization therefore by submitting Form BXA-699P Request to Dispose of Commodities or Technical Data Previously Exported, to the Office of Export Licensing at the address listed in § 771.2(h). (See § 774.3 for more information on reexport authorizations.) Such request shall comply with all applicable provisions of the Export Administration Regulations covering exports directly from the United States to the proposed destination. The request shall also be accompanied by any documents that would be required in support of an application for export license for shipment of the same commodities directly from the United States to the proposed destination. The Office of Export Licensing will advise the exporter of its decision.

(2) *Use of validated license.* An outstanding validated export license may also be used to dispose of commodities or software covered by

General License G-TEMP provided that the outstanding license authorizes direct shipment from the United States of the same commodity or software to the same new ultimate consignee in the new country of destination.

(3) *Use of a Permissive Reexport,* as defined in § 774.2.

(4) *Authorization to retain abroad beyond one year.* If the exporter wishes to retain a commodity(ies) and software abroad beyond the 12 months authorized in § 771.22(b), he shall request such authorization by submitting Form BXA-699P Request to Dispose of Commodities or Technical Data Previously Exported, 90 days prior to the expiration of the 12 month period. The request shall be sent to the Office of Export Licensing at the address listed in § 771.22(c)(2) and should include the name and address of the exporter, the date the commodities or software were exported, a brief product description, and the justification for the extension. If the Office of Export Licensing approves the extension request, the exporter will receive authorization for a one-time extension not exceeding six months. The Office of Export Licensing normally will not allow an extension for commodities and software that have been abroad more than 12 months, nor will a second six month extension be authorized.

(e) *Records.* In accordance with the provisions of § 787.13, the exporter shall retain for two years and make available for inspection, upon demand, by the Office of Export Enforcement all records of each export under this general license as well as the Customs Entry Number or any other evidence of the disposition of the commodities exported.

(Approved by the Office of Management and Budget under Control Numbers 0694-0010 and 0694-0029)

§ 772.8 [Amended]

5. In section 772.8(c)(1), the reference "General License GTE" is revised to read "General License G-TEMP" both places it appears.

§ 773.3 [Amended]

6. In section 773.3(j)(5), the parenthetical portion after the first sentence is deleted.

§ 774.2 [Amended]

7 Section 774.2 is amended by redesignating footnotes 4 and 5 as footnotes 5 and 6; and by revising paragraph (a)(1), as follows:

§ 774.2 Permissive reexports.

(a)

(1) May be exported directly from the United States to the new country of

destination under General License G-DEST, G-TEMP* G-COM, GFW, G-CEU, GCG, G-NNR, G-FTZ, GUS or BAGGAGE.

* Commodities legally exported from the United States may be reexported to a new country(ies) of destination under General License G-TEMP provided the restrictions described in § 771.22 are met and the commodities and software are returned to the country from which the reexport occurred.

§ 786.6 [Amended]

8. In § 786.6(a)(1)(ii) and (a)(2), the reference to "GTE" is revised to read "G-TEMP"

§ 799.2 [Amended]

9. In Supplement 1 to § 799.2, Interpretation 21, the reference to "GTE" is revised to read "G-TEMP" each place it appears.

Dated: September 25, 1989.

James M. LeMunyon,
Deputy Assistant Secretary for Export Administration.

[FR Doc. 89-23047 Filed 10-2-89; 8:45 am]

BILLING CODE 3510-DT-M

DEPARTMENT OF VETERANS AFFAIRS

38 CFR Part 3

RIN 2900-AD60

Basic Eligibility Determinations; Education

AGENCY: Department of Veterans Affairs.

ACTION: Proposed regulations.

SUMMARY: The Department of Veterans Affairs (VA) is amending the regulation which provides authority and guidelines for making a service-connected discharge determination needed to determine eligibility for educational assistance under the Vietnam Era GI Bill and the Post-Vietnam Era Veterans Educational Assistance Program (VEAP). The amended regulation adds a second rule for determining eligibility for VEAP rules for deciding when such a determination must be made for a veteran who has applied for benefits under the Montgomery GI Bill—Active Duty, and a rule for deciding when a determination of service connection for a disability must be made for a reservist who otherwise would be eligible for benefits under the Montgomery GI Bill—Selected Reserve.

DATES: Comments must be received on or before November 2, 1989. Comments will be available for public inspection until November 13, 1989.

ADDRESSES: Send written comments to: Secretary of Veterans Affairs (271A), Department of Veterans Affairs, 810 Vermont Avenue, NW Washington, DC 20420. All written comments received will be available for public inspection only in the Veterans Services Unit, room 132 of the above address between the hours of 8 a.m. to 4:30 p.m., Monday through Friday (except holidays) until November 13, 1989.

FOR FURTHER INFORMATION CONTACT: William G. Susling, Acting Assistant Director for Education Policy and Program Administration, Vocational Rehabilitation and Education Service, Veterans Benefits Administration, (202) 233-2092.

SUPPLEMENTARY INFORMATION: On pages 46635 and 46636 of the Federal Register (54 FR 46635) of November 18, 1988, VA published a notice of intent to amend part 3 in order to show when a service-connected discharge determination is needed in determining eligibility for educational assistance under the Montgomery GI Bill—Active Duty. Interested people were given 31 days to submit comments, objections or suggestions. VA received no comments, objections or suggestions.

On the same day as this proposal appeared in the Federal Register, the Veterans' Benefits and Programs Improvement Act of 1988 was enacted. That Act contains some provisions which affect the eligibility requirements for the Montgomery GI Bill—Active Duty. Some changes to the proposed text of § 3.315(c) are necessary in order to avoid a conflict between the regulations and the law. Rather than make these changes final, VA is seeking further comment. Moreover, after reviewing this proposal, VA has decided to generalize the paragraph to include when decisions concerning service connection must be made for those otherwise eligible to receive benefits under the Montgomery GI Bill—Selected Reserve.

The Department of Veterans Affairs has determined that this amended regulation does not contain a major rule as that term is defined by E.O. 12291, entitled Federal Regulation. The regulation will not have a \$100 million annual effect on the economy, and will not cause a major increase in costs or prices for anyone. It will have no significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based enterprises to compete with foreign-

based enterprises in domestic or export markets.

The Secretary of Veterans Affairs has certified that this amended regulation, if promulgated, will not have a significant economic impact on a substantial number of small entities as they are defined in the Regulatory Flexibility Act (RFA), 5 U.S.C. 601-612. Pursuant to 5 U.S.C. 605(b), the amended regulation, therefore, is exempt from the initial and final regulatory flexibility analyses requirements of sections 603 and 604.

This certification can be made because the regulation affects only individuals. It will have no significant economic impact on small entities, i.e., small businesses, small private and nonprofit organizations and small governmental jurisdictions.

(The Catalog of Federal Domestic Assistance number for the program affected by this regulation is 64.124)

List of Subjects in 38 CFR Part 3

Administrative practice and procedure, Claims, Handicapped, Health care, Pensions, Veterans.

Approved: September 13, 1989.

Edward J. Derwinski,
Secretary of Veterans Affairs.

In 38 CFR Part 3, Adjudication, § 3.315 is proposed to be amended by revising paragraph (c) to read as follows:

§ 3.315 Basic eligibility determinations—dependents, loans, education.

(c) *Veterans' educational assistance.*

(1) A determination is required as to whether a veteran was discharged or released from active duty service because of a service-connected disability (or whether the official service department records show that the veteran had at time of separation from service a service-connected disability which in medical judgment would have warranted discharge for disability) whenever any of the following circumstances exist:

(i) The veteran applies for benefits under 38 U.S.C. chapter 34 and is eligible for such benefits except for the 181 days active duty requirement;

(ii) The veteran applies for benefits under 38 U.S.C. chapter 32, the minimum active duty service required of 38 U.S.C. 3103A to not apply to him or her, and the veteran is eligible for such benefits except for the 181 days active duty requirement;

(iii) The veteran applies for benefits under 38 U.S.C. chapter 32, the minimum active duty service requirements of 38 U.S.C. 3103A apply to him or her, and the veteran would be eligible for such benefits only if—

(A) He or she was discharged or released from active duty for a disability incurred or aggravated in line of duty, or

(B) He or she has a disability that VA has determined to be compensable under 38 U.S.C. chapter 11; or

(iv) The veteran applies for benefits under 38 U.S.C. chapter 30 and—

(A) The evidence of record does not clearly show either that the veteran was discharged or released from active duty for disability or that the veteran's discharge or release from active duty was unrelated to disability, and

(B) The veteran is eligible for basic educational assistance except for the minimum length of active duty service requirements of § 21.7042(a) or § 21.7044(a) of this chapter.

(2) A determination is required as to whether a veteran was discharged or released from service in the Selected Reserve for a service-connected disability or for a medical condition which preexisted the veteran's having become a member of the Selected Reserve and which VA determines is not service connected when the veteran applies for benefits under 38 U.S.C. chapter 30 and—

(i) Either the veteran would be eligible for basic educational assistance under that chapter only if he or she was discharged from the Selected Reserve for a service-connected disability, or for a medical condition which preexisted the veteran's having become a member of the Selected Reserve and which VA finds is not service connected, or

(ii) The veteran is entitled to basic educational assistance and would be entitled to receive it at the rates stated in § 21.7136(a) or § 21.7137(a) of this chapter only if he or she was discharged from the Selected Reserve for a service-connected disability or for a medical condition which preexisted the veteran's having become a member of the Selected Reserve and which VA finds is not service connected.

(3) A determination is required as to whether a reservist has been unable to pursue a program of education due to a disability which has been incurred in or aggravated by service in the Selected Reserve when—

(i) The reservist is otherwise entitled to educational assistance under 10 U.S.C. chapter 106, and

(ii) He or she applies for an extension of his or her eligibility period.

(4) The determinations required by paragraphs (c)(1) through (3) of this section are subject to the presumptions of incurrence under § 3.304(b) and aggravation under § 3.306 (a) and (c) of this part, based on service rendered after January 31, 1955, and before

August 5, 1964, or after May 7 1975, and § 3.306(b) based on service rendered during the Vietnam era.

(Authority: 38 U.S.C. 1411(a)(1)(A)(ii), 1412(b)(1), 1602(1)(A), 1652(a), 10 U.S.C. 2133(b))

[FR Doc. 89-23246 Filed 10-2-89; 8:45 am]

BILLING CODE 8320-01-M

38 CFR Part 3

RIN 2900-AD71

Definition of Former Prisoner of War

AGENCY: Department of Veterans Affairs.

ACTION: Proposed rule.

SUMMARY: The Department of Veterans Affairs (VA) is proposing to amend its adjudication regulation defining former prisoner of war (POW) and is establishing criteria for deciding such status. The Veterans' Benefits and Services Act of 1988 provides the basis for redefinition. The effect of the change will be to permit VA to decide POW status for an extended class of veterans. **DATES:** Comments must be received on or before November 2, 1989. This change is proposed to be effective 30 days after the date of publication of the final rule. Comments will be available for public inspection until November 13, 1989.

ADDRESSES: Interested persons are invited to submit written comments, suggestions, or objections regarding this change to Secretary of Veterans Affairs (271A), Department of Veterans Affairs, 810 Vermont Avenue, NW., Washington, DC 20420. All written comments received will be available for public inspection only in the Veterans Services Unit, Room 132, at the above address between the hours of 8:00 a.m. and 4:30 p.m., Monday through Friday (except holidays), until November 13, 1989.

FOR FURTHER INFORMATION CONTACT: Bill Leonard, Consultant, Regulations Staff, Compensation and Pension Service, Veterans Benefits Administration, (202) 233-3005.

SUPPLEMENTARY INFORMATION: On pages 46634-35 of the Federal Register of November 18, 1988, VA published a proposed rule on the definition of "former prisoner of war." Interested persons were given until December 19, 1988, to submit comments on the proposed rule. Four comments were received.

Comments received included those of the Chairman and Ranking Minority Member of the Senate Veterans Affairs Committee and the Chairman of the House Veterans' Affairs Committee. These three commenters all stated that

the regulation as proposed did not implement the Congressional intent of The Veterans' Benefits and Services Act of 1988, Public Law 100-322. They pointed out that the law intended to convey former POW status to those service persons who were detained or interned by neutral nations without regard to the reason for detainment or internment. It was stated that Congress intended the controlling factor to be the circumstances under which individuals or groups of individuals were detained or interned as compared to circumstances experienced by persons forcibly detained by enemy governments during periods of war.

The current regulation, 38 CFR 3.1(y)(2)(ii), does not provide for consideration of the treatment of a serviceperson during detainment or internment for determinations of POW status during a period other than a period of war. This rule was promulgated in 1982 based on the authority of section 2, Public Law 97-37 which gave VA authority to determine if an incident of detainment or internment during a period other than a period of war was comparable to that which occurred during a period of war. VA considered whether the reasons for the capture as well as the deprivations endured by the captured serviceperson should be included as factors for determining whether or not the detainment or internment occurred under comparable circumstances. It was determined that, due to possible unavailability of information regarding treatment of the captured individuals, the reason for the detainment or internment would be the determinative factor as to a service person being considered a former POW during a period other than a period of war. This factor was carried forward into the rule proposed during 1988.

Based on the comments received in response to the publication of the proposed rule defining a former POW, VA recognizes the need for change in the determinative factor for decisions concerning POW status. We are proposing to make the determinative factor, in decisions which are not based on acceptable service department findings, to be the circumstances of detention or internment rather than the reason for same.

We are proposing to amend 38 CFR 3.1(y) to more closely follow the wording found in 38 U.S.C. 101(32)(B), requiring that decisions to recognize a serviceperson as a former POW will require a finding that he or she was forcibly detained or interned under circumstances comparable to those experienced by a POW of an enemy

government during a period of war. Examples of such circumstances are provided.

In an effort to minimize the burden of proof placed on VA claimants to show circumstances endured as a detainee or internee, we are proposing an amendment to recognize that each member of a group was individually treated in the same manner as the entire group was treated generally unless evidence is presented to show otherwise. Through claims experience, this provision will allow eventual recognition of certain groups as meeting or not meeting the criteria for recognition of its members as former POWs. Individual members of a group which is not shown to meet the criteria could establish entitlement through submission of evidence showing individual circumstances comparable to enemy government detainees or internees during wartime.

A fourth commenter suggested that the regulation provide a list of the countries and periods which would constitute eligibility for recognition of former POW status. The commenter felt that such a list would speed the determination process by reducing the number of reviews required by VA Central Office.

We cannot accommodate the commenter at this time because the VA lacks sufficient data for such determinations. With the VA Central Office approval requirement contained in the regulation, we hope to be able to identify groups and periods to allow such determinations in the future.

As this constitutes a major change from the initial proposed definition, we are again publishing a proposed rule.

The Secretary hereby certifies that this regulatory amendment will not have a significant economic impact on a substantial number of small entities as they are defined in the Regulatory Flexibility Act, 5 U.S.C. 601-612. The reason for this certification is that this amendment would not directly affect any small entities. Only VA beneficiaries could be directly affected. Therefore, pursuant to 5 U.S.C. 605(b), this amendment is exempt from the initial and final regulatory flexibility analysis requirements of sections 603 and 604.

In accordance with Executive Order 12291, Federal Regulation, the Secretary has determined that this regulatory amendment is non-major for the following reasons.

(1) It will not have an annual effect on the economy of \$100 million or more.

(2) It will not cause a major increase in costs or prices.

(3) It will not have significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic or export markets.

(The Catalog of Federal Domestic Assistance program numbers are 64.104, 64.105, 64.109, and 64.110)

List of Subjects in 38 CFR Part 3

Administrative practice and procedure, Claims, Handicapped, Health care, Pensions, Veterans.

Approved: September 8, 1989.

Edward J. Derwinski,

Secretary of Veterans Affairs.

In 38 CFR Part 3, Adjudication, § 3.1 is proposed to be amended by revising paragraph (y) to read as follows:

§ 3.1 Definitions.

(y) "Former prisoner of war." The term "former prisoner of war" means a person who, while serving in the active military, naval or air service, was forcibly detained or interned in the line of duty by an enemy or foreign government, the agents of either, or a hostile force.

(1) *Decisions based on service department findings.* The Department of Veterans Affairs shall accept the finding of the appropriate service department that a person was a prisoner of war during a period of war unless a reasonable basis exists for questioning it. Such findings shall be accepted only when detention or internment is by an enemy government or its agents.

(2) *Other decisions.* In all other situations, including those in which the Department of Veterans Affairs cannot accept the service department finding, the following factors shall be used to determine prisoner of war status:

(i) *Circumstances of detention or internment.* To be considered a former prisoner of war, a serviceperson must have been forcibly detained or interned under circumstances comparable to those under which persons generally have been forcibly detailed or interned by enemy governments during periods of war. Such circumstances include, but are not limited to, physical hardships or abuse, psychological hardships or abuse, malnutrition, and unsanitary conditions. Each individual member of a particular group of detainees or internees shall, in the absence of evidence to the contrary, be considered to have experienced the same circumstances as those experienced by the group.

(ii) *Reason for detention or internment.* The reason for which a serviceperson was detailed or interned is immaterial in determining POW status, except that a serviceperson who is detailed or interned by a foreign government for an alleged violation of its laws is not entitled to be considered a former POW on the basis of that period of detention or internment, unless the charges are a sham intended to legitimize the period of detention or internment.

(3) The Director of the Compensation and Pension Service, VA Central Office, shall approve all VA regional office determinations establishing or denying POW status, with the exception of those service department determinations accepted under paragraph (y)(1) of this section.

(4) *In line of duty.* The Department of Veterans Affairs shall consider that a serviceperson was forcibly detained or interned in line of duty unless the evidence of record discloses that forcible detention or internment was the proximate result of the serviceperson's own willful misconduct. Willful misconduct means an act involving conscious wrongdoing or known prohibited action. It involves deliberate or intentional wrongdoing with knowledge of or wanton and reckless disregard of its probable consequences.

(5) *Hostile force.* The term "hostile force" means any entity other than an enemy or foreign government or the agents of either whose actions are taken to further or enhance anti-American military, political or economic objectives or views, or to attempt to embarrass the United States.

(Authority: 38 U.S.C. 101(32))

[FR Doc. 89-23249 Filed 10-2-89; 8:45 am]

BILLING CODE 8320-01-M

38 CFR Part 21

RIN 2900-AC91

Extension of Time Limits for Claims

AGENCY: Department of Veterans Affairs.

ACTION: Proposed regulatory amendments.

SUMMARY: The Department of Veterans Affairs (VA) is proposing to amend its rules to provide increased protection of a veteran's rights to secure benefits and services under the vocational rehabilitation program. These proposed regulatory changes will help assure that the veteran is not adversely affected if

VA fails to take actions required by VA procedures for informing veterans of the time limits during which information in support of claims must be provided.

DATES: Comments must be received on or before November 2, 1989. Comments will be available for public inspection until November 13, 1989. We propose to make these amendments effective 30 days after publication of the final regulations.

ADDRESSES: Send written comments to the Secretary of Veterans Affairs (271A), Department of Veterans Affairs, 810 Vermont Avenue NW Washington, DC 20420 All written comments received will be available for public inspection only in the Veterans Services Unit, room 132 at the above address, between the hours of 8 a.m. to 4:30 p.m., Monday through Friday (except holidays) until November 13, 1989.

FOR FURTHER INFORMATION CONTACT: Morris Triestman, Rehabilitation Consultant, Vocational Rehabilitation and Education Service, Department of Veterans Benefits, (202)-233-2886.

SUPPLEMENTARY INFORMATION: Under current policy contained in § 21.32, the failure of VA to furnish notice of a time limit for the submission of evidence by the veteran in support of a claim does not extend the period allowed for these actions. Under the proposed changes, the period allowed for filing information in support of a claim will be extended if VA fails to inform the veteran of these time limits.

VA has initiated a review of the rules governing the vocational rehabilitation program to identify any existing rules which may not satisfy current standards for procedural due process. The amendments which we are proposing are the results of this review.

These proposed regulatory amendments do not meet the criteria for a major rule as that term is defined by Executive Order 12291, Federal Regulation. These proposed regulatory amendments will not have a \$100 million annual effect on the economy, will not cause a major increase in costs or prices and will not have any other significant adverse effects on the economy.

The Secretary of Veterans Affairs has certified that these proposed regulatory amendments, if promulgated, will not have a significant economic impact on a substantial number of small entities as they are defined in the Regulatory Flexibility Act (RFA), 5 U.S.C. 601-612. Pursuant to 5 U.S.C. 605(b), the proposed regulatory amendments, therefore, are exempt from the initial and final regulatory flexibility analyses requirements of sections 603 and 604.

This certification can be made because the proposed regulatory amendments only affect the eligibility of certain veterans with service-connected disabilities for benefits and assistance under the vocational rehabilitation program. The proposed regulatory amendments will have no significant economic impact on small entities, i.e., small business, small private and nonprofit organizations and small governmental jurisdictions.

(The Catalog of Federal Domestic Assistance number for the program affected by these proposed regulatory amendments is 64.116)

List of Subjects in 38 CFR Part 21

Civil rights, Claims, Education, Grant programs, Loan programs, Reporting requirements, Schools, Veterans, Vocational education, Vocational rehabilitation.

Approved: September 13, 1989.

Edward J. Derwinski,
Secretary of Veterans Affairs.

38 CFR Part 21, Vocational Rehabilitation and Education, is proposed to be amended as follows:

1. In § 21.32, paragraph (b) and the cross-references at the end of the section are revised and paragraph (c) is added to read as follows:

§ 21.32 Time limit.

(b) *Failure to furnish claim or notice of time limit.* The failure of VA to furnish a claimant:

(1) Any form or information concerning the right to file a claim or to furnish notice of the time limit for the filing of a claim is not a basis for adjusting the periods allowed for these actions;

(2) Appropriate notice of time limits within which evidence must be submitted to perfect a claim shall result in an adjustment of the period during which the time limit runs. The period during which the time limit runs shall be determined in accordance with paragraph (c) of this section. As to appeals see § 19.129 of this chapter.

(Authority: (38 U.S.C. 3013)

(c) *Adjustment of time limit.* (1) In computing the time limit for any action required of a claimant or beneficiary to perfect the types of claims described in paragraph (a) of this section, the first day of the specified period will be excluded and the last day included. This rule is applicable in cases in which the time limit expires on a workday. Where the time limit would expire on a Saturday, Sunday, or holiday, the next succeeding workday will be included in the computation.

(2) The period during which the veteran must provide information necessary to perfect his or her claim does not begin to run until the veteran has been notified of this requirement for submission of information. The date of the letter of notification informing the veteran of the action required and the time limit for accomplishing the action shall be "The first day of the specified period" referred to in paragraph (c)(1) of this section.

(Authority: U.S.C. 3001, 3013, 201(c))

Cross-Reference: Due Process. See § 3.103.

2. In § 21.322, paragraph (c)(1)(i)(B), (ii)(B), (iii), (2)(i)(B) and (C) are revised to read as follows:

§ 21.322 commencing dates of subsistence allowance.

(c) *Increases for dependents—*

(1) *

(i)

(B) VA receives any necessary evidence within 1 year of the date VA requested the evidence and informed the veteran of the time limits during which this evidence must be submitted. If VA fails to inform the veteran of these time limits, the period for submission of the evidence is adjusted in accordance with § 21.32 of this part.

(ii)

(B) VA receives any necessary evidence within 1 year of the date VA requested the evidence and informed the veteran of the time limits during which this evidence must be submitted. If VA fails to inform the veteran of these time limits, the period for submission of the evidence is adjusted in accordance with § 21.32 of this part;

(iii) The effective date of the increase will be the date VA receives all necessary evidence if that evidence is received more than one year from the date VA requested the evidence and informed the veteran of the time limits during which this evidence must be submitted. If VA fails to inform the veteran of these time limits, the period for submission of the evidence is adjusted in accordance with § 21.32 of this part.

(2)

(i)

(B) Date notice is received of the dependent's existence if evidence is received within 1 year from the date VA requested the evidence and informed the veteran of the time limits during which this evidence must be submitted. If VA fails to inform the veteran of these time limits, the period for submission of the evidence is adjusted in accordance with § 21.32 of this part.

(C) Date VA receives evidence of the dependent's existence if this date is more than 1 year after VA requested this evidence and informed the veteran of the time limits during which this evidence must be submitted. If VA fails to inform the veteran of the time limits, the period for submission of the evidence is adjusted in accordance with § 21.32 of this part.

[FR Doc. 89-23247 Filed 10-2-89; 8:45 am]

BILLING CODE 8320-01-M

38 CFR Part 21

RIN 2900-AD77

Disabling Effects of Chronic Alcoholism

AGENCY: Department of Veterans Affairs.

ACTION: Proposed regulation.

SUMMARY: The Veterans' Benefits and Improvement Act of 1988 provides that the disabling effects of chronic alcoholism shall not be considered to be the result of the veteran's willful misconduct for the purpose of extending a delimiting date under any education benefit or rehabilitation program administered by the Department of Veterans Affairs (VA). The intended effect of this proposed rule is to implement this provision of the statute with respect to the vocational rehabilitation program.

DATES: Comments must be received on or before November 2, 1989. Comments will be available for public inspection until November 13, 1989. The proposed effective date of the proposed regulation, like the effective date of the law which it interprets, is November 18, 1988.

ADDRESSES: Interested persons are invited to submit written comments, suggestions, or objections to the Secretary of Veterans Affairs (271A), Department of Veterans Affairs, 810 Vermont Avenue, NW., Washington, DC 20420. All written comments received will be available for public inspection at the above address only between the hours of 8:00 a.m. and 4:30 p.m. Monday through Friday (except holidays) until November 13, 1989.

FOR FURTHER INFORMATION CONTACT: Morris Trnestman, Rehabilitation Consultant, Policy and Program Development, Vocational Rehabilitation and Education Service, Veterans Benefits Administration, (202) 233-6496.

SUPPLEMENTARY INFORMATION: The Veterans' Benefits and Improvement Act

of 1988, Public Law 100-689, provides that the disabling effects of chronic alcoholism shall not be considered the result of the veteran's willful misconduct for the purpose of extending a delimiting date under any educational assistance or rehabilitation program administered by VA. In order to include this provision of section 109, Public Law 100-689, in rules governing the vocational rehabilitation program an amendment is made to § 21.42(c). Under § 21.42(c) the basic 12-year period of eligibility does not run during any period of 30 days or more during which the veteran was unable to participate in a vocational rehabilitation program because of his or her medical condition. Section 21.42(c) is amended to specifically include chronic alcoholism as a condition for which the basic 12-year eligibility period for vocational rehabilitation may be adjusted. The proposed regulation also defines what VA considers as the disabling effects of chronic alcoholism for the purpose of adjusting the basic 12-year period of eligibility. This proposed regulation will have no effect on provisions of the regulations relating to the compensation and pension program.

VA has determined that this proposed regulation does not contain a major rule as that term is defined in Executive Order 12291, Federal Regulation. The proposal will not have a \$100 million annual effect on the economy, will not cause a major increase in costs or prices, and will not have any other significant adverse effects on the economy.

It is proposed to make this amendment retroactively effective. This is an interpretative rule which implements statutory provisions. Moreover, VA finds good cause exists for making this rule, like the section of the law which it implements, retroactively effective to the date of enactment. A delayed effective date would be contrary to statutory design; would complicate implementation of this provision of law; and might result in a denial of a benefit to a veteran who is entitled by law to that benefit.

The Secretary certifies that this proposed regulation will not, if promulgated, have a significant economic impact on a substantial number of small entities as they are defined in the Regulatory Flexibility Act (RFA), 5 U.S.C. 601-612. Pursuant to 5 U.S.C. 605(b), this proposed rule is therefore exempt from the initial and final flexibility analyses requirements of §§ 603 and 604. The reasons for this certification are that this proposed regulation only affects the rights of individual beneficiaries. No new

regulatory burdens are imposed on small entities by this regulation.

(The Catalog of Federal Domestic Assistance number is 64.116)

List of Subjects in 38 CFR Part 21

Civil rights, Claims, Education, Grant programs, Loan programs, Reporting requirements, Schools, Veterans, Vocational education, Vocational rehabilitation.

Approved: September 8, 1989.

Edward J. Derwinski,
Secretary of Veterans Affairs.

38 CFR part 21, Vocational Rehabilitation and Education, is proposed to be amended by revising paragraph (c) of § 21.42 to read as follows:

§ 21.42 Basic period of eligibility deferred.

(c) *Medical condition prevents initiation or continuation.* (1) The basic 12-year period of eligibility shall not begin to run or continue to run during any period of 30 days or more in which the veteran's participation in vocational rehabilitation is infeasible because of the veteran's medical condition, which condition may include the disabling effects of chronic alcoholism, subject to paragraph (c)(5) of this section. The 12-year period shall begin or resume when it is feasible for the veteran to participate in a vocational rehabilitation program, as that term is defined in § 21.35 of this part.

(2) The term "disabling effects of chronic alcoholism" means alcohol-induced physical or mental disorders or both, such as habitual intoxication, withdrawal, delirium, amnesia, dementia, and other like manifestations of chronic alcoholism which, in the particular case:

(i) Have been medically diagnosed as manifestations of alcohol dependency or chronic alcohol abuse; and

(ii) Are determined to have prevented commencement or completion of the affected individual's rehabilitation program.

(3) A diagnosis of alcoholism, chronic alcoholism, alcohol dependency, chronic alcohol abuse, etc., in and of itself, does not satisfy the definition of "chronic alcoholism."

(4) Injury sustained by a veteran as a proximate and immediate result of activity undertaken by the veteran while physically or mentally unqualified to do so due to alcoholic intoxication is not considered a disabling effect of chronic alcoholism.

(5) The disabling effects of chronic alcoholism, which prevent initiation or continuation of participation in a

vocational rehabilitation program after November 17 1988, shall not be considered to be the result of willful misconduct.

(Authority: 38 U.S.C. 1503(b)(1), Pub. L. 100-689)

[FR Doc. 89-23248 Filed 10-2-89; 8:45 am]

BILLING CODE 8320-01-M

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[FRL-3654-5]

Approval and Promulgation of Air Quality Implementation Plans; Massachusetts; Extension of Public Comment Period

AGENCY: Environmental Protection Agency (EPA).

ACTION: Extension of public comment period.

SUMMARY: On August 14, 1989 (54 FR 33245), EPA proposed approval of a revision submitted by the Commonwealth of Massachusetts for the Acushnet Company, Plant A. On September 12, 1989, Acushnet Company requested an extension of the public comment period. EPA has evaluated this request and is hereby granting a thirty (30) day extension of the public comment period.

DATES: Comments should be received on or before October 13, 1989.

FOR FURTHER INFORMATION CONTACT: Cynthia L. Greene; (617) 565-3244; FTS 835-3244.

Authority: 42 U.S.C. 7401-7642.

Dated: September 20, 1989.

Paul Keough,

Acting Regional Administrator, Region I.

[FR Doc. 89-23299 Filed 10-2-89; 8:45 am]

BILLING CODE 6560-50-M

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

49 CFR Part 531

[Docket No. LVM 89-01; Notice 2]

Passenger Automobile Average Fuel Economy Standards; Proposed Exemptions and Alternative Standards

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

ACTION: Proposed decision to grant exemptions from average fuel economy

standards and to establish alternative standards.

SUMMARY: This consolidated notice responds to individual petitions filed by three low volume manufacturers, Lamborghini, LondonCoach, and Maserati, each requesting exemption from the generally applicable passenger automobile average fuel economy standards, and seeking establishment of lower alternative standards for each model year (MY) from which they seek exemption. This notice proposes to grant exemptions and establish alternative standards as follows:

Lamborghini of North America (Lamborghini) petitioned to be exempted for MYs 1983 and 1984. This notice proposes to exempt Lamborghini and establish an alternative standard of 13.7 mpg for MYs 1983 and 1984.

London Coach Co., Inc. (LondonCoach) petitioned to be exempted for MYs 1985 through 1987. This notice proposes to exempt LondonCoach and to establish an alternative standard of 21.0 mpg for MYs 1985 through 1987.

Officine Alfieri Maserati S.p.A. (Maserati) petitioned to be exempted for MYs 1982-1985. In a separate notice published today, the agency denies Maserati's request for MYs 1982 through 1983 because the Maserati petition was not timely filed for those years and good cause was not shown for the late filing. This notice proposes to exempt Maserati for MYs 1984 and 1985, and to establish alternative standards of 17.3 mpg for MY 1984 and 16.6 mpg for MY 1985.

DATES: Comments on the proposals in this notice must be received by NHTSA on or before November 17, 1989.

ADDRESS: Comments on this notice must refer to Docket No. LVM 89-01; Notice 2 and should be submitted to: Docket Section, NHTSA, Room 5109, 400 Seventh Street, SW Washington, DC 20590. Docket hours are from 8:00 a.m. to 4:00 p.m. Monday through Friday.

FOR FURTHER INFORMATION CONTACT: Mr. Orron Kee, Office of Market Incentives, NHTSA, 400 Seventh Street, SW., Washington, DC 20590. Mr. Kee's telephone number is (202) 366-0846.

SUPPLEMENTARY INFORMATION:

Background

Title V of the Motor Vehicle Information and Cost Savings Act (Cost Savings Act), which is codified at 15 U.S.C. 2001-2002, provides for an automotive fuel economy regulatory program under which standards are established for the corporate average fuel economy (CAFE) of the annual production fleets of passenger

automobiles and light trucks. Title V was added in 1975 to the Cost Savings Act by the Energy Policy and Conservation Act (EPCA). Responsibility for the automotive fuel economy program was delegated by the Secretary of Transportation to the Administrator of NHTSA.

Section 502 specified CAFE standards for passenger automobiles of 18, 19, and 20 mpg for MYs 1978, 1979, and 1980, respectively, and 27.5 mpg for model year 1985 and thereafter. The Secretary of Transportation was required to establish standards for MYs 1981 through 1984 by July 1, 1977. Section 502(a)(3) requires that the standards for each of those model years be set at a level which (1) is the maximum feasible average fuel economy level and (2) would result in steady progress toward meeting the standard for MY 1985. On June 30, 1977, NHTSA adopted CAFE standards for passenger automobiles for MYs 1981 through 1984 (42 FR 33534). These standards were 22 mpg for 1981, 24 mpg for 1982, 26 mpg for 1983, and 27 mpg for 1984.

Title V provides that NHTSA has broad discretion to decide whether to amend the standards. If NHTSA decides to amend the standards for MY 1985 and thereafter, however, the agency is required to comply with the Administrative Procedure Act (APA) (5 U.S.C 501 *et seq.*) and to set the amended standards at the "maximum feasible" level of average fuel economy. Pursuant to that authority, the agency reduced the MY 1986-88 standards to 26 mpg.

Section 502(c) of the Cost Savings Act provides that a low volume manufacturer of passenger automobiles may be exempted from the generally applicable average fuel economy standards for passenger automobiles if those standards are more stringent than the maximum feasible average fuel economy for that manufacturer and if NHTSA establishes an alternative standard for the manufacturer at its maximum feasible level. Under the Act, a low volume manufacturer is one that manufactures (worldwide) fewer than 10,000 passenger automobiles in the model year for which the exemption is sought (the affected model year) and that manufactured fewer than 10,000 passenger automobiles in the second model year before the affected model year. In determining maximum feasible average fuel economy, the agency is required by section 502(e) of the Act to consider:

- (1) Technological feasibility;
- (2) Economic practicability;
- (3) The effect of other Federal motor vehicle standards on fuel economy; and

(4) The need of the Nation to conserve energy.

Selection of the Type of Alternative Standard

The Act permits NHTSA to establish alternative average fuel economy standards applicable to exempted low volume manufacturers in one of three ways: (1) A separate standard may be established for each exempted manufacturer; (2) classes, based on design, size, price, or other factors, may be established for the automobiles of exempted manufacturers, with a separate average fuel economy standard applicable to each class; or (3) a single standard may be established for all exempted manufacturers.

If exemptions are granted to the petitioners for the model years covered by their petitions, NHTSA believes it is appropriate to establish separate standards for each manufacturer because the agency has already used that approach for other low volume manufacturers that petitioned for exemptions during MYs 1978-1989. NHTSA has reached final decisions on several exemption petitions filed by low volume manufacturers for the 1978 through 1989 model years; Avanti Motor Corporation for MYs 1978 through 1985 (49 CFR 531.5(b)(1)), Rolls-Royce Motors, Inc. for MYs 1978 through 1989 (49 CFR 531.5(b)(2)), Checker Motors Corporation for MYs 1978 through 1982 (49 CFR 531.5(b)(3)), Aston Martin Lagonda, Inc. for MYs 1979 through 1985 (49 CFR 531.5(b)(4)), and Excalibur Automobile Corporation for MYs 1978 through 1985 (49 CFR 531.5(b)(5)).

Timing of Petitions

Title 49 CFR part 525 sets forth the required contents of and procedures for processing petitions for exemption from the generally applicable passenger automobile average fuel economy standards. 49 CFR 525.6(b) specifies that each petition for exemption must be filed "not later than 24 months before the beginning of the affected model year, unless good cause for later submission is shown; " The reasons for including this deadline in § 525.6 were to facilitate the low volume manufacturers' planning to comply with the alternative standards, and to ensure that the agency's analysis of those manufacturers' maximum feasible average fuel economy would not be simply a "rubber stamping" of the individual manufacturer's planned fuel economy, caused by insufficient leadtime for the manufacturer to make changes. See 41 FR 53827-53828; December 9, 1976.

However, the agency recognized that there would be situations when good cause existed for not filing 24 months before the start of the model year. NHTSA has recognized two situations as establishing good cause for failure to submit a timely petition. First, there are situations in which the necessary supporting data for the petition were unavailable until after the due date had passed. For example, a recently incorporated manufacturer might not have adequate time to file an exemption petition 24 months prior to the model year. Second, there are situations in which a legitimately unexpected noncompliance occurs. An example is if a company providing a low volume manufacturer with its engines goes out of business, and the manufacturer is forced to make an unanticipated engine switch, resulting in lower than expected fuel economy. See 44 FR 21051 at 21055, April 9, 1979.

Timing of Exemptions

The agency has stated on several occasions that it interprets section 502 as providing the agency broad discretion to decide whether an amendment of an average fuel economy standard is warranted. (53 FR 15241, at 15243, April 28, 1988; 53 FR 39115, at 39116, October 5, 1988) In the absence of explicit guidance in title V on the exercise of its discretion, NHTSA has looked to the statutory scheme as a whole and the Administrative Procedure Act (APA) to determine whether it should or could amend a CAFE standard for a bygone year. The agency has concluded that for passenger automobiles produced by other than low volume manufacturers, such retroactive amendment is inconsistent with several aspects of the statutory scheme. (53 FR 15241, April 28, 1988)

A recent Supreme Court decision, *Bowen v. Georgetown University Hospital*, 109 S.Ct. 468 (1988), confirms that an agency's ability to adopt retroactive rules is very limited. In delivering the opinion of the Court, Justice Kennedy stated that "a statutory grant of legislative rulemaking authority will not, as a general matter, be understood to encompass the power to promulgate retroactive rules unless that power is conveyed by Congress in express terms." 109 S.Ct. at 471.

While this decision provides additional support for NHTSA's determination that it would be inappropriate (if not illegal) to retroactively amend the industry-wide CAFE standards, there are compelling reasons to distinguish low volume exemptions from the general principle

that retroactive rulemaking is prohibited.

As an initial matter, while it is true that section 502(c) of the Cost Savings Act provides that the Secretary may grant low volume exemptions "by rule, in fact, the agency's consideration of an application for such an exemption has more of the characteristics of a case-by-case adjudication. In this regard, although the Supreme Court concluded in *Georgetown University Hospital* that the Medicare Act, 42 U.S.C. 1395 *et seq.*, does not provide authorization to retroactively adopt the cost-limit rules at issue in that case, the Court recognized that "case-by case inquiry into the accuracy of reimbursement determinations for individual providers" was authorized. *Id.* at 472.

Moreover, although Justice Scalia's concurrence expresses an extremely limited view of an agency's authority to issue retroactive rules, his opinion recognizes that "implicit authorization of particular retroactive rulemaking can be found in existing legislation. 109 S.Ct. at 480. As an example, Justice Scalia referred to a situation in which an agency misses a statutory deadline. Here, the agency's failure to act upon timely applications for low volume exemptions from the industry-wide CAFE standards would appear to fall within the exception noted by Justice Scalia, particularly since the manufacturers were in no way responsible for the agency's inaction.

Similarly, this case seems to fit within the principle established by *Addison v. Holly Hill Fruit Products, Inc.*, 322 U.S. 607 (1944). As Justice Scalia recognized, *Addison* stands for the proposition that retroactive rulemaking is implicitly authorized where "the Administrator would, by his inaction, have totally eliminated the congressionally prescribed exemption. 109 S.Ct. at 479. If NHTSA could not issue exemptions from the industry-wide CAFE standards for low volume manufacturers after the commencement of a model year, the agency also would, by inaction, have "totally eliminated the congressionally prescribed" low volume manufacturer exemption for the manufacturers and years in question.

These manufacturers filed timely applications for low volume exemptions because they recognized that they could not meet the generally applicable CAFE standards. If the Act were read to preclude NHTSA from acting upon those timely applications at this time, those manufacturers would be unfairly penalized by agency inaction that was beyond their control. In order to avoid such a result, the Motor Vehicle

Information and Cost Savings Act must be construed to implicitly authorize the grant of retroactive low volume exemptions under these circumstances.

Agency Response to Petitions

Methodology Used to Project Maximum Feasible Average Fuel Economy Level for Petitioners

In this particular proceeding, NHTSA is not conducting rulemaking in advance of the model years for which the fuel economy standards are applicable. The vehicles which are the subject of this rulemaking have already been produced and tested by the Environmental Protection Agency (EPA). To determine the fuel economy benefits of the technology incorporated on these vehicles, NHTSA relied on the EPA test figures to establish the fuel economy level actually achieved by the petitioners. (45 FR 84108, December 22, 1980; 47 FR 20639, May 13, 1982) NHTSA then considered whether there were any technological or other improvements that would have been technologically feasible and economically practicable for the petitioners' cars, but were not incorporated on those cars.

NHTSA has interpreted "technological feasibility" as meaning that technology which was available for use in automobiles in a given model year and which would have improved the fuel economy for those automobiles. (42 FR 33533, June 30, 1977) The areas examined for technologically feasible improvements were weight reduction, aerodynamic improvements, engine improvements, drive line improvements, reduced rolling resistance, and mix shifts.

The agency considered two methods of weight reduction: downsizing and materials substitution. The goal of downsizing is to reduce the exterior dimensions and mass of the car without significantly reducing the interior passenger and luggage volume of the car. Materials substitution refers to the substitution of lighter materials, such as aluminum, plastics, and high strength low alloy steels, for currently used materials.

Mix shifts refers to shifting the percentage of vehicles sold in each of a manufacturer's model types for the purpose of increasing the manufacturer's average fuel economy. That is, the manufacturer can try to switch customers from its less fuel-efficient models to its more fuel-efficient models without reducing its total sales.

"Economic practicability" has been interpreted as meaning the financial capability of a manufacturer to improve

its average fuel economy by incorporating technologically feasible changes in its automobiles. (42 FR 33533 June 30, 1977)

Lamborghini

Background Information on Lamborghini

Lamborghini is a very small manufacturer of high performance sports cars. Lamborghini itself manufactures the engines, transmissions, and many other components used in its vehicles.

The company underwent a reorganization in bankruptcy during 1978 and 1979. It produced no more than 75 cars for worldwide sales in any model year between 1979 and 1982 and did not export any cars to the United States during MYs 1978 through 1982. Lamborghini sold 7 cars in the United States during MY 1983 and 9 during MY 1984. Lamborghini's total production in 1983 was 178 vehicles, and in 1984 it was 231. By letter dated December 15, 1980, Lamborghini filed a petition for exemption for MY 1983. On November 17 1981, this petition was amended to include MY 1984.

Methodology used to project maximum feasible average fuel economy level for Lamborghini

The cars sold by Lamborghini in MYs 1983 and 1984 were all one vehicle configuration, the Countach, with a fuel economy of 13.7 mpg. This figure was used as a baseline and any changes found technologically feasible and economically practicable were added thereto to arrive at a proposed determination of Lamborghini's maximum feasible average fuel economy for MYs 1983 and 1984. Throughout this analysis, NHTSA has considered only those improvements which would be compatible with the basic design concepts of Lamborghini automobiles. Lamborghini automobiles have traditionally been high performance sports cars with luxury features in the interior. Design changes which would significantly reduce the cars' performance or eliminate items traditionally offered on these types of vehicles, such as air conditioning, were not examined in consideration of the economic practicability criterion. Such changes to the basic design might well significantly reduce the demand for these cars, thereby reducing sales and causing a serious economic injury to the low volume manufacturer.

Weight reduction

In determining whether Lamborghini could have made weight reductions on its 1983 and 1984 cars, the agency

considered two options: downsizing and materials substitution. The Lamborghini is already a very short two seater automobile with relatively small exterior dimensions. Accordingly, NHTSA has tentatively concluded that downsizing would not have been economically practicable for 1983 and 1984 Lamborghini cars.

The other primary means of weight reduction is materials substitution. Taking this step would have required a change of suppliers and some vehicle design by Lamborghini. Again, considering the company's economic position at the time it manufactured its MY 1983 and 1984 cars, NHTSA has tentatively concluded that weight reduction by materials substitution would not have been economically practicable for Lamborghini in those model years.

Aerodynamic Improvements

The 1983 and 1984 Lamborghini automobiles had a relatively small frontal area, which gives less wind resistance and greater fuel economy than a larger frontal area. Generally speaking, Lamborghini and those vehicles it considers as its competition have already been designed with much attention to the aerodynamics of the vehicles. Consequently, for these Lamborghini cars to have shown fuel economy gains as a result of aerodynamic improvements, a complete redesign of the vehicles would have been necessary. After considering the financial position of the company at the time, NHTSA has tentatively concluded that fuel economy improvements as a result of improved aerodynamics would not have been economically practicable for the MY 1983 and 1984 Lamborghini cars.

Engine improvements

NHTSA also considered whether Lamborghini could have improved the fuel economy of its MY 1983 and 1984 cars by either reducing the engine displacement or by using an alternative engine. The engine used in those vehicles had a displacement of 4754 cubic centimeters, or roughly 290 cubic inches. The company stated that a reduction in the size of its engines would result in its vehicles not offering comparable performance to that of its competitors, thereby reducing sales of Lamborghini cars.

Additionally, Lamborghini designs and builds its own engines. Thus, a reduction in the size of the engine would have required extensive design and testing of a smaller engine at a time when the company was coming out of a major financial reorganization. For both

these reasons, NHTSA has tentatively concluded that a reduction of engine size would not have been economically practicable for MY 1983 and 1984 Lamborghini cars.

NHTSA believes the only opportunity for engine improvements would have been to increase the efficiency of the existing engine. In order to judge the feasibility of such action, NHTSA compared the fuel economy of the Lamborghini to cars of similar market intent. The fuel economy of the Lamborghini was compared to the Ferrari 308, the Lotus Turbo Esprit, and other similar vehicles. After "normalizing" for characteristics important to fuel efficiency, the Lamborghini's fuel economy was 3.9-5.0 mpg higher than the Ferrari and Lotus, and 0.4-1.2 mpg below that of high-volume models such as the Chevrolet Corvette, Porsche 928, and Alfa Romeo GTV6. Thus, the agency has tentatively concluded there is little opportunity to improve the fuel efficiency of the existing engine without sacrificing the performance necessary in Lamborghini's segment of the market.

Drive Line Improvements

The primary drive line improvements to enhance achievable fuel economy are transmission improvements and the use of a lower axle ratio. Lamborghini already uses a manual five-speed transmission, with the fifth gear functioning as an overdrive. This is the most fuel-efficient type of transmission currently available. Accordingly, NHTSA tentatively concludes that it would not have been technologically feasible for Lamborghini to have improved its 1983 and 1984 fuel economy by means of transmission improvements.

The 1983 and 1984 Lamborghini cars used a 4.09 axle ratio. While this is a relatively high axle ratio, the company stated in its petition that any significant reduction in the axle ratio would considerably worsen the cars, drivability, and hurt sales. In addition, acceleration performance necessary to compete in this segment of the market would suffer. Thus, NHTSA has tentatively concluded that it would not have been economically practicable to change the axle ratio.

Mix Shifts

Since Lamborghini sold only one vehicle configuration in the 1983 and 1984 model years, no fuel economy improvement could have been achieved by means of mix shifts.

Impacts of Other Federal Standards

Lamborghini claimed that its MY 1983 and 1984 models which complied with U.S. vehicle standards showed fuel economy values 5 to 10 percent lower than for those same models which did not comply with U.S. standards. However, the agency has already accounted for that fuel economy difference by using EPA's fuel economy figures for the U.S. standard vehicles as the baseline in its analysis. Those figures reflect whatever impact compliance with the U.S. vehicle standards has on the fuel economy of those vehicles. Therefore, for the purposes of the Lamborghini petition for the 1983 and 1984 model years, NHTSA has tentatively assumed that there is no unaccounted-for negative impact on fuel economy caused by applicable Federal standards.

The Need of the Nation to Conserve Energy

The agency recognizes there is a need to conserve energy to promote energy security and to improve balance of payments. However, as stated above, NHTSA has tentatively determined that it would not have been technologically feasible or economically practicable for Lamborghini to achieve an average fuel economy above a level of 13.7 mpg in the 1983 and 1984 model years. Denying an exemption to Lamborghini or setting higher alternative standards than the 13.7 mpg level in both affected model years would not, therefore, have resulted then and would not result now in any additional fuel consumption or in any effect on the need of the Nation to conserve energy.

Proposed Alternative Standards

This agency has tentatively concluded that it would not have been technologically feasible or economically practicable for Lamborghini to have improved the fuel economy of its 1983 and 1984 model year cars above an average of 13.7 mpg, that compliance with other Federal automobile standards did not adversely affect achievable fuel economy, and that the national effort to conserve energy would not then have been and would not now be affected by granting the requested exemptions and establishing alternative standards. Consequently, this agency tentatively concludes that the maximum feasible average fuel economy for Lamborghini was 13.7 mpg in the 1983 model year and 13.7 mpg in the 1984 model year. Therefore, NHTSA proposes to exempt Lamborghini from the generally applicable standards of 26.0 mpg and 27.0 mpg for MYs 1983 and 1984,

respectively, and to establish alternative standards of 13.7 mpg for Lamborghini for both years.

LondonCoach

Background Information About LondonCoach

On September 6, 1985, LondonCoach Co., Inc. petitioned the agency for alternative standards for MYs 1985-1987 for a taxicab known as the "London Taxi" and a limousine known as the "London Sterling. LondonCoach was organized in May 1984 for the purpose of manufacturing and selling vehicles for hire, namely taxicabs and limousines. The body and chassis of the vehicles are purchased from Carbodies Limited of Coventry, England. U.S. built Ford engines and transmissions are installed by LondonCoach. LondonCoach produced 75 vehicles for combined MYs 1985 and 1986, and estimated production to be 75 vehicles for MY 1987. Prior to 1985, LondonCoach did not manufacture or sell any vehicles in the United States. The fuel economy value for these vehicles is 21.0 mpg. Accordingly, LondonCoach qualifies as a "low volume manufacturer" and seeks an exemption from the CAFE standards for MYs 1985 through 1987.

Timeliness of LondonCoach's Petition

LondonCoach was unable to file 24 months before the start of MY 1985 because the corporation was not organized until May 1984. LondonCoach had no fuel economy data on which to base its petition until the conclusion of EPA testing. EPA testing of the vehicle was completed in August 1985. LondonCoach filed its petition for the 1985 through 1987 model years on September 6, 1985. Accordingly, pursuant to 49 CFR § 525.6(b), NHTSA has tentatively concluded that LondonCoach has shown good cause for late filing of its petition for the affected model years.

Methodology Used to Project Maximum Feasible Average Fuel Economy Level for LondonCoach

Based on an EPA test conducted on August 7, 1985, the combined city and highway fuel economy value for the LondonCoach vehicle was 21.04 mpg. The petitioner contemplated that the maximum feasible fuel economy level for model years 1985 through 1987 would be no less than 21.0 mpg. LondonCoach purchases the body and chassis from Carbodies Limited of Coventry England and installs U.S. Ford engines and transmissions. No immediate changes were contemplated by LondonCoach which would enhance the feasible fuel

economy for these vehicles. Under the Act, this agency considered whether any technical or other improvements would have been feasible for the 1985 through 1987 model year LondonCoach vehicles, regardless of whether the company had any actual plans to incorporate any improvements.

Throughout this analysis, NHTSA has considered only those improvements which would have been compatible with the basic design concepts and intended uses of LondonCoach vehicles. NHTSA assumes that LondonCoach will continue to produce the taxicab and limousine versions of the automobiles. The automobile's intended purpose is as a vehicle for hire to provide passengers with an exceptionally large passenger compartment allowing easy accessibility to the vehicle.

LondonCoach expected its taxis to fill a void left by the 1982 termination of production by the Checker Cab Co. by providing the public with vehicles designed primarily for taxicab purposes. The petitioner also anticipated that the vehicles will be used by handicapped and elderly persons as an alternative mode of transportation that is more accommodating than conventional taxi vehicles. Hence, design changes which would have made the cars unsuitable for multiple passengers or removed features that are necessary to preserve the unique characteristics of the LondonCoach vehicles were not examined.

Further, these vehicles are designed to be operated up to 60,000 miles per year, have an average service life of 10 years, and to be extremely maneuverable on city streets. Therefore, these vehicles must remain highly durable. Any changes that would alter the basic uses of the vehicle, or which could significantly reduce the demand for these automobiles were not considered because of the economic hardship that would result to the low volume manufacturer.

Baseline Fuel Economy

The MY 1985 LondonCoach vehicles were measured by the EPA as achieving a CAFE of 21.0 mpg. No change to the vehicle's specifications were planned by the manufacturer for MY 1986 or MY 1987. Therefore, the 1985 fuel economy rating is valid for the MY 1986 and 1987 vehicles.

LondonCoach offers a single body style vehicle with two variations for the taxicab and the limousine. The two versions have an equivalent test weight of 3875 pounds and each achieves 21.0 mpg. Therefore, both the London Taxi and the London Sterling can be

considered to be identical for fuel economy purposes.

Accordingly, the fuel economy rating of 21.0 mpg was used as the baseline. The agency has considered whether any possible changes would be technologically feasible and economically practicable in order to determine LondonCoach's maximum feasible average fuel economy for MYs 1985 through 1987.

Weight Reduction

A reduction in the size of the vehicle would not be feasible since LondonCoach purchases the body and chassis structure of the automobile as an assembly from Carbodies. This arrangement allows little opportunity for significant weight reductions in the body and chassis of the vehicle. Further, LondonCoach intends to offer the public the use of distinctive London taxis on streets in the United States. A smaller version of the London taxi would alter the intended market and demand for the vehicles.

LondonCoach intended to produce a vehicle specifically designed with a large passenger compartment allowing easy entrance and exit from the vehicle, as well as providing a large luggage compartment. LondonCoach vehicles have a combined EPA passenger and cargo volume that is greater than any U.S. passenger automobile except Ford and General Motors large station wagons. The passenger volume alone is greater than any automobile offered for sale in the U.S.

The Checker Cab, which was also designed for taxicab service, had a passenger volume of 100 cubic feet and CAFE of 19.1 mpg in its final year of production, model year 1981. LondonCoach's passenger volume is 144 cubic feet with its average fuel economy of 21.0 mpg. The agency determined that the fuel consumption per cubic foot of passenger volume for the LondonCoach automobiles is between 16 and 43% more efficient when compared with other vehicles used for taxicab service. These other taxi vehicles achieve either equivalent or only slightly better fuel economies than the LondonCoach vehicle. Therefore, LondonCoach vehicles achieve fuel economy comparable to that of other vehicles that are typically used for taxicab services.

The other primary means to achieve weight reduction is by materials substitution. The petitioner is not in a position to change the materials used in constructing the body and chassis of the vehicle because it purchases the assembled body and chassis from Carbodies. It would not be economically practicable for Carbodies to retool its

facilities to produce a vehicle using lighter materials because LondonCoach buys such a small number of vehicles from Carbodies. The exact percentage of Carbodies' taxi body and chassis production that was purchased by LondonCoach is not known.

The LondonCoach automobiles are constructed from steel. Although the use of aluminum could produce significantly lighter automobiles, this could reduce the durability of the cars. The need to provide a durable, long-life structure for taxi service militates against weight reduction in this manner. The materials currently used by Carbodies have a proven record of durability, safety, and structural integrity with its 29 year history in the United Kingdom.

In an effort to comply with the average fuel economy standards, the petitioner has selected a Ford Motor Co. 2.3 liter engine which is approximately 350 pounds lighter and considerably more efficient than the engine used in the vehicle manufactured by Carbodies and sold in the United Kingdom. The use of the Ford engine and automatic transmission yields a weight reduction of approximately 8% of the total weight of the vehicle. The petitioner stated that the engine and transmission that it selected are the lightest available that comply with EPA emission standards. The agency has determined that this is among the smallest engines that could be used in such a heavy automobile.

Given the limited resources of the petitioner as a low volume manufacturer and the substantial expense and engineering effort required to redesign in order to downsize or substitute materials while remaining in compliance with other Federal Motor Vehicle Safety Standards (FMVSS), NHTSA has tentatively concluded that further weight reduction would not have been economically practicable for LondonCoach MY 1985-1987 vehicles.

Aerodynamic Improvements

Since LondonCoach has an arrangement with Carbodies to purchase the body and chassis, it would not be feasible for LondonCoach to make any immediate aerodynamic design improvements to increase fuel economy. In addition, LondonCoach intended to market the distinctive London taxis for use in the United States. These automobiles are recognized in the United States as being the large London taxis. The large frontal area, boxy proportions and unique shape of the vehicles give rise to the recognition and the market for these cars. While these features may not be aerodynamically efficient, they are necessary to meet the

intended demand for this specific vehicle.

Alterations in the shape of the vehicle for aerodynamic improvements could result in a decrease of the passenger or luggage areas, or alter recognition of the automobile as a London taxi. These changes would significantly reduce LondonCoach's intended market and cause economic harm to the low volume manufacturer. Significant improvements in aerodynamics would require major alterations requiring substantial development, testing and leadtime in addition to the expense. Additionally, these vehicles would not be operated at highway speeds as often as the average passenger car, making aerodynamic improvements unnecessary as a practical matter. Due to these factors, NHTSA has tentatively concluded that it would not have been economically practicable for LondonCoach to implement aerodynamic improvements to increase the fuel economy of its automobiles for MYs 1985 through 1987.

Engine Improvements

This agency has examined the question of whether LondonCoach could have improved the fuel economy of its 1985 through 1987 automobiles by using a different engine than the one currently used. The petitioner specifically chose to substitute the Ford Motor Co. 2.3 liter OHC, 4 cylinder in-line gasoline engine for the one that is installed in the vehicle manufactured and sold in the United Kingdom. The Ford engine is 350 pounds lighter and more efficient than the one used in the United Kingdom. It has been used in Ford vehicles, especially in the Ford LTD and Mustang, which have complied with EPA standards for the past 10 years. The engine selected has among the lowest horsepower offered by a manufacturer of vehicles intended for use as taxis or limousines.

Because of the low volume of production, it is impractical for LondonCoach to consider producing its own engine. LondonCoach considered using the diesel engine Carbodies uses in the UK version of the automobile, but this engine does not meet U.S. emissions standards. The small engine compartment of the vehicle limits the selection of available U.S. certified diesel engines, and the manufacturer decided that there were no significant fuel economy advantages to justify offering a diesel, considering the relatively low cost of gasoline in the United States. Furthermore, all diesel passenger car engines of the appropriate size that were certified in MY 1985 were imported, potentially creating another

problem for a small company in development and production. Although the fuel economy could increase by using a diesel engine, the agency has determined that it would not have been economically feasible for LondonCoach to choose such engines due to the overall higher cost of diesel engines. LondonCoach does anticipate adopting the engine design improvements that Ford incorporates in its own cars which would result in improved fuel economy in future years.

A larger engine could improve fuel economy if it operated at more nearly optimum efficiencies on the EPA test cycle, but the extra weight would offset any such improvement. Further, the vehicle is intended to be used at low speeds in urban areas. Therefore, a larger, more powerful engine would not enhance fuel economy at these low speeds. After considering these factors, NHTSA has tentatively determined that it would not have been technologically feasible nor economically practicable for LondonCoach to improve its fuel economy by using an alternative engine.

Drive Line Improvements

The primary drive line improvements to enhance achievable fuel economy are transmission improvements and the use of a lower rear axle ratio. The transmission chosen is a Ford C-3 3-speed automatic transmission that is compatible with the Ford engine. Although an additional transmission gear or a lock up clutch on the torque converter could improve fuel economy, it would have been economically impractical for LondonCoach to match the engine with a different transmission. This would have required extensive redesign beyond the economic capabilities of a low volume manufacturer. Further, there would have been little fuel economy improvement in actual service from these changes for vehicles that are intended to be driven primarily at low speeds in urban traffic.

The overall drive ratio of LondonCoach vehicles, N/V (engine rpm/vehicle speed in top gear) is 58.8 on air-conditioned models. Although this ratio is high, a lower value would have been impractical and would have penalized performance since the engine is so small in relation to the weight of the automobiles. NHTSA has determined that such changes to the overall drive ratio or to the transmission would have been economically impracticable for LondonCoach. Based on this analysis, the agency has tentatively determined that it would not have been technologically feasible or economically practicable for LondonCoach to improve its fuel

economy by making drive line improvements.

Mix Shifts

The two versions of the LondonCoach vehicles are with different trim appointments. One is known as the London Taxi and the other is the London Sterling. Both have the same fuel efficiency of 21.0 mpg when equipped with air conditioning. The only configurations offered by LondonCoach with different fuel economies are those same vehicles without air conditioning. This means that LondonCoach offers four possible options: the London Taxi with air conditioning, the London Taxi without air conditioning, the London Sterling with air conditioning, and the London Sterling without air conditioning. The models without air conditioning attain a fuel economy of 22.4 mpg. Because there are basically only two configurations, i.e., a model with air conditioning and a model without air conditioning, there is little opportunity to affect fuel economy through mix shifts. Further, since the intended use of the vehicles is to carry fare-paying passengers, it is unlikely that there would have been any significant demand for the model without air conditioning. Therefore, the agency believes that it would not have been economically practicable for LondonCoach to have made any significant increase in fuel economy through mix shifts.

Impacts of Other Federal Standards

LondonCoach did not claim any negative impacts on its average fuel economy as a result of applicable Federal safety damageability, emission, or noise standards. In the absence of a specific showing of fuel economy penalty arising from those standards, NHTSA concludes that whatever fuel economy was lost as a result of compliance with Federal standards was built into the EPA's fuel economy test results. With respect to the LondonCoach petition, the NHTSA has tentatively assumed that there is no unaccounted-for negative impact on fuel economy caused by applicable Federal standards.

The Need of the Nation to Conserve Energy

The agency recognizes there is a need to conserve energy to promote energy security and to improve balance of payments. However, as stated above, NHTSA has tentatively determined that it would not have been technologically feasible or economically practicable for LondonCoach to achieve an average fuel economy above the level of 21.0 mpg in

the 1985 through 1987 model years. Since LondonCoach was producing such a small number of vehicles and could not achieve higher average fuel economy than these levels in the 1985 through 1987 model years, granting it an exemption and setting alternative standards at those levels for those model years would not then have resulted and would not now result in any additional fuel consumption or have any effect on the need of the Nation to conserve energy.

Proposed Alternative Standards

This agency has tentatively concluded that it would not have been technologically feasible or economically practicable for LondonCoach to achieve a higher average fuel economy than 21.0 mpg in MYs 1985 through 1987 that compliance with other Federal automobile standards did not adversely affect achievable fuel economy, and that the national effort to conserve energy would not then have been and would not now be affected by granting the requested exemption and establishing an alternative standard. Consequently, this notice proposes to conclude that the maximum feasible average fuel economy for LondonCoach in MYs 1985 through 1987 is 21.0 mpg. Therefore, the agency proposes to exempt LondonCoach from the generally applicable standard of 27.5 mpg for MY 1985, and 26.0 mpg for MYs 1986 through 1987.

Maserati

Background Information About Maserati

Maserati's automobiles have traditionally been expensive high performance vehicles. According to its petition, Maserati's reputation is based on a combination of performance and luxury. The company experienced an extended period of financial instability in the late 1970's and early 1980's. In 1974, Citroen, then owner of Maserati, put Maserati into voluntary bankruptcy. This action resulted in Maserati totally ceasing all production for more than a year during 1975 and 1976. The company produced very few cars through MY 1981, and the models it did produce were simply continuations of its older models. However, a loan from the Italian government permitted Maserati to develop and introduce a new model, the Biturbo, in Europe in 1982. This new model helped return Maserati to profitability. In fact, Maserati had projected sales of 4,100 vehicles in the United States in MY 1985, up from sales of 52 vehicles in MY 1983. According to *Ward's Yearbook*, world wide

production of all Maserati models was 6180 in 1984 and 5668 in 1985.

Maserati produced two models during MYs 1982 through 1985. One of these models, the Quattroporte, was the first "new" vehicle produced by Maserati after the company was reorganized in bankruptcy. However, this vehicle was designed on very short notice, using as many components in Maserati's inventory as possible. The company's management determined that they needed to generate revenue quickly to reverse the significant operating losses Maserati had accumulated. The Quattroporte, according to Maserati's petition, "cannot play a leading role in the company's future."

The other model is the Biturbo, which is primarily responsible for the company's improved financial status.

The Biturbo was introduced in Europe in 1982 and in the United States for MY 1984. It was a completely new design by Maserati that was not required to use components in the company's inventory. The Biturbo is much lighter and more aerodynamic than the Quattroporte. Further, the Biturbo is powered by a 152 cubic inch displacement (CID) V-6 engine with two turbochargers and 3 valves per cylinder, while the Quattroporte is powered by a 301 CID V-8 engine with only 2 valves per cylinder.

Methodology Used to Determine Maserati's Maximum Feasible Average Fuel Economy for the 1984 and 1985 Model Years

Throughout this analysis, NHTSA has considered only those improvements

which would have been compatible with the basic design concepts of Maserati automobiles. Design changes that would have made the cars something other than high performance luxury vehicles or remove items traditionally offered on expensive, high-performance vehicles were not considered. Such changes to the basic design or performance might have significantly reduced the demand for these automobiles, thereby reducing sales and causing additional economic pressure on Maserati.

Baseline Fuel Economy

Table I shows the projected composition of Maserati's fleet and its EPA measured fuel economy for MYs 1984 and 1985:

TABLE I—COMPOSITION OF MASERATI'S U.S. FLEET

Model year	Model	Transmission type	Sales	Combined fuel economy (mpg)	CAFE (mpg)
1984	Quattroporte	A3L	182	10.0	17.3
	Biturbo	M5	1,884	18.7	17.9
1985 Biturbo	Quattroporte	A3L	143	10.0	
	M5	505	18.7		
	Biturbo (no-light-off catalyst)	M5	675	17.7	
	Biturbo	A3	678	15.7	16.6

Unadjusted CAFE for actual sales.
Actual EPA adjusted figure.

Maserati expected its sales to more than double between MYs 1984 and 1985. The sales in both years are substantial when compared with MY 1983, when Maserati sold only 52 cars in the United States. The configurations of the Biturbo model increased from one for MY 1984 to three in MY 1985. The one Biturbo configuration available in 1984 was carried forward unchanged to 1985. This was planned as the Biturbo configuration that would be certified as complying with the California emissions standards in the 1985 model year. The "no-light-off catalyst" configuration of the Biturbo eliminated the catalysts near the exhaust manifold. Maserati did this to reduce its costs for the Biturbo, by saving the cost of the additional catalyst. Maserati's original intention was to offer this less costly, single catalyst version of the Biturbo as the 49-State version, and continue to offer the Biturbo with the additional "light-off" catalyst as the California version. However, when Maserati finished its compliance testing for the no-light-off

catalyst version of the Biturbo, it learned that this version also complied with the California emissions standards. Thus, both versions of the Biturbo were offered as 50-State models in the 1985 model year. Finally, Maserati introduced a configuration of the Biturbo with a 3-speed automatic transmission for MY 1985. This change allowed Biturbo purchasers to order the car with an automatic transmission.

For the purposes of this proposed determination of Maserati's maximum feasible average fuel economy, 17.9 mpg was used as the baseline for MY 1984 and 16.8 mpg was used as the baseline for MY 1985. Any changes found technologically feasible and economically practicable were added to these levels to arrive at these proposed determinations of Maserati's maximum feasible average fuel economy for MYs 1984 and 1985.

Weight Reduction

In analyzing this area, there are significant differences between the two

Maserati models. The older Quattroporte has a curb weight of 4,740 pounds. This is heavy even when compared with other high performance vehicles. However, the newer Biturbo model has a curb weight of 2,600 pounds, which is at the lower end of the weight range for high performance vehicles. For example, the Biturbo weighed less during MYs 1984 and 1985 than the Chevrolet Corvette and the Nissan 300 ZX.

The agency has examined two means by which Maserati could have reduced the weight of its MY 1984/85 vehicles. The first is downsizing, which requires a complete redesign of a vehicle. In the case of the Quattroporte, Maserati stated in its petition that this model could not play a leading role in the company's future. Instead, the company chose to concentrate its financial and engineering efforts to improving fuel economy on the newer Biturbo model. Recognizing the limited capital and engineering resources available to Maserati, NHTSA has tentatively

determined that it would not have been economically practicable for Maserati to downsize its Quattroporte model in the affected model years.

With respect to the Biturbo, Maserati introduced that model in the United States in MY 1984. Its fuel economy was 77 percent higher than the Quattroporte, and it was a lightweight high performance sedan. Since Maserati had just made the necessary investments to introduce this model in MY 1984, NHTSA tentatively determines that it would have been neither economically practicable nor technologically feasible for Maserati to have downsized the Biturbo for MYs 1984 and 1985.

The other means examined for achieving weight reduction was materials substitution. In the case of the Quattroporte, Maserati did not attempt to use materials substitution to reduce its weight. While weight reduction for this model would have been technologically feasible had Maserati made use of materials substitution, such a capital investment appears to have been beyond the financial capabilities of Maserati for MYs 1984 and 1985. This is particularly true in view of the company's large investment in its new Biturbo model. Therefore, NHTSA has tentatively determined that it would not have been economically practicable for Maserati to have used materials substitution to reduce the weight of its Quattroporte during MYs 1984 and 1985.

Maserati seems to have been very conscious of vehicle weight when designing the Biturbo. As noted above, the Biturbo has a curb weight of 2600 pounds, which is lower than the curb weight of high-performance vehicles produced by Nissan and General Motors. NHTSA has tentatively concluded that it would not have been technologically feasible for Maserati to have further reduced the weight of its Biturbo by means of materials substitution. Accordingly, NHTSA tentatively determines that it would not have been technologically feasible or economically practicable for Maserati to have improved the average fuel economy of its 1984/85 vehicles by means of weight reduction.

Aerodynamic Improvements

The Quattroporte has a relatively large frontal area. Aerodynamic improvements would have probably increased the fuel economy of this model during the affected model years. However, aerodynamic improvements to this model, whether achieved by redesigning the body or using add-on devices, would have required considerable development and testing. Since Maserati was devoting its limited

resources to developing and introducing its Biturbo model, NHTSA has tentatively determined that it would not have been economically practicable for Maserati to have improved the fuel economy of the Quattroporte by means of aerodynamic improvements.

The Biturbo model has a frontal area more than 10 percent less than the Quattroporte. Since it was a new model for MY 1984, further reductions of the frontal area or aerodynamic improvements would not be practical until a major redesign is done for a future model year. The Biturbo was designed under severe financial constraints, precluding the extensive development required to optimize aerodynamics. NHTSA tentatively determines that it would not have been technologically feasible or economically practicable for Maserati to have improved the fuel economy of its Biturbo by means of aerodynamic improvements.

Engine Improvements

The Quattroporte was equipped with a 301 CID V-8 engine during the affected model years. As noted above, this engine was carried over from past model years. Maserati achieved some fuel economy gains from the engine by using a leaner carburetion mix. However, the most significant fuel economy gains would have been achieved by reducing the size of the engine, or redesigning it to accommodate more advanced technology. Any such course of action would have required Maserati to have diverted its resources from designing and introducing the Biturbo model. NHTSA has tentatively determined that such a diversion of resources to improve the engine of the Quattroporte would not have been economically practicable for Maserati for the affected model years.

The Biturbo was equipped with a 152 CID V-6 engine during the affected model years. To increase the thermal efficiency and maintain a high level of performance, the engine includes two turbochargers. A third valve was also added to each cylinder to promote complete combustion of the fuel mixture. All Maserati models meet 50-state emissions standards. The 1985 Biturbo "no-light-off catalyst" model was intended to be a 49-state certification model. It turned out, however, that despite the elimination of the catalysts near the exhaust manifold, this model also met California emissions standards. If Maserati had included the "light off catalyst" on all 1985 models, its CAFE would be somewhat higher. For the reasons stated below in the discussion

of drive line improvements, this was not an economically practicable alternative. NHTSA has therefore tentatively determined that it would not have been technologically feasible and economically practicable to have improved the fuel economy of the Biturbo by means of engine improvements.

Drive Line Improvements

The primary drive line improvements to enhance achievable fuel economy are transmission improvements and the use of a lower rear axle ratio. The Quattroporte used a 3-speed automatic transmission with a lockup torque converter made by Chrysler in both affected model years. A 5-speed manual transmission would probably increase fuel economy for the Quattroporte. However, the vehicle is marketed as a high-performance luxury car. These types of cars are traditionally equipped with automatic transmissions. If the Quattroporte were offered only with a manual transmission, it could lose potential customers who would demand an automatic transmission. Given this risk and Maserati's need to generate revenue in the wake of its then recent financial difficulties, NHTSA has tentatively determined that it would not have been economically practicable for Maserati to have used manual transmissions on its Quattroporte during the affected model years.

A 4-speed automatic transmission with a lockup torque converter would have also probably improved the fuel economy achieved by the Quattroporte. However, it is not clear that any available 4-speed automatic transmission with a lockup torque converter would have had adequate capacity for the horsepower rating (288) of the Maserati 301 CID engine. General Motors offers a 4-speed automatic transmission with a lockup torque converter on the Corvette, but that engine has a horsepower rating of 230. Even if it were technologically feasible to equip the Quattroporte engine with a 4-speed automatic transmission, it would have required substantial development and certification costs for Maserati. These costs would have diverted Maserati's resources from the development of its Biturbo. After considering this, NHTSA has tentatively determined that it would not have been technologically feasible and economically practicable for Maserati to have used a 4-speed automatic transmission with a lockup torque converter on the Quattroporte for the affected model years.

The majority of the Biturbo models are sold with a manual five-speed transmission with overdrive, which is a very efficient transmission. For 1984, the Biturbo was offered only with a 5-speed manual transmission, so NHTSA tentatively determines that no transmission improvements were technologically feasible for the Biturbo during the 1984 model year. For 1985, the Biturbo was offered with a 5-speed manual transmission and a 3-speed automatic transmission without a lockup torque converter. A small part of the MY 1985 production used a Zahnradfabrik Friedrichshafen (ZF) three-speed automatic transmission. Maserati investigated other available automatic transmissions, but none existed with adequate torque capacity for the Biturbo engine and that would fit the packaging constraints of this small car. A major redesign of the body structure to accommodate a more efficient automatic transmission would have been expensive and would have delayed the introduction of the automatic transmission in the U.S. market, where it was an important option.

Until recently, Maserati was operating at a very low level of production. The second catalyst was removed from some of the 1985 Biturbos, with the intention of reducing production costs for the 49 State vehicles and improving performance without reducing demand for those vehicles. This was an action taken to reduce production costs and improve its sales potential as a high performance car. While this action did lower the fuel economy of these vehicles, the concept of economic practicability is broad enough to recognize the severe recent financial crises experienced by Maserati when determining the maximum feasible average fuel economy for that company. After considering Maserati's critical need to earn profits in light of its recent financial difficulties, NHTSA has tentatively determined that it would not have been economically practicable for Maserati to have increased its 1985 fuel economy by installing two catalysts on all manual transmission versions of its Biturbo model.

The overall drive ratios on both Maserati models during the affected model years were fairly high, but very similar to those of other high performance vehicles, both domestic and imported. While fuel economy could have been increased by reducing these drive ratios, the performance of the vehicles would have been reduced as a result of these reductions. Such reductions would very likely have reduced the demand for Maserati

vehicles. NHTSA has previously stated that it does not consider such changes to be economically practicable, especially given the then recent difficulties of Maserati. Accordingly, NHTSA has tentatively determined that it would not have been technologically feasible and economically practicable for Maserati to have improved its 1984 and 1985 fuel economy by means of drive line improvements.

Mix Shifts

In Maserati's case, this would primarily involve shifting purchasers from its Quattroporte to its Biturbo model. More than 90 percent of Maserati's sales in MY 1984 were Biturbos, and more than 92 percent of its sales in MY 1985 were Biturbos. Further mix shifts to reduce the sales of Quattroportes were not feasible because of the already dominant position of the Biturbo. Therefore, NHTSA has tentatively determined that it would not have been technologically feasible and economically practicable for Maserati to have improved its 1984 and 1985 fuel economy through mix shifts.

Impacts of Other Federal Standards

Compliance with emissions standards has made fuel economy improvements difficult for Maserati. As a low volume, financially-troubled manufacturer, Maserati has been slow to develop and introduce technology that would permit better optimization of emissions and fuel economy. However, Maserati did not claim any negative impacts on its average fuel economy as a result of applicable Federal safety, damageability, emission, or noise standards. In the absence of a specific showing of fuel economy penalty arising from those standards, NHTSA will assume that whatever fuel economy was lost as a result of compliance with Federal standards was built into the EPA's fuel economy test results. With respect to the Maserati petition, NHTSA has tentatively assumed that there is no unaccounted-for negative impact on fuel economy caused by applicable Federal standards.

The Need of the Nation to Conserve Energy

The agency recognizes there is a need to conserve energy to promote energy security and to improve balance of payments. However, as stated above, NHTSA has tentatively determined that it was not technologically feasible or economically practicable for Maserati to attain an average fuel economy above the level of 17.9 mpg for MY 1984 and 16.8 mpg for MY 1985. Since Maserati was producing such a small number of

vehicles and could not achieve higher average fuel economy than these levels in the 1984 and 1985 model years, granting Maserati an exemption and setting alternative standards at those levels for those model years would not then have resulted and would not now result in any additional fuel consumption or in any effect on the need of the Nation to conserve energy.

Proposed Alternative Standards

This agency has tentatively concluded that it would not have been technologically feasible or economically practicable for Maserati to achieve a higher average fuel economy than 17.9 mpg for MY 1984 and 16.8 mpg for MY 1985, that compliance with other Federal automobile standards did not adversely affect achievable fuel economy, and that the national effort to conserve energy would not then have been and would not now be affected by granting the requested exemption and establishing an alternative standard. Consequently, this notice proposes to conclude that the maximum feasible average fuel economy for Maserati is 17.9 mpg for MY 1984 and 16.8 mpg for MY 1985. Therefore, the agency proposes to exempt Maserati from the generally applicable standard of 27.0 mg for MY 1984, and 27.5 mpg for MY 1985.

NHTSA has analyzed this proposal and determined that neither Executive Order 12291 nor the Department of Transportation regulatory policies and procedures apply, because the proposal would not establish a "rule," which term is defined as "an agency statement of general applicability and future effect. The exemptions are not generally applicable, since they apply only to the manufacturers discussed in this notice. If the Executive Order and the Departmental policies and procedures were applicable, the agency would have determined that this proposed action is neither major nor significant. The principal impact of this proposal is that the exempted companies would not be required to pay civil penalties for achieving what the agency has tentatively determined to be their maximum feasible average fuel economy for the model years in question. Since this proposal sets an alternative standard at the level determined to be each company's maximum feasible level, no fuel would have been or would now be saved by establishing a higher alternative standard. The impacts for the public at large will be minimal.

In accordance with 5 U.S.C. 601 *et seq.*, the Regulatory Flexibility Act, I certify that this proposed rule would not, if promulgated, have a "significant

economic impact on a substantial number of small entities. The rationale for this certification is that this proposal applies specifically to three low volume manufacturers and not to industry in general.

The agency has also considered the environmental implications of this proposal in accordance with the National Environmental Policy Act. As an initial matter, this is not a "major Federal action. Moreover, this proposal, if adopted, would not significantly affect the human environment. Regardless of the fuel economy of the exempted vehicles, they were required to meet the emissions standards which measure the amount of emissions per mile traveled. Thus, the quality of the air is not affected by the proposed exemptions and alternative standards. Further, since the exempted passenger automobiles cannot achieve better fuel economy than is proposed herein, granting these proposed exemptions would not affect the amount of fuel available.

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

Interested persons are invited to submit comments on the proposal. It is requested but not required that 10 copies be submitted. If applicable, it is requested that two copies of films, tapes, and other similar materials be provided.

All comments must not exceed 15 pages in length. (49 CFR 553.21). Necessary attachments may be appended to these submissions without regard to the 15-page limit. This limitation is intended to encourage commenters to detail their primary arguments in a concise fashion.

If a commenter wishes to submit certain information under a claim of confidentiality, three copies of the complete submission, including purportedly confidential business information, should be submitted to the Chief Counsel, NHTSA, at the street address given above, and seven copies from which the purportedly confidential information has been deleted should be submitted to the Docket Section. A request for confidentiality should be accompanied by a cover letter setting forth the information specified in the agency's confidential business information regulation. 49 CFR Part 512.

All comments received before the close of business on the comment closing date indicated above for the

proposal will be considered, and will be available for examination in the docket at the above address both before and after that date. To the extent possible, comments filed after the closing date will also be considered. Comments received too late for consideration in regard to the final rule will be considered as suggestions for further rulemaking action. Comments on the proposal will be available for inspection in the docket. The NHTSA will continue to file relevant information as it becomes available in the docket after the closing date, and it is recommended that interested persons continue to examine the docket for new material.

Those persons desiring to be notified upon receipt of their comments in the rules docket should enclose a self-addressed, stamped postcard in the envelope with their comments. Upon receiving the comments, the docket supervisor will return the postcard by mail.

List of Subjects in 49 CFR Part 531

Energy conservation, gasoline, imports, motor vehicles.

In consideration of the foregoing, it is proposed that 49 CFR part 531 be amended to read as follows:

PART 531—[AMENDED]

1. The authority citation for part 531 would continue to read as follows:

Authority: 15 U.S.C. 2002, delegation of authority at 49 CFR 1.50.

2. Sections 531.5 would be amended by revising paragraphs (b)(7) and adding paragraphs (b)(8) and (b)(9) to read as follows:

§ 531.5 Fuel economy standards.

(b)
(7) *Maserati*.

Model year	Average fuel economy standard (miles per gallon)
1984	17.9
1985	16.8

(8) *Lamborghini*.

Model year	Average fuel economy standard (miles per gallon)
1983	13.7
1984	13.7

(9) *LondonCoach*.

Model year	Average fuel economy standard (miles per gallon)
1985	21.0
1986	21.0
1987	21.0

Issued on September 26, 1989.

Barry Felrice,
Associate Administrator for Rulemaking.
[FR Doc. 89-23089 Filed 10-2-89; 8:45am]
BILLING CODE 4910-59-M

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 222

RIN 0648-AB47

[Docket No. 80106-9148]

Endangered Fish or Wildlife; Permits for the Incidental Taking of Endangered Marine Species

AGENCY: National Marine Fisheries Service (NOAA Fisheries), NOAA, Commerce.

ACTION: Proposed rule.

SUMMARY: Revisions are proposed to 50 CFR part 222 to establish procedures for issuing permits under section 10 of the Endangered Species Act (ESA) for the incidental taking of endangered marine species that are under the jurisdiction of the Secretary of Commerce. These permits are authorized by the 1982 amendments to the ESA. The proposed regulations would allow permits to be issued for a take of endangered marine species incidentally to an otherwise lawful activity, provided certain conditions are met.

DATE: Comments on this proposed rule must be received by December 4, 1989.

ADDRESS: Send comments to Dr. Nancy Foster, Director, Office of Protected Resources, National Marine Fisheries Service, 1335 East West Highway, Silver Spring, MD 20910.

FOR FURTHER INFORMATION CONTACT: Patricia Montano or Margaret Lorenz, Office of Protected Resources, 301-427-2322.

SUPPLEMENTARY INFORMATION:

Background

The 1982 amendments to the ESA revised section 10(a) to allow the Secretaries of Commerce and the Interior greater flexibility in regulating the incidental taking of endangered

species. Prior to the amendments, taking could be allowed incidentally to most Federal activities and federally regulated or funded activities under section 7 of the ESA, but could not be allowed incidentally to strictly private activities. The 1982 amendments authorize the Secretaries to issue permits, under limited circumstances, allowing a taking of endangered species incidentally to an otherwise lawful activity.

These regulations propose procedures for issuing permits for the incidental take of endangered species under the jurisdiction of NOAA Fisheries, Department of Commerce. These species are identified in 50 CFR 222.23(a), and are referred to in this document as endangered marine species. All other endangered species are under the jurisdiction of the U.S. Fish and Wildlife Service, Department of the Interior, and are subject to the incidental taking provisions at 50 CFR 17.22 and 17.32.

Section 10(a)(1)(B) of the ESA authorizes NOAA Fisheries to permit a taking of an endangered marine species otherwise prohibited by section 9(a)(1)(B) of the ESA if the taking is incidentally to, and not the purpose of, an otherwise legal activity. Section 9(a)(1)(B) prohibits the taking of any endangered species within the United States or its territorial sea. Thus, ESA section 10 incidental take permits can be issued only for activities which may incidentally take endangered marine species within the United States or the U.S. territorial sea. These permits will not be issued for activities, such as commercial fishing, that occur outside the territorial sea.

Section 10(a)(2)(A) requires each applicant for an incidental take permit to submit a conservation plan that specifies (i) the impact which will likely result from such taking; (ii) what steps will be taken to minimize and mitigate such impacts, and the funding that will be available to implement such steps; (iii) what alternative actions to such taking have been considered and the reasons why such alternatives are not being used; and (iv) such other measures that NOAA Fisheries may require as being necessary or appropriate for purposes of the plan.

The proposed regulations would establish two categories of permits: an ESA section 10 individual incidental take permit and an ESA section 10 general incidental take permit. The individual permit would cover the activities of a single applicant, such as a corporation, that resulted in the incidental take of an endangered marine species. A general permit would cover the activities of members of a group or

organization, such as a fishing association, who wish to conduct activities in a specific geographical area that have similar impacts on endangered marine species. After a general permit is issued, members of the group, as well as unaffiliated individuals such as fishermen who were not members, could obtain coverage under its terms by applying for and receiving a certificate of inclusion. An applicant for a certificate of inclusion must agree to comply with the terms and conditions of the general permit and the conservation plan.

As required by section 10(a)(2)(B), NOAA Fisheries will issue the permit if it finds, after notice in the *Federal Register* and opportunity for comments, that (i) the taking will be incidental; (ii) the applicant will, to the maximum extent practicable, minimize and mitigate the impacts of the taking; (iii) the applicant will ensure that adequate funding for the plan will be provided; (iv) the taking will not appreciably reduce the likelihood of the survival and recovery of the species in the wild; and (v) any additional measures required by NOAA Fisheries as being necessary or appropriate for the purposes of the conservation plan will be met. NOAA Fisheries will prescribe terms and conditions to ensure that appropriate conservation measures are taken, including reporting requirements, and may revoke the permit if the terms and conditions of the permit are not being complied with.

Relation to Section 7 of the ESA

The incidental take provisions of section 10 parallel certain provisions of section 7 of the ESA. Section 7(a)(2) requires all Federal agencies, in consultation with NOAA Fisheries, to ensure that any action authorized, funded, or carried out by the agency is not likely to jeopardize the continued existence of any endangered or threatened marine species or result in the destruction or adverse modification of the critical habitat of that species. Under section 7(b)(4), when an agency action that may involve incidental taking is found to be consistent with section 7(a)(2), NOAA Fisheries issues an incidental take statement authorizing an incidental take and specifying the terms and conditions necessary to monitor the taking and minimize the impact of such taking. Thus, Federal agencies and private entities regulated or funded by the Federal agency may carry out activities resulting in the incidental take of endangered species consistent with the incidental take statement without violating the ESA and without a section 10 permit.

Congress amended section 20 of the ESA to address incidental taking associated with actions that are not covered by section 7. Under section 10, individuals or entities not otherwise covered by a section 7 incidental take statement can apply for incidental take permits. These permits would provide exemptions from the taking prohibitions similar to those made under section 7 incidental take statements given to Federal agencies.

Since the section 7 incidental take statement only covers activities where there is continuing Federal involvement or control, section 10 incidental take permits may be appropriate for certain Federally regulated or funded activities where there is no continuing Federal involvement over a project once the Federal permit, authorization or funding is made. Federally regulated or funded projects that sustain Federal involvement throughout the life of the project remain subject to the provisions of section 7 of the ESA.

Section 10 permits may also be issued in cases where a section 7 incidental take does not appear to be provided for, such as the taking of marine mammals incidentally to commercial fishing operations within the U.S. territorial sea. A section 7 incidental take statement cannot be issued in this case since in order to issue an incidental take statement for marine mammals, the taking must be authorized under section 101(a)(5) of the Marine Mammal Protection Act which applies to activities other than commercial fishing.

Pre-application Assistance

Any person considering applying for an ESA section 10 incidental take permit may contact NOAA Fisheries for assistance before submitting an application. To the extent practicable, NOAA Fisheries will (1) review the requirements of these regulations and determine if a permit is necessary; (2) identify and provide information on listed and proposed species that may be present in the vicinity of the proposed action; (3) identify possible alternatives to avoid an incidental take; and (4) identify possible mitigating measures. Persons engaging in pre-application discussion are in no way required to apply for a permit.

Conservation Plan

In developing a conservation plan, the applicant must use the best scientific and commercial data available to identify potential impacts to the endangered species and to incorporate the most effective use of research and technology to monitor, minimize and

mitigate such impacts. The applicant has the responsibility for securing appropriate data for the preparation of a conservation plan although NOAA Fisheries will provide assistance to the extent practicable (see "Pre-application Assistance" above). All information requirements must be satisfied before NOAA Fisheries will process a permit application.

The conservation plan need only address listed species, although the applicant may include species that have been proposed for listing to facilitate early resolution of potential endangered species conflicts. This may avoid delays in processing or the need to revise the conservation plan and modify the permit should the species become listed after the permit is issued. However, failure to include proposed species will not be a factor in deciding whether to issue or deny a requested permit.

Duration of Permits

Since some projects may take many years to complete, applicants may need long-term permits. To provide sufficient incentives for the private sector to participate in the development of long-term conservation plans, NOAA Fisheries has the discretion to issue ESA section 10 incidental take permits that run for periods significantly longer than are commonly provided for under current administrative practices. In determining the duration of a permit, NOAA Fisheries will consider the duration of the proposed activities as well as the possible positive and negative effects associated with issuing a long-term permit, including the extent to which the conservation plan is likely to enhance the habitat of the endangered species or increase the survivability of the species.

Since circumstances and information may change over time, the original plan might need to be revised. Therefore, any plan approved for a long-term permit must contain a procedure by which NOAA Fisheries and the permit holder will deal with unforeseen circumstances.

Terms and Conditions of Permits

Permit conditions will be based on the extent of a project's anticipated impacts on the species at issue. In establishing terms and conditions necessary and appropriate to minimize adverse impacts to endangered species, NOAA Fisheries will consider the scope, magnitude and duration of a proposed project, the anticipated level of take, and the availability of technologically and economically feasible methods of avoiding or reducing incidental takings. Examples of possible mitigating

measures include restricting the time or area of certain activities (such as the use of explosives), relocating individual animals from designated sites, and modifying techniques or equipment (such as fishing gear or water intake structures).

Classification

NOAA Fisheries has determined that this action will not have a significant impact on the human environment and has prepared an environmental assessment for this proposed rulemaking. Therefore, an environmental impact statement is not required. The environmental assessment is available upon request (see **FOR FURTHER INFORMATION CONTACT**).

The Under Secretary for Oceans and Atmosphere, Department of Commerce, determined that this is not a major rule requiring a regulatory impact analysis under E.O. 12291. The proposed regulations are not likely to result in (1) an annual effect on the economy of \$100 million or more; (2) a major increase in costs or prices for consumers, individual industries or government agencies; or (3) significant adverse effect on competition, employment, productivity, innovation or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic or export markets.

The General Counsel of the Department of Commerce has certified to the Small Business Administration that this proposed rule, if adopted, will not have a significant economic effect on a substantial number of small entities because the rule reflects changes made to the Endangered Species Act and is intended to provide guidance for potential applicants concerning procedures and requirements for obtaining permits to take endangered species incidentally to an otherwise lawful activity.

This proposed rule contains a collection of information subject to the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 *et seq.*) and has been submitted to the Office of Management and Budget for approval. The proposed rule contains three sets of information collections subject to the Paperwork Reduction Act: (1) Applications for incidental take permits under § 222.22(b); (2) applications for certificates of inclusion under § 222.22(g)(1); and (3) reporting requirements of issued permits under § 222.22(d)(1). Public reporting burden for this collection of information is estimated to average 80 hours for permit applications, .5 hours for certificate of inclusion applications, and .5 hours for reports. These estimates include the

time for reviewing instructions, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding these burden estimates or any other aspect of this collection of information, including suggestions for reducing this burden, to the Office of Protected Resources, National Marine Fisheries Service, 1335 East West Highway, Silver Spring, MD 20910, and to the Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, DC 20503 (Attn: Paperwork Reduction Project—0648-XXXX).

This rule does not contain policies with federalism implications sufficient to warrant preparation of a federalism assessment under E.O. 12612.

List of Subjects in 50 CFR Part 222

Endangered and threatened wildlife; Administrative practice and procedure; Exports; Fish; Imports; Marine mammals.

Regulation Promulgation

For the reasons set out in the preamble, 50 CFR part 222 is proposed to be amended as follows:

PART 222—ENDANGERED FISH OR WILDLIFE

1. The authority citation for part 222 continues to read as follows:

Authority: 16 U.S.C. 1531 *et seq.*

2. A new § 222.22 is added to read as follows:

§ 222.22 Permits and certificates of inclusion for the incidental taking of endangered species.

(a) *Scope.* The Assistant Administrator may issue permits to take endangered marine species incidentally to an otherwise lawful activity under section 10(a)(1)(B) of the Endangered Species Act of 1973 (known as ESA section 10 incidental take permits). If the applicant represents an individual or a single entity, such as a corporation, the Assistant Administrator will issue an ESA section 10 individual incidental take permit. If the applicant represents a group or organization whose members wish to conduct activities in a specific geographical location with similar impacts on endangered marine species, the Assistant Administrator will issue an ESA section 10 general incidental take permit. To be covered by a general permit, each individual conducting the activity must have a certificate of inclusion. The regulations in this section apply only to those endangered species under the jurisdiction of the Secretary of

Commerce, identified in § 222.23(a) of this part.

(b) *Permit application procedures.*

Applications should be sent to the Assistant Administrator for Fisheries, National Marine Fisheries Service, 1335 East West Highway, Silver Spring, MD 20910. The sufficiency of the application will be determined by the Assistant Administrator in accordance with the requirements of this section. At least 120 days should be allowed for processing. Each application must be signed and dated and include the following:

(1) The type of permit requested: "ESA Section 10 Individual Incidental Take Permit" or "ESA Section 10 General Incidental Take Permit.

(2) The name, address and telephone number of the applicant. If the applicant is a partnership or a corporate entity or applying on behalf of an organization or group, the applicable details.

(3) The species or stocks, by common and scientific name, and a description of the status, distribution, seasonal distribution, habitat needs, feeding habits and other biological requirements of the affected species or stocks.

(4) A detailed description of the proposed activity, including the anticipated dates, duration, level of activity and specific location. If the request is for a general permit, an estimate of the total level of activity expected to be conducted under the terms and conditions of the permit.

(5) A conservation plan, based on the best scientific and commercial data available, which specifies:

(i) The anticipated impact (*i.e.*, amount, extent and type of anticipated taking) of the proposed activity on the species or stocks;

(ii) The anticipated impact of the proposed activity on the habitat of the species or stocks and the likelihood of restoration of the affected habitat;

(iii) The steps (specialized equipment, methods of conducting activities, or other means) that will be taken to monitor, minimize and mitigate such impacts, and the funding available to implement such measures; and

(iv) The alternative actions to such taking that were considered and the reasons why those alternatives are not being used.

(v) A list of all sources of data used in preparation of the plan, including reference reports, environmental assessments and impact statements, and personal communications with recognized experts on the species or activity who may have access to data not published in current literature.

(c) *Issuance criteria.* (1) In determining whether to issue a permit,

the Assistant Administrator will consider the following:

(i) The status of the affected species or stocks;

(ii) The potential severity of direct, indirect and cumulative impacts on the species or stocks and habitat as a result of the proposed activity;

(iii) The availability of effective monitoring techniques;

(iv) The use of the best available technology for minimizing or mitigating impacts; and

(v) the views of the public, scientists and other interested parties knowledgeable of the species or stocks or other matters related to the application.

(2) To issue the permit, the Assistant Administrator must find that

(i) The taking will be incidental;

(ii) The applicant will, to the maximum extent practicable, monitor, minimize and mitigate the impacts of such taking;

(iii) The taking will not appreciably reduce the likelihood of the survival and recovery of the species in the wild;

(iv) The applicant has amended the conservation plan to include any measures not originally proposed by the applicant that the Assistant Administrator requests as being necessary or appropriate; and

(v) There are adequate assurances that the conservation plan will be funded and implemented, including any measures required by the Assistant Administrator.

(d) *Permit conditions.* In addition to the general conditions set forth in part 220 of this subpart, every permit issued under this section will contain such terms and conditions as the Assistant Administrator deems necessary and appropriate, including, but not limited to the following:

(1) Reporting requirements or rights of inspection for determining whether the terms and conditions are being complied with;

(2) The species and number of animals covered;

(3) The authorized method of taking;

(4) The procedures to be used to handle or dispose of any animals taken; and

(5) The payment of a fee to reimburse the National Marine Fisheries Service the cost of processing the application.

(e) *Duration of permits.* The duration of permits issued under this section will be such as to provide adequate assurances to the permit holder to commit funding necessary for the activities authorized by the permit, including conservation activities. In determining the duration of a permit, the Assistant Administrator will consider

the duration of the proposed activities, as well as the possible positive and negative effects associated with issuing a permit of the proposed duration on listed species, including the extent to which the conservation plan is likely to enhance the habitat of the endangered species or increase the long-term survivability of the species.

(f) *Certificates of inclusion.* (1) Any individual who wishes to conduct an activity covered by an ESA Section 10 general incidental take permit must apply to the Assistant Administrator for a certificate of inclusion.

(2) Each application must be signed and dated and include the following:

(i) The name of the ESA section 10 general incidental take permit under which the applicant wants coverage.

(ii) The name, address and telephone number of the applicant. If the applicant is a partnership or a corporate entity, the applicable details.

(iii) A description of the activity the applicant seeks to have covered under the general permit including the anticipated dates, duration, and specific location; and

(iv) A signed certification that the applicant has read and understands the general permit and conservation plan and will comply with their terms and conditions and will fund and implement applicable measures of the conservation plan.

(3) To issue a certificate of inclusion, the Assistant Administrator must find that

(i) The applicant will be engaged in the activity covered by the general permit and

(ii) The applicant has made adequate assurances that the applicable measures of the conservation plan will be funded and implemented.

3. Section 222.24 is amended by adding a final sentence to paragraph (d) and by removing the last sentence from paragraph (e), to read as follows:

§ 222.24 Procedures for issuance of permits.

(d) The requirements of this paragraph pertain solely to the permits issued under § 222.23.

§ 222.25 [Amended]

4. Section 222.25 is amended by replacing "§ 222.23(c)" with "§§ 222.22(c) and 222.23(c) of this part.

§ 222.27 [Amended]

5. Section 222.27 is amended by replacing "certificates of exemption" and "certificate of exemption" with

"permits" and "permit" respectively, wherever they appear.

§ 222.31 [Amended]

6. Section 222.31 is amended by replacing "§§ 222.23 through 222.28 (Scientific permits)" with "part 222, subpart C (Endangered Fish or Wildlife Permits)" wherever it appears.

Dated: September 27 1989.

James E. Douglas, Jr.,

Acting Assistant Administrator for Fisheries.

[FR Doc. 89-23210 Filed 10-2-89; 8:45am]

BILLING CODE 3510-22-M

50 CFR Part 228

[Docket No. 90518-9118]

RIN 0648-AC69

Incidental Take of Marine Mammals

AGENCY: National Marine Fisheries Service (NOAA Fisheries), NOAA, Commerce.

ACTION: Proposed rule and request for comments.

SUMMARY: NOAA Fisheries is proposing regulations that would allow the harassment of marine mammals during exploration for oil and gas in the Chukchi Sea and the Beaufort Sea for the next 5 years. Any taking of marine mammals that results in more than harassment would be a violation of the Marine Mammal Protection Act of 1972 which allows an incidental, but not intentional, take of marine mammals if certain conditions are met. Two of the six species of marine mammals authorized for an incidental take are considered depleted, and four are not depleted.

These regulations do not permit the actual activities associated with exploration, but rather allow an incidental take of these marine mammals during exploration. The Department of the Interior is responsible for permitting activities associated with oil and gas exploration.

Through the preparation of an Environmental Assessment, a finding was made that the impact on populations of marine mammals will be negligible, and there will be no unmitigable adverse impacts on the availability of the species for subsistence by Alaska natives. A copy of the Environmental Assessment is available on request from the address below.

On request, public hearings also will be held in Anchorage, Alaska and Washington, DC. The dates of the hearings will be published in the Federal Register.

DATE: Comments on the proposed rule must be received by December 4, 1989. A public hearing will be held in Barrow, Alaska on Friday, November 10.

ADDRESSES: Comments should be submitted to Nancy Foster, Director, Office of Protected Resources, National Marine Fisheries Service, 1335 East-West Highway, Silver Spring, MD 20910. Send Comments on the collection of information burden estimate to the Office of Information and Regulatory Affairs, Project (0648-0151), Office of Management and Budget, Washington, DC 20503.

FOR FURTHER INFORMATION CONTACT:

Margaret Lorenz, Protected Species Management Division, Office of Protected Resources, National Marine Fisheries Service, 1335 East-West Highway, Silver Spring, MD 20910, 301-427-2322.

SUPPLEMENTARY INFORMATION:

Background

Section 101(a)(5) of the Marine Mammal Protection Act of 1972 (MMPA) gives the Secretary of Commerce (Secretary) authority to allow, on request by U.S. citizens who engage in a specified activity (other than commercial fishing) in a specified geographical region, the incidental (but not intentional) taking of small numbers of marine mammals. Permission may be granted for a period of 5 years or less.

The taking of marine mammals is allowed only if NOAA Fisheries finds, based on the best scientific evidence available, that the taking will have a negligible impact on the species or stocks and will not have an "unmitigable adverse impact" on the availability of the species or stock for subsistence uses. Also, regulations must be published that include permissible methods of taking and other means to ensure the least adverse impact on the species and its habitat and on the availability of the species for subsistence uses. Also, the regulations must include requirements for monitoring and reporting.

This request is for an incidental take of six species of marine mammals: the beluga whale, bowhead whale, gray whale, bearded seal, ringed seal, and spotted seal. Two of the species, the bowhead and gray whale, are considered depleted under the MMPA and endangered under the Endangered Species Act (ESA). In 1986, both of these Acts were amended to allow incidental takings of depleted, endangered, or threatened marine mammals. Previously, only non-depleted marine mammals could be taken under this exemption to the MMPA. On September 29, 1989,

NOAA Fisheries and the U.S. Fish and Wildlife Service, Department of the Interior, jointly published general regulations implementing the 1986 amendments. Among other things, the amendments revised the scope of the regulations, the definition of negligible impact, and added a new definition for unmitigable adverse impact. Negligible impact is defined as "an impact resulting from the specified activity that cannot be reasonably expected to, and is not likely to, adversely affect the species through effects on annual rates of recruitment or survival. Unmitigable adverse impact means "an impact resulting from the specified activity (1) that is likely to reduce the availability of the species to a level insufficient for a harvest to meet subsistence needs by (A) causing the marine mammals to abandon or avoid hunting areas, (B) directly displacing subsistence users, or (C) placing physical barriers between the marine mammals and the subsistence hunters; and (2) that cannot be sufficiently mitigated by other measures to increase the availability of marine mammals to allow subsistence needs to be met.

Endangered Species Act

Before the 1986 amendments to the MMPA and the ESA, the more restrictive provisions of the MMPA prevailed, and an incidental take of endangered or depleted marine mammals could not be allowed even if the anticipated take would result in only negligible impacts. The new amendments allow a take of endangered animals under the MMPA, but additional authority is needed to allow takings under the ESA.

Under the ESA, Federal agencies are required to consult with NOAA Fisheries on any action authorized, funded or carried out by the agencies that may affect endangered or threatened species or critical habitat. After consultation with the agencies, NOAA Fisheries issues a biological opinion which includes an assessment of impacts and a conclusion on whether the action is likely to jeopardize the continued existence of endangered or threatened species. NOAA Fisheries addressed the activities covered in this proposed rule in biological opinions conducted for Outer Continental Shelf Lease Sales in the Arctic Region including all areas of the Beaufort Sea, Chukchi Sea and Hope Basin Planning Area. An updated opinion issued November 23, 1988, and covering the entire Arctic Region, concluded that leasing and exploration activities are not likely to jeopardize the continued

existence of any endangered or threatened whales. However, because an incidental take of these species had not yet been authorized under the MMPA, the Incidental Take Statement attached to the opinion did not include an authorized take. The statement will be amended when these proposed regulations, which would allow an incidental take under the MMPA, are final. Also, NOAA Fisheries will issue a biological opinion on this authorization because the granting of an incidental take of marine mammals is a Federal action that requires a Section 7 ESA consultation.

Summary of Request

The request for a take of bowhead and gray whales was received on February 16, 1988 from a group of oil companies: Amoco Production Co., Inc., Chevron U.S.A., Inc., Exxon Co. U.S.A., Shell Western E&P Inc., Unocal Corp., and Western Geophysical Co. of America. An amended petition received February 23, 1989, requested as incidental take exemption for four additional species of marine mammals, none of which are depleted.

The petitioners describe the request for taking an incidental and unintentional harassment of marine mammals during pre-lease and post-lease exploration for oil and gas resources in Alaska State waters and on the Outer Continental Shelf. They are requesting a take by harassment, and do not anticipate any lethal takes. The MMPA defines "takes" as harass, hunt, capture or kill, or attempt to harass, hunt, capture, or kill any marine mammal.

Exploration activities will include geological and geophysical surveys, drilling of stratigraphic test wells, exploratory drilling for oil and gas, and associated support activities. Potential causes of taking are noise, oil spills and physical obstruction. This request does not cover future development or production of offshore oil and gas fields. Also, the petition does not request a take of marine mammals during the period in the spring when bowhead whales are migrating through the Chukchi Sea and the Beaufort Sea around Pt. Barrow (usually late March or early April to early or mid June). An exemption is requested for 5 years.

On April 13, 1988, NOAA Fisheries published in the *Federal Register* (53 FR 12170) a Notice of receipt of request for rulemaking from the oil companies and a request for information. At the end of the 90-day comment period, comments had been received from Alaska native groups, conservation groups, Federal, State, and local government agencies,

private industry and other interested parties.

Based on the comments received and NOAA Fisheries review of the request, additional information was sought from the petitioners on August 18, 1988, concerning the anticipated levels of activity, the effects on marine mammals, plans for monitoring and reporting, and measures for mitigating any adverse impacts on the availability of the species for subsistence. NOAA Fisheries also suggested that the request be amended to include the incidental take of several non-depleted marine mammals since we believe they may be affected by the activities associated with exploration; these species are the beluga whale, ringed seal, spotted seal and bearded seal.

Summary of Proposed Rule

NOAA Fisheries proposes to allow an incidental take of marine mammals in the Beaufort and Chukchi Seas from 1989-1994 by individuals who are conducting pre-lease and post-lease oil and gas exploratory activities. A taking will not be allowed when bowhead whales are using the spring lead system to migrate through the Chukchi Sea and the Beaufort Sea past Pt. Barrow. The proposed regulations include requirements for monitoring and reporting and measures to effect the least practicable adverse impact on the species and its habitat and on the availability of the species for subsistence uses. The regulations are proposed based on a finding that exploration in the Chukchi and Beaufort Seas may involve the taking (by harassment) of six species of marine mammals. However, NOAA Fisheries believes that the total impact of the taking will have a negligible impact on the species and on the availability of the species for subsistence uses. All activities must be conducted in a manner that minimizes adverse effects on the species and their habitat. The proposed regulations require those who request a Letter of Authorization to submit a plan to monitor the effects on the populations of marine mammals that are present during exploratory activities. The plan and the person or persons designated to observe and record the effects of exploration activities must be approved by NOAA Fisheries. Also, the applicant for an authorization must identify what measures have been taken to minimize any adverse impacts on the availability of marine mammals for subsistence uses if the activity takes place in or near a traditional subsistence hunting area. Each request will be evaluated on the specific activity and the specific location, and each

authorization will identify allowable methods or conditions that are specific to that activity and location. A report on all exploratory activities must be submitted to NOAA Fisheries within 90 days after the completed activity. A notice of issuance of Letters of Authorization will be published in the *Federal Register*. Any substantive modifications of the Letters will be subject to public review unless NOAA Fisheries determines that an emergency exists which requires immediate action.

A Letter of Authorization must be requested by each group or individual conducting an exploratory activity where there is the likelihood of taking by harassment of any of the six species of marine mammals considered in this rule. The granting of each Letter will be based on a determination that the total level of taking by all applicants in any one year is consistent with the estimated level used to make a finding of negligible impact and a finding of no unmitigable adverse impacts. If the level of activity is more than anticipated, such as more support vessels or aircraft, more drilling units, or more miles of geophysical surveys, NOAA Fisheries will reevaluate its findings to determine if they continue to be appropriate. The individual Letters of Authorization will include monitoring and reporting requirements that are specific to each activity.

Description of Activity

The petitioners have supplied information on the kinds and the level of activities they expect to occur over the next five years. NOAA Fisheries has used this estimated level of activity as a basis for its findings. If requests for Letters of Authorization exceed the highest estimated level of activity, NOAA Fisheries will reevaluate its findings to determine if they continue to be appropriate before any Letters are issued.

Activities that are covered in the request are geophysical surveys, exploratory drilling and support activities. Geophysical surveys are divided into two classes: Deep seismic and shallow hazard. Both kinds of surveys use a "reflective" method to acquire data. Both include an energy source that generates a seismic signal, hydrophones that receive the signal, and electronic equipment on board a seismic vessel that amplifies and records the signal. Energy sources used in deep seismic surveys release bursts of compressed air or water. Sound sources in shallow hazard surveys operate at lower energy levels and generate less

acoustic pressure than deep seismic surveys.

The four principal forms of exploratory drilling structures currently in use or under development for Arctic exploration are artificial islands, bottom-founded structures, drillships and semi-submersible vessels.

The exploratory activities discussed in the petition are currently being conducted in Arctic waters. Seismic surveys have been made in the Beaufort and Chukchi Seas since the 1960s. Exploratory drilling has not been conducted as yet in the Chukchi Sea, but has taken place in the Beaufort Sea.

Marine seismic surveys operate only during the open-water season which is variable. In the southern Chukchi Sea, open water may occur July through mid-November and in the Beaufort and northern Chukchi Seas, open water may occur from August through October. Often, there is no more than 60 days of open water. The scope of the petition is limited to "open-water" seismic surveys and does not include any on-ice survey activity near spring lead systems. Seismic surveys and exploratory drilling will continue for at least the next 7 to 10 years. They will occur on tracts already leased and those offered in future lease sales.

Over the next 5 year, pre-lease survey activity (deep seismic) will occur in unleased portions of the Beaufort and Chukchi Seas. Pre-lease surveys will likely be concentrated in the proposed sale areas during the open water season. The industry estimates that the number of vessels conducting pre-lease and post-lease surveys in all areas of the Beaufort and Chukchi Sea in any open-water season should not exceed six.

The following number of trackline miles is anticipated in each area:

Beaufort Sea—Pre-lease Activity:	
OCS Sale 124:.....	1,500 trackline miles.
State waters (Sales 52, 65, 68).	1,500 trackline miles.
Chukchi Sea—Pre-lease Activity:	
Chukchi Sea OCS Sale 126.	4,000 trackline miles.
Hope Basin OCS Sale 133.	1,500 trackline miles.

Post-lease surveys (usually shallow hazard) will take place as a result of Lease Sale 97 in the Beaufort Sea, Lease Sale 109 in the Chukchi Sea and previous OCS Lease Sales in the Beaufort Sea (BF 71 and 87). In the Beaufort Sea, surveys will take place in 345 square kilometers in the Lease Sale 97 area and 805 square kilometers in previously leased sales for a total of 1,105 kilometers. In the Chukchi Sea,

under the highest level of anticipated activity, it is estimated that shallow-hazard seismic activity will take place on about 73 tracts for a total of 13,479 trackline kilometers.

During all years of exploration in the entire Arctic Region, Minerals Management Service (MMS) predicts that shallow-hazard seismic activity will cover 80,000 trackline kilometers. However, the level of activity considered for this exemption includes only the activities that will occur during the 5 years the exemption will be effective.

Before drilling can begin, lessees must file an Outer Continental Shelf Plan of Exploration and Environmental Report with the Minerals Management Service as well as an Application for Permit to Drill. The Plan of Exploration is reviewed by the State of Alaska for consistency with the Alaska Coastal Management Program under the provisions of the Coastal Zone Management Act. Because only one Plan of Exploration has been filed with MMS for Lease Sale 97 in the Beaufort Sea, the information on exploratory drilling comes from the Final Environmental Impact Statement filed for the lease sale. The high case assumption (based on low, mean, and high assumptions) suggests that 24 exploratory wells and 11 delineation wells will be drilled from 1989 through 1993 on tracts leased in Sale 97 and three previous sales. The mean case assumption suggests 10 exploratory and 4 delineation wells. There may be as many as 5 or as few as 2 drilling units operating during any single year in the Beaufort Sea. In addition, two drilling units may be operating each year in State waters of the Beaufort. Inshore drilling units are usually bottom-founded structures. Generally, a well is not drilled on every block leased since one to three wells are normally drilled to prove a formation that may span a cluster of leases.

In the Chukchi Sea (OCS Lease Sale 109), 351 blocks were leased. Although no plans of exploration have been filed with MMS, the high case assumption suggests that 33 exploratory and 40 delineation wells will be drilled from 1989-1996. From 1989 through 1993, when the regulations will be in effect, 21 exploratory and delineation wells may be drilled under the high-case assumption. The mean case assumes 16 exploratory and 12 delineation wells. As few as two or as many as seven drilling units could be working each year in the Chukchi Sea. These estimates for drilling units are for both floating as well as bottom-founded units. No exploratory activity is anticipated at this time in State waters of the Chukchi Sea.

An appropriate drilling unit will be selected by the lessees when an application for Permit to Drill is filed with MMS or the State of Alaska. Although the level of support activities is speculative, supplies during the drilling season will be transported to the drill ships by helicopters and supply vessels. Bottom-founded units will be resupplied from barges. During 1989-1993, 13 barge trips probably will be made to the Chukchi Sea. The first three of the barge trips would take place in 1991. The high-case estimate suggests up to 27 barge trips during the peak year of exploration. It is assumed that an average of 3 helicopters will service an average of 2 drilling units, and one flight per day per helicopter is estimated.

In the Beaufort Sea, most of the equipment used in exploratory drilling will arrive by barge. To date, annual barge traffic that supports onshore and offshore oil and gas development in the North Slope area has ranged from 2 to 26 trips. Helicopter traffic is estimated at one trip per day per well drilled. The Final Environmental Impact Statement (FEIS) estimates that it takes 90 days to drill and test a well, and it predicts 90 helicopter trips in a year a well is drilled. However, Amoco's Plan of Exploration, which has been filed with MMS, suggests that two helicopter trips per well will take place each day, but it will take only 70 days to drill and test a well.

The number of required support vessels for each drilling unit will depend on the type of characteristics of the unit and the sea-ice conditions. For drilling operations in open water, MMS requires the operator to maintain an emergency standby vessel to be in the immediate vicinity of the drilling unit to ensure evacuation of personnel in the event of an emergency. Depending on ice conditions, two or more icebreaking vessels may be required to perform ice management tasks for the floating unit. Based on exploration plans submitted for OCS Lease Sale 87 tracts, it is assumed that up to three ice management vessels would be used to support each floating unit in the Beaufort Sea.

Biological Information

The geographical area covered by the request is the continental shelf of the Arctic Ocean adjacent to Alaska. This area includes the waters and seabed of the Chukchi Sea off the northwest coast of Alaska, and the Beaufort Sea off the northern coast of Alaska. This area encompasses all waters north of the Bering Strait that are east of the U.S. Russia Convention Line of 1867 and are

within 200 miles of the northern coast of Alaska.

Arctic Region Marine Mammals

1. Bowhead Whale (*Balaena Mysticetus*)

The bowhead whale is the most northern of the great whales. The size of the Western Arctic population of this species has recently been estimated to number 7,800 animals (IWC, in press). These whales migrate northward in the spring from their wintering areas in the Bering Sea. They pass through the Bering Strait and eastern Chukchi Sea from late-March to early June through open leads and polynyas in the shear zone between the shorefast ice and the offshore pack ice. Their path varies in distance from shore depending on water depth and coastal topography, and is often within a few kilometers at coastal promontories such as Cape Lisburne and Point Barrow. The lead system at Point Barrow is especially narrow, and all whales are believed to funnel through the leads or broken pack ice near the Point.

In the Beaufort Sea, the shorefast ice zone is broader and the leads are progressively farther offshore as they extend eastward. Past Pt. Barrow, the leads begin to branch offshore and the migration corridor widens into multiple lead systems as they extend toward Banks Island in Canada. Although activities such as calving, socialization, and some active feeding occur in the spring, the main activity is migration.

Bowhead whales are generally absent in the Chukchi Sea and the Alaska portion of the Beaufort Sea in the mid-summer. Although at least the southern Chukchi Sea is relatively open, the northern Chukchi and Beaufort Seas are still generally ice-covered until early August, or later in some years. The majority of the population is feeding in Canadian waters from June through August.

As early as the beginning of August, bowhead whales return to the eastern Alaska Beaufort Sea, particularly the offshore waters which may be part of their summer feeding grounds. The path of the ensuring fall migration is relatively broad across the Beaufort Sea shelf. Many whales follow nearshore paths while others occur far offshore. Most whale sightings in the fall are in depths between 20 m and 50 m and from 10 to 50 km offshore.

By early September, both feeding and migration activities occur in the Alaska Beaufort Sea. The best documented feeding area is east of Barter Island during September, including the waters offshore of Demarcation Bay. Feeding bowheads have also been observed at

numerous other areas along the Beaufort Sea coast, presumably where hydrographic conditions support the development of significant concentrations of zooplankton such as copepods, euphausiids, and mysids.

Depending on ice conditions and proximity to freeze-up, the bowhead may actively feed and migrate from September to early November. As the whales leave the Beaufort Sea in the fall they pass into the Chukchi Sea. Their migration route past Pt. Barrow is less well known and may be less well defined. Some whales apparently follow the edge of the pack ice west toward Wrangel Island while others head southwest across open waters of the Chukchi Sea toward the Chukchotsk Peninsula of Siberia. Feeding is not documented in the Chukchi Sea but probably occurs, if less frequently, than in the Alaskan Beaufort Sea.

Most movements observed by bowheads in Alaska waters of the Chukchi Sea appear to be purposeful, with little milling or resting. Eventually, the whales pass out of the Arctic Region through the Bering Strait where they will over-winter in the central and western Bering Sea among the broken pack ice and polynyas until the next spring.

Bowhead whales have no natural predators in the Arctic other than man. Bowhead whales are hunted by Eskimo whalers both on their spring and fall migrations through Alaska waters. Native villages that hunt bowhead whales in northern Alaska are Wales, Point Hope, Point Lay, Wainwright, Barrow, Nuiqsut, and Kaktovik. Strike quotas are allocated to each village through an agreement with the Alaska Eskimo Whaling Commission, up to the total strikes allowed under a cooperative agreement with NOAA based on quotas set by the International Whaling Commission (IWC). Most villages conduct their hunts in the spring in the open ice leads. However, Kaktovik and Nuiqsut hunt only in the fall since the bowheads do not pass these villages in the spring. Barrow hunts in both spring and fall if they have unused strikes remaining in their quota after their spring hunt, or are transferred unused strikes from other villages.

2. Gray Whales (*Eschrichtius Robustus*)

The northern Bering and Chukchi Seas are the main summer feeding grounds for the California gray whale population. The Bering Strait is an important migratory corridor for gray whales moving north between late May and August, and returning to the Bering Sea from September to November on their way to southern waters. Gray whales are regular residents in the Chukchi Sea

from June through October, although the majority of the population probably summers south of the Bering Strait. From July through mid-October, some gray whales are found regularly as far north as Pt. Barrow, and a few occasionally travel as far east as Canada.

Present knowledge of the summer-fall distribution and abundance of gray whales is incomplete. Up to one-fourth of the total gray whale population, estimated at 21,113 (IWC in press), may enter the northern Chukchi Sea to feed in the summer and early fall (July-October). They are known to inhabit coastal waters of the Siberian Peninsula as well as Alaskan waters.

Gray whales have been observed feeding in the Chukchi Sea well into October. Most whales are found feeding in nearshore waters averaging 20.5 m in depth and within 14.5 km of shore (Moore *et al.*, 1986). Offshore feeding also occurs, but is less well documented. It is not known if these whales observed in the Chukchi Sea represent a resident summer feeding population or are transient whales that move between the Bering and Chukchi Seas during the summer.

Gray whales normally avoid heavy ice conditions. They remain south of the polar ice pack, and typically leave these northern waters ahead of freeze-up.

Gray whales have few natural predators in the Arctic other than polar bears and man. Polar bears are not a common predator, even though they are known to feed on whale carcasses. There is little subsistence taking of gray whales by Alaska natives. A few have been taken over the years (averaging less than one whale a year), and they are not actively hunted by any of the northern Alaska villages. The few takes are usually in the fall by bowhead whalers seeking to supplement a poor season. The Soviets, however, harvest up to 179 gray whales annually under a subsistence harvest allocation from the IWC.

3. Other Marine Mammal Populations

In addition to the bowhead and gray whale, there are 14 other species of marine mammals that inhabit the Beaufort and/or Chukchi Seas. Of these, four are endangered: the right, sei, humpback and fin whales. The right and sei whales are rare in Arctic waters. The few that have been seen in the Chukchi Sea are probably stray individuals well outside the normal ranges of their populations. Humpback and fin whales are occasional inhabitants of the Chukchi Sea, usually in low numbers. Both are at the northern edge of their summer range when in the Chukchi Sea,

and have been sighted only irregularly in the Alaska portion of the Chukchi.

Although three other cetaceans, the minke whale, killer whale, and harbor porpoise are present in Arctic waters, they are generally considered uncommon, and are more abundant in the Bering Sea.

However, beluga whales (*Delphinapterus leucas*) are present in large numbers in Alaska waters. There are an estimated 16,000 to 18,000 beluga whales in the Bering-Arctic population off Alaska with an estimated 11,500 of these migrating to and from the Beaufort Sea each summer (Davis and Evans, 1982). The entire population migrates westward out of Canadian Arctic waters during the fall season. Their migration route is generally associated with the seasonal pack ice edge (Hazard, 1988) which varies in distance from shore year to year. A few may inhabit or pass through coastal waters, but most are observed along the ice front.

A second population of 1,500 to 2,500 beluga whales move into the Chukchi Sea in early summer after the Beaufort Sea stock has passed through on their spring migration north. This second group summers in the Kasegaluk Lagoon area. Both calving and feeding occur in the nearshore waters outside the lagoon. There is a subsistence take of beluga whales by Alaska natives. The average annual kill in Alaska is 365 with 93 taken in the Alaskan Beaufort Sea and 150 from the Eastern Chukchi Sea (Hazard 1988).

In addition to whales and porpoises, four species of seals inhabit the Arctic Region: the bearded seal, ribbon seal, ringed seal and spotted seal. While the ribbon seal is considered uncommon, the ringed seal (*Phoca hispida*) is the most abundant and widely distributed marine mammal in the Beaufort Sea (Frost *et al.*, 1987; 1988b). Although there is not a good estimate of its abundance or distribution during the open water season, it is widely distributed in Arctic Alaska with an estimated population size of 1 to 1.5 million animals (Kelly 1988a). The Chukchi Sea is regarded as better ringed seal habitat than either the Beaufort or Bering Sea. Ringed seals are generally considered year-round residents of the seasonal shortfast-ice zone throughout their range, but there is an influx of seals through the Bering Strait into the Chukchi Sea in May and June. Nonbreeding subadults are believed to remain offshore except for periods in the spring and fall when they move into the outer edges of the shorefast ice to haul out (Kelly 1988a). There is a subsistence take of ringed seals by Alaska natives. The estimated current total annual take in Alaska

exceeds 3,000 (Kelly 1988a). The Eskimo Walrus Commission records the species and number of all seals taken in five villages in the Bering Strait and Yukon-Kuskokwim regions.

Bearded seals (*Erignathus barbatus*) are the second most abundant pinniped in Arctic waters off Alaska, estimated to number about 250,000 to 300,000 (Kelly 1988b). Their overall summer distribution is quite broad with major concentrations in the Chukchi Sea in association with the edge of the polar pack ice. Since they are benthic feeders, they are limited to shelf areas less than 200 meters depth, and prefer depths of 25 to 50 meters. There is a subsistence take of bearded seals by Alaska natives. In recent years, records have not been kept consistently, but between August 1985 and June 1986, 791 bearded seals were harvested from several villages in the Bering Strait region (Kelly 1988b).

The spotted seal (*Phoca largha*) is an ice-associated species closely related to the harbor seal. They inhabit broken pack ice in the winter and move to coastal habitats in the summer when the ice retreats. They migrate into the Chukchi and Beaufort Seas in the summer, and overwinter in the Bering Sea. The total Bering Sea population is estimated at 200,000 to 250,000 (Quakenbush, 1988). The percentage of the population occupying the Chukchi and Beaufort Seas is unknown. They are more numerous in the Chukchi Sea where major haulouts are known at Kasegaluk Lagoon. They are common in the coastal waters in the vicinity of Peard Bay especially near the mouth of the Kugrua River. In the Beaufort Sea, an estimated 1,000 seals haul out on beaches, barrier islands, and remote sandbars at river deltas, mainly in the western Beaufort Sea. Known haulouts are at the Colville River Delta, Oarlock Island in Dease Inlet, and at the mouth of the Piasuk River in Smith Bay (Oliver, 1987). Spotted seals are taken in subsistence harvests by Alaska natives especially in the Bering Strait and Yukon-Kuskokwim regions. From 1966 to 1976, Alaska's spotted seal harvest ranged from 850 to 3,600 per year and averaged about 2,400 annually (Lowry 1984). From September 1985 to June 1986, the combined harvest from five villages was 986 (Iya, unpublished data).

Walrus and Polar Bears. Polar bears are common in the Arctic Region. Walrus are seen only occasionally. The U.S. Fish and Wildlife Service has jurisdiction over these species, and will determine whether these species will be affected by oil and gas exploration in the Beaufort and Chukchi Seas.

Studies of Effects of Exploration on Marine Mammals

In the past 5 years, several studies have been conducted on the possible effects of OCS activities on bowhead and gray whales. Although studies on the effects of oil on marine mammals have continued using baleen from dead specimens (Geraci and St. Aubin 1986), none has been conducted on living baleen whales. The effects of noise disturbance of bowhead whales from industrial activities was studied during a 5-year program in the Canadian Beaufort Sea (Richardson and Green 1983, Richardson *et al.* 1985a, b, 1986, 1987). Two recent studies investigated noise disturbance of bowhead whales in Alaskan waters (LGL 1987 Miles *et al.* 1987).

Research specific to gray whales and energy exploration include a study by Kent *et al.* (1983) on the responses of migrating gray whales to natural oil seeps in southern California and a study by Malme *et al.* (1983 and 1984) on the potential effects of underwater noise from petroleum industry activities off the California coast.

Although studies have been conducted on the beluga whale's reaction to aircraft and certain kinds of boats (Richardson and Green 1987, Fraker 1978, and Fraker and Fraker 1979), there is no information on the species' reaction to seismic vessels or other industrial activities.

There have been several studies by Smith and Geraci (1975 and 1977) of the consequences of ringed seals coming into contact with crude oil. However, other than studies regarding the effects of on-ice seismic surveys on ringed seals, there are no disturbance studies or other behavioral observations that document the reactions of ringed, bearded, or spotted seals to industrial activities.

Noise Disturbance Studies

Many of the sounds produced by industrial activities are at low frequencies (below 1000 Hz) which is also the range of most bowhead whale vocalizations. Such low-frequency noises could travel long distances to waters used by bowhead whales for migration and feeding in spring and fall.

There has been little opportunity to assess directly the impacts of industrial activities on bowhead whales in Alaska waters because seasonal drilling restrictions were imposed for the first three Beaufort Sea Federal oil and gas lease sales and because most prior OCS activities in Arctic Alaska (all of which are still in the exploration phase) have

occurred in the Beaufort Sea during the winter when bowhead whales are not present. During the spring, the ice leads used by the migrating whales are offshore and away from any gravel islands where most Beaufort Sea wells have been drilled to date, and exploratory drilling in the spring lead systems has not occurred.

Recently, exploration at a few drilling locations has been permitted during the fall migration of bowhead whales. Most of these locations have also been shoreward of the main migration corridor. In 1986, Shell Western conducted exploratory drilling during the beginning of the fall migration, and Unocal subsequently drilled an exploratory well during the migration. The two wells which were located in the nearshore migration path of the bowhead whales, were drilled using a drillship, an icebreaker and icebreaking support vessels. Drill-associated noises were monitored to determine their effects on the migrating whales (LGL 1987).

Data from these studies suggested that migrating bowhead whales avoided and could have been displaced by the offshore drilling operation. No whales were sighted closer than 9.5 km from the drillship, and few were sighted closer than 15 km (LGL 1987). Significant numbers of bowhead whales passed south of the rig as well as north of it. One whale was tracked for 6.8 hours while it travelled 32 km. The whale moved in an arc around the drilling operation maintaining a distance of about 23–27 km from the drillship. Bowhead whales observed between 15 and 30 km from the drillship apparently did not exhibit "strong" (i.e., definite responses which usually involved major changes in respiration, surfacing, and dive cycles) behavioral responses.

There was no evidence that the drilling operation (including the support vessels) act as a barrier to migration (LGL 1987). However, during the study period, ice conditions were light and animals could pass north or south of the rig. No evidence exists to determine if whales would or would not approach an operating rig to continue their migration during heavy ice conditions if the rig was located in the migration path.

Disturbance responses of bowhead whales summering in the Canadian Beaufort to industrial activities have been the focus of a 5-year study (Richardson 1981, 1982, 1985; Richardson et al. 1985a,b, 1986, 1987). Sound sources, besides ambient noise, included geophysical seismic exploration, drilling and associated machinery noise, dredging, icebreaker activity, boat and aircraft traffic, and construction of

gravel islands or other offshore structures. Behavior near actual and simulated activities associated with offshore oil exploration was compared with presumably undisturbed behavior. In general, bowhead whales showed considerable tolerance of ongoing noise from dredging or drilling, but tended to react more strongly to a moving or rapidly changing noise source such as an approaching boat or aircraft or the startup of noise sources (Richardson et al. 1985a,b, 1986, 1987).

In a study by Miles et al. (1987), a simulation model was used to investigate the effects on bowhead whales of noise associated with a drilling operation. Roughly half of the whales in this study showed avoidance responses to industrial sounds which had a 30 dB signal to noise (S:N) ratio. A smaller proportion of the whales observed by Richardson et al. reacted when the S:N was about 20 dB, which would occur at greater ranges than those estimated by Miles et al., and a few bowhead whales may react with even lower signal to noise ratios.

In the Canadian Beaufort Sea, responses of whales to moving boats was the most consistent and second-most pronounced of all disturbance factors tested (Montague 1985). In most cases, bowhead whales oriented away from a moving vessel up to 4 km away and actively swam away from vessels 2 km or less away.

In the Richardson studies (1982, 1985a), there was no clear relationship between the size of the vessel and the distance of the response. The whales ceased to avoid the vessel when it passed out of range, but they may have remained scattered for longer periods. Collisions between bowhead whales and vessels can be avoided if vessels take appropriate steps or if the whales can detect the vessels.

The reaction of bowhead whales to aircraft is more variable than to vessel noise. Most reactions to fixed-wing aircraft occur at altitudes of less than 1,500 feet (Richardson et al. 1985a). Reaction to helicopters may have a similar area of influence (M. Dahlheim, NOAA Fisheries, pers. comm.).

Beluga whales respond to noise and vessel traffic based on the "behavior" of the sound source. For example, Fraker and Fraker (1979) reported that whales closely approached stationary operations such as barge camps and dredges, but in shallow waters were frightened by moving barges at distances of up to 2.4 km. Belugas often approached within a few kilometers of drilling operations on artificial islands and even closer to drilling ships (Fraker 1977 Fraker and Fraker 1979). Belugas

also respond to helicopters flying at altitudes below 150m (Fraker 1978, Fraker and Fraker 1979). As with vessels and fixed-wing aircraft, helicopters seemed to affect feeding belugas less than those not feeding (Hazard 1988).

Studies and Probabilities of Oil Spills

MMS has concluded that the probability of an oil spill resulting from a blowout during exploratory drilling is extremely low (Martin 1986). To date, there has been no oil spilled as a result of a blowout during exploratory drilling on the U.S. outer continental shelf. MMS cites several studies of offshore drilling statistics that indicate the probability of a blowout during offshore exploration on the U.S. OCS is around 0.64 percent or about 1 blowout per 156 wells drilled.

MMS cites legal authorities and operational procedures (Murrell et al. 1987) that are supposed to be in place to ensure safe drilling practices on OCS leases. Such authorities include operational requirements contained in regulations, OCS Operating Orders, lease stipulations, inspection requirements, and conditions of approval of Exploration Plans, Applications for a Permit to Drill, and Critical Operations and Curtailment Plans.

However, if an oil spill should occur during exploration activities from either a blowout or an operational discharge, the conditional probabilities (expressed as percent chance) that an oil spill will contact a certain bowhead whale habitat (i.e., spring or fall migration corridors, feeding areas) within 3 to 30 days have been calculated to range from nil (less than 0.5 percent) to nearly 100 percent depending on spill location and season (MMS 1985, 1987a,b).

Although there are no data on effects of oil on bowhead whales in the open ocean, Albert (1981) speculated that the most likely adverse effects of oil contact to bowhead whales would be (1) conjunctivitis and corneal eye inflammation leading to reduced vision and possibly blindness, (2) development of skin ulcerations from existing eroded areas on the skin surface with subsequent possibility of bacteremia, (3) compromising of tactile hairs as sensory structures, and (4) development of bronchitis or pneumonia as the result of inhaled irritants.

While marine mammals may feed on contaminated prey, it appears to be difficult for them to consume enough oil in this manner to be poisoned by absorbed hydrocarbons. As in humans, cetaceans could develop lung damage from aspirating regurgitated

hydrocarbons (Geraci and St. Aubin 1986).

Hansen (1985) reviewed the literature on the potential effects of oil spills on whales and other marine mammals, and suggested that the level of effects would be related to the degree of exposure of a cetacean to an oil spill. Baleen whales, such as the bowhead and gray whale, may be less likely to avoid oil slicks than more mobile small cetaceans, and the bowhead whales' association with sea-ice may also provide less ability or opportunity for avoidance than for subarctic species (Geraci and St. Aubin, 1986).

Other effects of oil spills on whales may include reduction in availability of food within localized areas near the spill site and in areas where the oil slick occurred. However, Richardson (1987) suggests that it is unlikely that accidental oil spills would have a significant or lasting effect on zooplankton in the study area, or on the availability of zooplankton to bowheads. Nonetheless, there may be uncertain long-term effects of oil ingestion and hydrocarbon accumulation.

Although no research has been conducted specifically on the effects of oil pollution on beluga whales, possible effects of oil on odontocetes (tooth whales) include oil fouling, such as blocking of the digestive track, damage to eyesight or skin, poisoning from ingestion or inhalation, chronic toxicity from exposure to components passed through the food chain, changes in prey populations due to pollution, and reduction in suitable habitat (Hazard 1986). Some cetaceans can detect and avoid oil slicks. In one experiment, bottlenose dolphins avoided surfacing in a slick of darkened mineral oil after two or three initial surfacings in the oil (Geraci and St. Aubin 1982). Although Geraci et al (1983) pointed out that while visual and tactile perceptions led dolphins to avoid oil in an undisturbed and stress-free setting, free-ranging dolphins may enter slicks because of urgency or because of their inability to detect oil in rough or turbid waters or where prey is very dense. It seems likely that oil could be particularly difficult to detect in Arctic waters because of the widespread ice cover and extended hours of darkness in winter. Physical and biological factors directing the movements of belugas, such as the location of leads and polynyas in the spring and the ice front in autumn, the use of estuaries in the summer, and association with seasonal fish runs, could affect the whales' ability to avoid pollution.

Effects on ringed seals of contact with crude oil were reported to include eye irritation, kidney lesions and possible liver damage (Geraci and Smith 1975, Smith and Geraci 1975). Six ringed seals that were immersed for 24 hours in crude oil shortly after capture survived but showed evidence of the above pathological conditions. Three ringed seals held in captivity in Guelph, Ontario, for a longer period all died within 71 minutes of immersion, apparently as the combined result of stress and exposure to oil (Smith and Geraci 1975). It was suggested that vulnerability of ringed seals to environmental disturbances such as oil spills would vary with condition of the animals; older seals and those in poor nutritional health would be most vulnerable (Kelly 1988).

Effects of Exploration on Marine Mammals and on Subsistence Uses

Bowhead Whales

The primary concern of NOAA Fisheries in the Arctic Region is the bowhead whale. The entire population of bowhead whales is susceptible to impacts in this area during their spring migration through nearshore leads. In the fall, a large portion of the bowhead whale population may again be exposed to disturbance from exploration noise when they migrate through the Arctic Region both nearshore and offshore with the pack ice.

To date, the exposure of bowhead whales to the effects of OCS activities has largely been confined to the Canadian Beaufort Sea. In Alaska waters, limited drilling during the fall migration of the whales has only recently begun.

The ability of the bowhead whale to accommodate increasing industrial disturbance is uncertain. Some accommodation undoubtedly can occur, but the level of stress imposed on the species as a result cannot be predicted. A decreased use by bowhead whales of the Canadian Beaufort Sea industrial areas, as evidenced from aerial surveys during the summer, has been noted (Richardson *et al.* 1985a,b, 1986, 1987). However, changes in bowhead whale abundance has also occurred outside the main industrial area. One suggested cause for the decreased use is the effect of increased disturbance from industrial activity that began in the early 1970's and significantly increased since 1980. Variation in food availability (zooplankton concentrations) may also have been involved.

Present and proposed OCS exploratory and development activities in the Arctic Region may eventually

adversely affect the successful life cycle of bowhead whales. At present, we are unable to predict what these tolerance thresholds might be, but we do not believe the foreseeable additive effects of previous and planned sales should exceed this level of concern. Continued efforts to monitor distribution patterns and indicators of population health, such as reproductive success, recruitment, growth rates and behavior are important to assure the combined effects from all OCS activities are not likely to have more than a negligible impact on the bowhead whale population.

Large or widespread noise disturbance along the spring or fall migration paths or in feeding areas could affect bowhead whales by interfering with successful feeding, migration, or other behavioral activities. The range or level of noise required to produce these effects depends on the location and source of noise, and on the acoustic propagation properties of the environment. Although some impacts to individuals may occur, we do not believe proposed exploratory activities will produce noise levels expected to reduce appreciably the likelihood of survival and recovery of the bowhead whales by reducing the reproduction, numbers, or distribution of the species. This conclusion is based on the assumption that exploratory activities will not occur within the spring lead system during the bowhead migration.

Subsistence. Bowhead whales return to the eastern Alaskan Beaufort Sea as early as the beginning of August to begin their fall migration out of the Beaufort Sea. Unlike the spring hunt in the Chukchi Sea, the ice conditions in the Beaufort Sea progress from open water to freeze-up through the hunting season and successful hunting often depends both on favorable weather and ice conditions. Restrictions on drilling in the Beaufort Sea during the bowhead whale fall migration were imposed by MMS and the State of Alaska in response to concerns that drilling might disrupt the fall migration. The open-water season for exploration activities in the Beaufort Sea coincides with the hunting season for the villages of Kaktovik and Nuiqsut. Most exploratory drilling has been shoreward of the main migration corridor. Also, drilling is limited to above threshold depth until 50 percent of the whales have passed the drilling location. Also, any drilling that occurs during the fall migration requires monitoring to determine the effects of noise associated with exploration.

In Kaktovik, hunting activities generally occur within 10 miles of the

coastline, but sometimes as much as 20 miles offshore (Jacobson and Wentworth, 1982). According to village elders, Kaktovik was a pre-historic whaling site. However, Kaktovik's most recent whaling began in 1964. From 1973 to 1988, Kaktovik landed at least one whale every year except in 1975, 1985 and 1987 for a total of 27 whales. Fall whaling in Nuiqsut occurs along the coast as far east as the Canning River with Flaxman Island as the most heavily used site. Nuiqsut has been a whaling community since 1973, and landed a whale in 1973, 1982, 1986 and 1987.

These and other whaling communities are concerned that heavy boat and air traffic and associated noise cause whales to abandon traditional migratory paths; that whalers are prevented from scouting for whales because of heavy boat traffic; and that industry boats moving directly in the path of whaling crews prevent the pursuit of a whale. Concern has been expressed by whalers because Kaktovik did not land a whale in 1985 when there was considerable seismic activity occurring during the fall bowhead whale migration and, again, in 1987 when both seismic and drilling activities occurred during the migration. However, in 1986 when Kaktovik landed three whales and in 1988 landed one, exploratory activities also were taking place in the vicinity of the hunting grounds. Bad ice conditions in 1985 and bad weather conditions in 1987 may have prevented whaling crews from reaching their traditional hunting grounds. Data gathered during aerial surveys in 1985 indicate that whales were present in the traditional hunting areas that year. On the other hand, 1986 was an exceptionally good ice year and a good year for hunting.

In 1986, the first Oil/Whalers Working Group's "Cooperative Program for the Beaufort Sea" provided for the coordination of oil and gas industry exploration activities in the Beaufort Sea with the Eskimo subsistence hunt of bowhead whales. This cooperative agreement was renegotiated for the 1987 and the 1988 season. These agreements are entered into by the Alaska Eskimo Whaling Commission (AEWC) and exploration companies that are operating in the Beaufort Sea at the time of the fall bowhead whale migration. The purpose of the agreement is to ensure that exploratory drilling does not interfere with or restrict the fall hunt of bowhead whales by the residents of the villages of Kaktovik and Nuiqsut. The town of Barrow also hunts for bowhead whales in the fall, but so far has not been a party to the agreement since it can hunt only if there is an unused quota

available. Agreements are conditioned on the renewal of a NOAA-AEWC Memorandum of Understanding which is based on the satisfaction of NOAA that the cooperative program is consistent with and not prohibited under relevant provisions of the law. Basically the agreement provides for reliable communication among crews on the whaling and industry vessels, and includes a process for resolving disputes.

Gray Whales

In Arctic waters, gray whales are most likely to be encountered in the southern Chukchi Sea and the Bering Strait region, and would be affected most by oil and gas exploration activities in those areas. As much as one-fourth of the gray whale population may enter the northern Chukchi Sea through the Bering Strait. Although some individuals may suffer disturbances or other impacts from the proposed activities, due to the good overall condition of the gray whale population and to its widespread distribution in the Bering and Chukchi Seas, such impacts are not likely to be more than negligible.

However, additive impacts that could result from past and future OCS activities in the Arctic Region, the Bering Sea, and in other regions outside Alaska, may have the potential to affect the population adversely. Annually, the gray whale population migrates by or through at least eight oil lease areas in U.S. waters alone (Rice et al., 1984). Continued monitoring of the health of the gray whale population and the effects of OCS activities in these areas is necessary to assess whether the combined impacts are affecting the gray whales adversely.

Subsistence. There is little subsistence take of gray whales by Alaska natives although a few have been taken over the years (averaging less than one whale a year). The few takes are usually in the fall by bowhead whalers seeking to supplement a poor season. Since gray whales are not actively hunted by any of the northern Alaska villages, exploratory activities will not limit their availability for subsistence uses.

Beluga Whales

This species occurs in all of the Alaska OCS oil and gas lease sale areas. During the ice-free months, the largest concentrations are found in the eastern Beaufort Sea north of Canada although a few have been seen off Barter Island. The spring migration passes through the Chukchi Sea and the Beaufort Sea lease areas. Major summer concentrations occur in the North Aleutian Basin, Norton Basin, Hope

Basin and Barrow Arch. During the fall, many belugas pass through the lease sale areas of the Beaufort Sea although this westward migration takes place primarily offshore. Information on sensitivity to oil and gas activities is limited. However, because they form dense aggregations, their populations as a whole may be significantly affected by local degradation of the environment. The effects of habitat changes on belugas could take various forms including direct mortality, displacement, increased stress or illness, changes in reproductive success, changes in fat reserves or energy expenditures, and changes in the ability to communicate, navigate or locate prey (Hazard 1988). Marine mammals may abandon areas as their habitat deteriorates, or they may exhibit high site tenacity. Belugas return to estuaries in northern Quebec every year despite severe overhunting that has reduced population levels. Although belugas in Kotezebue Sound (Chukchi Sea) are intensely hunted, and in the Mackenzie Delta (Canada) are hunted and exposed to dramatic increases in vessel traffic and industrial noise, they return each year. In other areas, where vessel traffic has increased, belugas have disappeared. Thus, site tenacity may better reflect the critical value of the habitat than the level of human-imposed stress (Hazard 1988).

Subsistence. Belugas have never been observed in large numbers during the summer in coastal waters of the Beaufort Sea, and there have been only a few nearshore sightings in the autumn (Frost, Lowry and Burns 1988). In the Chukchi Sea, the spring migration of belugas generally is in association with the bowhead migration, and the proposed regulations do not authorize a take during the bowhead whale spring migration. However, beluga whales are present in the summer in some coastal areas of the Chukchi Sea where they are hunted for subsistence. Although no exploration activities are planned in State waters of the Chukchi Sea, offshore exploration should be sited and timed so that belugas are not displaced or prevented from entering these areas.

Bearded, Ringed and Spotted Seals

Potential adverse effects of noise disturbances on ringed seals, particularly those associated with on-ice seismic activities in the Arctic, were considered by Burns and Kelly (1982) and Kelly et al. (1986). Displacement of seals from breathing holes and lairs was found to occur in local areas, but was not significant to the population. Effects on ringed seals of contact with oil was discussed previously. Although bearded

seals would likely show the same effect of contact with oil as ringed seals, potentially greater harm to bearded seals may result from development activities that adversely affect their benthic foods. Petroleum oil spills have resulted in mortality of benthic invertebrates, including bivalve molluscs.

No studies have been conducted on the effects of industrial noise and other human activities on bearded seals. Bearded seals generally appear to be less readily disturbed by human activities than are many other pinnipeds (Kelly 1988), and Burns (1981) noted that bearded seals are less wary in the spring than in winter.

Although the long-term effects of oil and the effects of oil on the specific food chain of spotted seals are not known, the effects of energy exploration on spotted seals probably are the same as for ringed and bearded seals.

Subsistence. Most of the subsistence take of bearded, ringed and spotted seals occurs in the Bering Strait Region of Alaska where exploration activity will be limited to pre-lease geophysical surveys in the Hope Basin Area. Also, most seals are widely distributed at sea during the open water season, the time exploratory activities considered in this rulemaking will take place.

Conclusions

The Marine Mammal Commission, in response to NOAA Fisheries' request for comments, concurs with the petitioners' judgement that noise and disturbance from exploration are likely to have no more than temporary and localized effects on bowhead and gray whale behavior and movements, and that these effects are not likely to affect the survival or productivity of the whales or have more than temporary and localized effects on the availability of whales for native subsistence hunting. However, the Commission notes that the survival and productivity of the bowhead whale could be affected if noise or disturbance interfered with breeding, caused increased energy expenditures and food requirements, caused animals to avoid or abandon important or breeding areas, or disrupted feeding for more than a few hours or days in more than a single summer feeding season.

NOAA Fisheries agrees with this assessment and concludes that noise and disturbance will not adversely affect the marine mammal species through effects on annual rates of recruitment or survival if certain conditions are met.

The Commission also notes that noise and disturbance from exploration and related activities are not likely to have

significant adverse effects on survival, productivity, or availability to native subsistence hunters due at least partially to the fact that activities would be limited in time and space. That is, an activity that interferes with feeding or breeding, or increases energy expenditures, for short periods may have negligible effects on survival or productivity, whereas the same activity might cause more than negligible impacts if it occurred in the same area year after year. Therefore, it is important to recognize that this does not mean that disturbance and noise from development and production activities, which could occur in certain locations for many years, also would have negligible effects.

NOAA Fisheries agrees with the Marine Mammal Commission that noise and disturbance will not have an unmitigable adverse impact on the availability of marine mammals for subsistence needs if certain conditions are met.

The Commission concurs with the petitioners that during exploration activities there is a low probability of oil spills occurring and contacting either bowhead or gray whales or habitats important to their survival or productivity. However, a low probability of occurrence does not, by itself, provide justification for concluding that oil spills would have negligible impacts. The potential impact of an oil spill is independent of its probability of occurrence, and the possible severity of that impact should be factored into the negligible impact determination. In this case, it may be reasonable to assume that, because the possibility of a spill occurring is so small, there is no need to consider the possible impacts of a spill, not that the impacts would be negligible if in fact a spill did occur.

The final regulations implementing the 1986 amendments to the MMPA and ESA include a discussion on weighing the likelihood of occurrence against the severity of the potential impact. The legislative history of the 1986 amendments states: "the degree of certainty of occurrence required in these judgements should be inversely proportional to the resultant harm to the overall population. NOAA Fisheries agrees with the Commission that while there is a low probability of oil spills occurring and contacting whales or seals or habitats important to their survival or productivity, the impacts would not be negligible if an oil spill occurred. Yet, NOAA Fisheries believes a finding of negligible impact is appropriate because of the low probability of an oil spill during the exploration phase.

The Commission adds, "the judgement that exploration and related activities would have negligible effects on marine mammals, especially the bowhead whale, is based on several assumptions. One is that changes in diving and movement patterns in response to ship and aircraft operations do not affect breeding or feeding in ways that would have either immediate or long-term effects on survival or productivity. Another assumption is that noise and disturbance would not cause whales to abandon or avoid traditional breeding areas, feeding areas, migratory routes, and native hunting grounds. The assumption is also made that there are alternative feeding areas, breeding areas, migratory routes, and hunting grounds that can be used with little or no effect on survival, productivity, or availability of whales to subsistence hunters.

The Commission believes that although these assumptions may be reasonable, their validity has not been verified. This would require accurate determinations of migration routes and the knowledge of age- or size-specific survival and reproductive rates of the bowhead, gray and beluga whales. Monitoring programs need to be established that are capable of detecting behavioral changes in whales that may be caused by exploration activities. NOAA Fisheries agrees that it is important to verify these assumptions.

In addition, NOAA Fisheries believes the populations of the bearded, ringed, and spotted seals and beluga whales also need to be better assessed, and the status of these populations needs to be monitored. To assess and minimize the possible adverse effects of offshore oil and gas exploration on these animals, studies need to be made to identify important habitat areas and to determine if noise or disturbance causes avoidance or abandonment of traditional habitat areas. Existing data are not sufficient to predict the effects of OCS exploration and development on seals particularly in the Chukchi and Beaufort Sea waters.

Based on the previous discussion, NOAA Fisheries makes the following specific conclusions regarding the proposed action.

Impact on Species

NOAA Fisheries concludes that based on the best scientific information available the effects of currently planned exploration will not adversely affect the species through effects on annual rates of recruitment or survival if certain conditions are met. The conclusion of "negligible impact"

applies only to exploration, and does not apply to the development and production phases of oil and gas activity in the Beaufort and Chukchi Seas. The conditions are designed to eliminate interference with normal breeding and feeding patterns and migration to ensure that the effects remain negligible.

First, a take of marine mammals would not be allowed in the Chukchi Sea and Beaufort Sea until the bowhead whale spring migration has passed Pt. Barrow. This would allow for the whales to use the spring lead system through which they migrate without any interference from exploration activities. Although the petitioners have stated that they do not seek authorization for a take during this time, they reserve the option to do so if operations become feasible. Also, they believe that if technology develops, drilling units and support vessels could be in the area during the early open water period while the subsistence hunt is in progress. Nonetheless, these activities are not included in the proposed authorization for an incidental take.

Second, each activity would require a site-specific monitoring program approved by NOAA Fisheries. The purpose of the program would be to monitor the effects of the activity on marine mammals in that area.

Third, findings for this exemption were based on the total level of activity estimated by the industry and MMS in its environmental impact statements. If the level of activity, including the number of trackline miles for seismic activity, drilling units, and all the support vessels and aircraft associated with exploration, is more than the level estimated by industry and MMS, NOAA Fisheries will re-evaluate its findings to determine if they continue to be appropriate based on the higher level of activity. Depending on the results of this evaluation, NOAA Fisheries could add further conditions to the authorization or withdraw it.

Impact on Subsistence

Although exploratory activities may occasionally place physical barriers between marine mammals and subsistence hunters (i.e. survey vessels and barges traveling to exploration sites) and marine mammals may avoid certain structures such as drillships, NOAA Fisheries concludes that these activities over the next 5 years are not likely to reduce the availability of the species to a level insufficient for a harvest to meet subsistence needs if certain conditions are met. We did not find any evidence that exploratory activities directly displaced hunters or

caused marine mammals to abandon hunting areas.

The conclusion that the activities will not have an "unmitigable adverse impact" applies only to exploration, and does not apply to the development and production phases of oil and gas activity in the Beaufort and Chukchi Seas.

The first condition concerns the spring migration of bowhead whales. As discussed previously, a take would not be allowed until NOAA Fisheries had determined that the spring migration of bowhead whales had passed Pt. Barrow. This would allow all the villages to participate in the spring hunt without any interference from exploratory activities.

Also, to lessen any possible effects concerning subsistence, NOAA Fisheries believes it is necessary for the exploration industry to continue cooperative efforts with villages that conduct subsistence hunts when exploration activities occur in the same areas. Therefore, the second condition would require applicants for a Letter of Authorization to contact the subsistence communities to discuss potential conflicts and to identify in the application what measures have been taken to minimize any adverse effects on the availability of marine mammals, especially the bowhead whale.

Third, if there is evidence in the future that exploration activities are reducing the availability of marine mammals for subsistence, NOAA Fisheries would reevaluate its findings regarding subsistence and the measures required to ensure the availability of the species for subsistence. Depending on the results of the evaluation, NOAA Fisheries could add further conditions to the authorization or withdraw it.

Monitoring

The purpose of a monitoring program is to determine the effects of exploration activities on populations of marine mammals that inhabit the Arctic region. Ideally, monitoring programs should be designed to determine the direct, indirect and cumulative effects of offshore oil and gas exploration activities on the survival and productivity of these species.

Every applicant for a Letter of Authorization must submit a site-specific plan for monitoring the effects on the populations of marine mammals that are present during exploratory activities. The plan, which must be approved by NOAA Fisheries Service, must identify what survey techniques will be used to determine the movement and activity of the marine mammals near the exploratory sites. Qualified observers, approved by NOAA

Fisheries, must monitor the behavior of the marine mammals present to determine the effects. The requirements for monitoring plans will vary depending on the activity, the location and the time. Not all monitoring plans will necessarily require a researcher or biologist as an observer, and activities that are not in areas known for the presence of marine mammals will require less extensive monitoring plans. NOAA Fisheries will coordinate monitoring plans so that the information obtained during monitoring is gathered in a consistent manner, and the information can be used to determine the cumulative impacts of exploration on marine mammals.

Although sponsoring a research program is not a requirement for obtaining a Letter of Authorization, NOAA Fisheries encourages research programs that would include (1) determinations of migration routes (especially bowhead whales) and the age or size-specific survival and reproductive rates of whales, (2) identification and characterization of feeding areas and habitat use and determination of their importance to the populations of marine mammals in the Arctic Region, (3) determination of the nature and effects of industrial noise in the Arctic Region on marine mammals including geophysical seismic sounds using airguns and drilling noise from both fixed and floating units and their support activities including icebreakers and dredges and (4) detection of cumulative effects.

Discussion of Comments

Those who favor NOAA Fisheries granting the oil companies an exemption mentioned the considerable amount of information that has been developed from studies concerning the interactions of exploratory operations with whales, and they believe this information indicates that exploratory operations have a negligible impact on marine mammals, and they do not have an adverse impact on the availability of the species for subsistence.

Those who expressed concern regarding the granting of an exemption question the conclusions of the petitioners regarding the effects of energy exploration on marine mammals, especially bowhead whales, and the effects on the availability of the bowhead whale for subsistence. The major concern mentioned by most commentators is the lack of information on the cumulative effects of energy exploration on the bowhead and gray whale. Generally, they believe that only if research occurs concurrently with

exploratory activities will change be detected. They believe that large-scale monitoring is the best method of detecting cumulative effects of industrial activities over a number of years.

Several commentators believe that the petitioners should add other species of marine mammals to their request because these species are also likely to be taken incidentally to these activities. Also, they felt the petitioners did not address adequately the mitigation measures that the MMPA requires if exploratory activities have an adverse impact on the availability of the bowhead whale for subsistence uses.

NOAA Fisheries appreciates the many thoughtful comments regarding the request for comments and information, and took these comments into account when preparing the Environmental Assessment and the proposed regulations. For example, in the first request for more information (August 1988), NOAA Fisheries suggested that the petitioners include four other species of marine mammals that we believe may be taken incidental to exploratory activities. These species are the beluga whale and the bearded, ringed and spotted seals. In February 1989, the petitioners agreed to this request. NOAA Fisheries forwarded comments regarding the inclusion of polar bears and walrus to the Fish and Wildlife Service which is conducting a review to determine if there will be a take of these species.

NOAA Fisheries also asked for more information on the level of exploratory activities to allow a better assessment of the effects on the species and on the availability of the species for subsistence. Also, the petitioners have been encouraged to continue working with the Alaska native groups to prevent in advance any adverse impact on the availability of the species for subsistence.

Classification

NOAA Fisheries prepared an environmental assessment for this proposed rulemaking and concluded that there will be no significant impact on the human environment as a result of this rule. A copy of the environmental assessment may be obtained at the address listed above.

The Undersecretary for Oceans and Atmosphere, NOAA, determined that this proposed rule is not a "major rule" requiring a regulatory impact analysis under Executive Order 12291. The proposed regulations are not likely to result in (1) an annual effect on the economy of \$100 million or more; (2) a major increase in costs or prices for consumers, individual industries, or

government agencies; or (3) significant adverse effect on competition, employment, productivity, innovation, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic or export markets.

The General Counsel of the Department of Commerce certified to the Small Business Administration that the proposed rule, if adopted, would not have a significant economic impact on a substantial number of small entities since only oil and gas exploration companies, which usually do not qualify as small businesses, would be affected. As a result, a regulatory flexibility analysis was not prepared.

This rule contains collection of information requirements subject to the Paperwork Reduction Act. In anticipation of this proposed rule, additional requirements were approved by the Office of Management and Budget (OMB) under section 3504(b) of the Paperwork Reduction Act issued under OMB Control Number 0648-0151. Public reporting burden for this collection of information is estimated to average 6 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to the National Marine Fisheries Service and OMB (see ADDRESSES).

This rule does not contain policies with federalism implications sufficient to warrant preparation of a Federalism Assessment under E.O. 12612.

NOAA Fisheries determined that this rule does not directly affect the coastal zone of any State with an approved coastal zone management program under the Coastal Zone Management Act (CZMA). This rule does not authorize oil exploration activities for which a consistency determination may be required. Rather, the rule authorizes the non-lethal taking of marine mammals incidental to such activities. This determination will be submitted to the State of Alaska's Division of Governmental Coordination for review under § 3.7 of the CZMA.

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List of Subjects in 50 CFR Part 228

Marine mammals, Reporting, Reporting and recordkeeping requirements.

Dated: September 27 1989.

James E. Douglas, Jr.,

Acting Assistant Administrator for Fisheries.

For reasons set forth in the preamble, 50 CFR part 228 is proposed to be amended as follows:

PART 228—REGULATIONS GOVERNING SMALL TAKES OF MARINE MAMMALS INCIDENTAL TO SPECIFIED ACTIVITIES

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

Authority: 16 U.S.C. 1371(a)(5).

2. Subpart D is added to read as follows:

Subpart D—Taking of Marine Mammals Incidental to Oil and Gas Exploration Activities in Alaska

- Sec.
228.31 Specified activity and specified geographical region.
228.32 Effective dates.
228.33 Permissible methods.

- Sec.
228.34 Prohibitions.
228.35 Level of activity.
228.36 Measures to ensure availability of species for subsistence.
228.37 Requirements for monitoring and reporting.
228.38 Letters of Authorization.

Subpart D—Taking of Marine Mammals Incidental to Oil and Gas Exploration Activities in Alaska

§ 228.31 Specified activity and specified geographical region.

Regulations in this subpart apply only to the incidental taking (by harassment) of marine mammals (bowhead, gray, and beluga whales and bearded, ringed, and spotted seals) by U.S. citizens engaged in oil and gas exploration in the Chukchi Sea or Beaufort Sea off the coast of Alaska. The geographical region includes Alaska state waters and outer continental shelf waters that have been leased for exploration or that are being considered for leasing. The activities include geophysical surveys and exploratory drilling and support operations (e.g. ice-breakers, supply vessels and aircraft).

§ 228.32 Effective dates.

Regulations in this subpart are effective for a 5-year period except for the time each year when bowhead whales are migrating through the spring lead system in the Chukchi Sea and Beaufort Sea. This period is approximately from mid-April through early June. Each year, the National Marine Fisheries Service will determine when the spring migration of bowhead whales has passed Pt. Barrow. The National Marine Fisheries Service will notify applicants when the migration is completed.

§ 228.33 Permissible methods.

(a) The incidental, but not intentional, taking of whales by U.S. citizens holding a Letter of Authorization is permitted using the following methods for exploration:

- (1) Geophysical surveys including shallow hazard and acoustic surveys, and
 - (2) Exploratory drilling including ice-breakers, support vessels and aircraft.
- (b) The methods and activities identified in § 228.33(a) must be conducted in a manner that minimizes to the greatest extent possible any adverse impacts on marine mammals, their habitat, and on the availability of these marine mammals for subsistence uses.
- (c) The National Marine Fisheries Service will evaluate each request for a Letter of Authorization based on the specific activity and the specific

geographical location. Each Authorization will identify allowable conditions or methods that are specific to that activity and location.

§ 228.34 Prohibitions.

(a) An incidental take of bowhead whales will not be allowed during their spring migration in the Chukchi Sea and Beaufort Sea (see § 228.32).

(b) An incidental take other than by harassment will not be allowed.

§ 228.35 Level of activity.

When Letters of Authorization are requested each year, the National Marine Fisheries Service will determine whether the level of activity identified in the requests exceeds that considered by the National Marine Fisheries Service in making a finding of negligible impact on the species and a finding of no adverse impact on the availability of the species for subsistence. If the level of activity is higher, the National Marine Fisheries Service will re-evaluate its findings to determine if those findings continue to be appropriate based on the higher level of activity. Depending on the results of the evaluation, the National Marine Fisheries Service could add further conditions to the authorization or withdraw it.

§ 228.36 Measures to ensure availability of species for subsistence.

When applying for a Letter of Authorization, the applicant must identify what measures have been taken to minimize any adverse effects on the availability of marine mammals for subsistence uses if the activity takes place in or near a traditional subsistence hunting area. The applicant must contact affected subsistence whaling communities to discuss potential conflicts with the siting, timing, and methods of proposed operations. The applicant must make reasonable efforts to assure that exploration activities do not interfere with any subsistence hunt.

§ 228.37 Requirements for monitoring and reporting.

(a) Holders of Letters of Authorization are required to cooperate with the National Marine Fisheries Service and other designated Federal, State, or local agencies to monitor the impacts of oil and gas exploration on marine mammals. The Holder must notify the National Marine Fisheries Service, Alaska Region, of any activities that may involve a potential take at least 90 days prior to the activity in order to satisfy § 228.37(d).

(b) Holders of Letters of Authorization must designate a qualified individual or

individuals to observe and record the effects of exploration activities on marine mammals. The observer must be approved by the National Marine Fisheries Service.

(c) When applying for a Letter of Authorization, the applicant must include a site-specific plan to monitor the effects on populations of marine mammals that are present during exploratory activities. This plan, which must be approved by the National Marine Fisheries Service, should identify what survey techniques will be used to determine the movement and activity of marine mammals near the exploratory sites including migration and other habitat uses, such as feeding. A qualified researcher should observe the behavior of the marine mammals present to determine if they are being affected. The monitoring program should document the acoustical effects on marine mammals and document or estimate the actual level of take. The requirements for monitoring plans will vary depending on the activity, the location, and the time.

(d) At its discretion, the National Marine Fisheries Service may place an observer on board drillships, aircraft, etc. to monitor the impact of exploration activities on marine mammals.

(e) The holder of a Letter of Authorization must submit a report to the Assistant Administrator for Fisheries within 90 days of the completion of any exploratory activities. This report must include the following information:

(1) Dates and types of activity;

(2) Dates and locations of any activities related to monitoring the effects of exploration on marine mammals;

(3) Results of the monitoring activities including an estimate of the actual level of take; and

(4) Results of behavioral, feeding, or population studies.

§ 228.38 Letters of authorization.

(a) Each company conducting an exploratory activity in the geographical area described in § 228.31 must apply for a Letter of Authorization for each geophysical survey or seismic activity and each drilling operation. The application must be submitted to the National Marine Fisheries Service at least 90 days before the activity is scheduled to begin.

(b) When a company submits an application for a Letter of Authorization, it must include the following:

(1) A plan to monitor the behavior and the effects of the activity on marine mammals;

(2) A description of the measures taken to minimize any potential conflicts between the proposed activity and subsistence hunting; and

(3) A description of the activity including the method to be used, the dates and duration of the activity, the specific location of the activity and the estimated area that will actually be affected by the exploratory activity.

(c) In addition to the provisions of § 228.6 (see General Regulations), any substantive modifications of the Letters of Authorization will be made after notice and opportunity for public comment.

(d) The requirement for notice and public review in § 228.38(c) will not apply if the National Marine Fisheries Service determines that an emergency exists which poses a significant risk to the well-being of the species or stocks of marine mammals concerned.

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50 CFR Parts 611, 672, and 675

[Docket No. 90370-9191]

RIN 0648-AC68

Foreign Fishing; Groundfish of the Gulf of Alaska, Groundfish Fishery of the Bering Sea and Aleutian Islands Area

AGENCY: National Marine Fisheries Service (NMFS), NOAA, Commerce.

ACTION: Proposed rule.

SUMMARY: The Secretary of Commerce (Secretary) proposes a rule that redefines directed fishing using directed fishing standards for various groundfish species in the Gulf of Alaska and in the Bering Sea and Aleutian Islands area. This action is necessary to promote conservation and management of groundfish. It is intended to further the goals and objectives contained in fishery management plans that govern these fisheries.

DATE: Comments are invited until November 1, 1989.

ADDRESS: Comments may be sent to Steven Pennoyer, Director, Alaska Region, National Marine Fisheries Service, P.O. Box 21668, Juneau, AK 99802. Copies of the environmental assessment/regulatory impact review/initial regulatory flexibility analysis (EA/RIR/IRFA) may be obtained from the same address. Comments on the environmental assessment are particularly requested.

FOR FURTHER INFORMATION CONTACT: Ronald J. Berg (Fishery Management Biologist, NMFS), 907-586-7230.

SUPPLEMENTARY INFORMATION:

Background

The domestic and foreign groundfish fisheries in the Exclusive Economic Zone (EEZ) of the Gulf of Alaska and Bering Sea and Aleutian Islands area are managed by the Secretary under the Fishery Management Plans (FMPs) for Groundfish of the Gulf of Alaska and the Groundfish Fishery of the Bering Sea and Aleutian Islands Area. The FMPs were prepared by the North Pacific Fishery Management Council (Council) under the authority of the Magnuson Fishery Conservation and Management Act (Magnuson Act) and are implemented by regulations for the foreign fishery at 50 CFR part 611 and for the U.S. fishery at 50 CFR parts 672 and 675.

At its January 16-19, 1989, meeting, the Council requested that NMFS prepare a regulatory amendment so that a more permanent change could be made to the regulatory text concerning directed fishing than that afforded by an emergency rule that was in effect from March 28 through September 23, 1989 (see 54 FR 13191, March 31, 1989; 54 FR 27384, June 29, 1989). The emergency rule modified the definition of directed fishing with respect to enforcement and also limited the amount of sablefish caught in the Bering Sea and Aleutian Islands area (BSAI) to 10 percent of Greenland turbot and Pacific ocean perch, and 1 percent of other groundfish, retained on board a vessel. The Council also requested that NMFS develop and include in the regulatory amendment definitions specific to the Gulf of Alaska (GOA) sablefish trawl fishery and the various BSAI groundfish fisheries.

The Council intends that amounts of groundfish species that are not available for a directed fishery should be caught only in amounts necessary to support directed fisheries for other groundfish species. At the same time, the Council does not intend that occasional catches of groundfish incidental to other directed fisheries should be discarded at sea and wasted unnecessarily. To the contrary, the Council recognizes that, given the variable composition of groundfish species in the ecosystem, fishermen can be expected to inadvertently catch other species while conducting directed fishing for a particular species. The Council intends that fishermen should be given the chance to adjust fishing practices during the course of a trip such that the resulting composition of the total catch at the end of the trip would not violate a directed fishing closure.

The Council often expressed this intent at its April 11-14, 1989, meeting during its review of the regulatory amendment drafted by NMFS. The Council heard testimony from fishing industry representatives concerning the need for a time period in which to adjust catches so that resulting catch for a species for which directed fishing had been prohibited would not violate a directed fishing closure. Other industry representatives testified that fishermen should not be allowed to retain amounts of groundfish on board after the date of the last offloading or transfer, because large amounts of groundfish for which directed fishing had been prohibited could be caught and retained without being in violation. As a result, these species of groundfish could be taken in excessively disproportionate amounts as allowable bycatch and cause the total allowable catch (TAC) to be reached before the fishing year ended. In such cases, additional catches of these species would have to be treated as prohibited species and discarded at sea as waste. Finally, other industry representatives testified that groundfish caught in another GOA regulatory area or district, or BSAI subarea, should not be considered for purposes of calculating percentages used in the definition, again, because larger amounts of groundfish for which a directed fishery had been closed could otherwise be caught, causing the TAC to be reached too early.

Council Recommendations

After considering testimony, the Council recommended that the regulatory amendment be implemented, but with the following changes:

1. The definition should be based on amounts of fish caught since the date of last offloading rather than on a haul or set basis, which would allow fishermen to adjust amounts of bycatch species over the time period of the trip;

2. Percentages used to define directed fishing should be reduced where appropriate to remove economic incentives to target on bycatch species, but not reduced so low as to require excessive discard of bycatch species and resultant wastage;

3. Fish and fish products retained onboard a vessel from a prior trip should not be used for purposes of calculating a percentage of a species when determining compliance with a directed fishing closure during a subsequent trip; and

4. Fish and fish products onboard a vessel that were caught in another GOA regulatory area or district, or BSAI subarea, should not be used for purposes of calculating a percentage

when determining compliance with a directed fishing closure.

Definitions

The definitions of directed fishing are specified in the relevant fishing regulations (see 50 CFR 672.2 for GOA groundfish and 50 CFR 675.2 for BSAI groundfish and 50 CFR 611 for foreign fishing). The codified definitions of directed fishing for both GOA and BSAI groundfish read as follows:

Directed Fishing, with respect to any species, stock or other aggregation of fish, means fishing that is intended or can reasonably be expected to result in the catching, taking or harvesting of quantities of such fish that amount to 20 percent or more of the catch, take, or harvest, or to 20 percent or more of the total amount of fish or fish products on board at any time. It will be a rebuttable presumption that, when any species, stock, or other aggregation of fish comprises 20 percent or more of the catch, take, or harvest, or 20 percent or more of the total amount of fish or fish products on board at any time, such fishing was directed to fishing for such fish.

The codified definition of directed fishing applicable to foreign fishing is different and is specified under 50 CFR part 611.

These codified definitions were superseded temporarily by emergency rule to allow time for the preparation of a regulatory amendment to resolve this issue (see 54 FR 13191, March 31, 1989; 54 FR 27384, June 29, 1989). The definition of foreign fishing was revised temporarily to be consistent with the appropriate temporary definitions. These temporary definitions are effective through September 23, 1989.

The definition of directed fishing has been a contentious issue. Under the codified definitions, catches of species for which directed fishing is prohibited are compared against catches of other fish over any period on an individual haul or set basis, as well as against the total amount of fish on board. If a fisherman catches groundfish species for which directed fishing is prohibited in an amount greater than an allowable percentage, the fisherman may be charged with a violation. Fishing industry representatives complain that they may be liable for their catches before they have had the chance to observe and sort them. If a catch is brought on board a vessel and a particular groundfish species is observed by enforcement officers to be in excess of the maximum allowable percentage of total catch, the vessel operator could be cited. The industry has contended that the codified definitions of directed fishing create

potential enforcement standards that are too burdensome.

Proposed rules

Although the codified definition in the Code of Federal Regulations was intended to encourage fishermen to modify fishing practices when excessive amounts of bycatch might result, the Secretary recognizes the bycatch permitted under these definitions is too high in many cases and further recognizes the burden that these definitions has imposed on fishermen who may not be aware of the true composition of their catches until they have observed them after retrieving their gear. The Secretary, therefore, proposes a rule that replaces the directed fishing definition and implements directed fishing standards for various groundfish species and gear types.

Pertinent to the Council's recommendations are the following three aspects of the proposed rule:

(1) The standards would be enforced on a trip basis, which means that fishermen would be held accountable for catches during the period of time since the date of last offloading or transfer of any fish or fish products, or until the vessel leaves the GOA regulatory area or district or BSAI subarea in which fishing commenced, whichever occurred first. Fishermen would be allowed to adjust catches of a species and the amounts of a species that are retained would be compared against other species and the total amount of fish and fish products retained during the same trip in determining whether the vessel was engaged in directed fishing.

(2) Any catches retained on board from a prior trip would not be used to compare the amounts of a particular species to other species and to the total amount of fish retained during a subsequent trip. A vessel is engaged in a single fishing trip from the commencement of any fishing activity until any offload or transfer of any fish or fish product from that vessel, or until the vessel leaves the GOA regulatory area or district or BSAI subarea where fishing activities commenced, whichever occurs first.

(3) The amount of a species caught in a GOA regulatory area or district or BSAI subarea can only be compared with amounts of other species and the total amount of fish and fish products on board a vessel that were caught in the same regulatory area or district or subarea. Thus, fishermen would not be allowed to calculate the percentage of a species caught in one regulatory area or

district or subarea using amounts of fish and fish products from another regulatory area or district or subarea.

As discussed below, proposed percentages used in the directed fishing standards are reduced from the codified definitions where necessary to better reflect natural rates of catch. Fishermen would have little economic incentive, if any, to target on species for which directed fishing is prohibited. As a result, if the Secretary prohibited directed fishing for a species for purposes of extending harvest of such species over a longer time period, it also would delay the point at which the species must be discarded at sea and result in reduced resource wastage. The Secretary has made a preliminary determination that this proposed rule is superior to the status quo and is consistent with the goals and objectives of both groundfish FMPs.

Editorial and related changes

The form of the proposed rule differs in several respects from the Council recommendations but is essentially the same in substance except as otherwise noted. The proposed rules establish standards for directed fishing. This approach is more flexible and will be more likely to accommodate future revisions. The actual percentages recommended by the Council are not changed except as indicated in the discussion on percentages below. In addition, the numbering and paragraph designations for various provisions are revised, some provisions are combined, and a variety of other minor revisions are included to ensure consistency, to provide clarity, and to accomplish the intent of the Council. For example, subparagraphs within the redesignated paragraph § 672.20(c)(3), *Notices of closure*, in 50 CFR part 672 are changed by renumbering and by removing the word "directed." This word makes this paragraph confusing, since it references management responses appropriate when the TAC for any target species or the "other species" category has been reached and has been declared a prohibited species.

Percentages

Recommendations made by the Council to change certain percentages used to determine whether a vessel is engaged in directed fishing in the Gulf of Alaska are limited to sablefish caught with trawl gear. Council recommendations for the BSAI are pertinent to all species.

Gulf of Alaska Groundfish

Sablefish typically are caught incidentally while targeting with trawl

gear for flounder, rockfish, pollock, and Pacific cod. The Council considered recommendations from its Advisory Panel, as well as testimony presented by the public, about the percentage of sablefish that ought to be used to define directed fishing for sablefish in the GOA by vessels using trawl gear. The Council recommended that the directed fishing percentage should be 5 percent or more for all groundfish species, except for Dover sole and Rex sole and rockfish of the genera *Sebastes* and *Sebastolobus*. For the exceptions, the directed fishing percent should be no less than 15 percent. The Council recommended this percentage to accommodate higher bycatch rates of sablefish in fisheries for Dover sole, Rex sole, and rockfish.

The Secretary proposes a directed fishing standard for sablefish caught with trawl gear in the GOA based upon 5 percent of all fish and fish products excluding rockfish of the genera *Sebastes* and *Sebastolobus*, for which the percentage is 15 percent. The Secretary is not proposing the Council's recommended percentage of Dover sole and Rex sole at this time. A definition of directed fishing for any species must be tied to an established TAC for that species. Since only a single TAC is specified for the flatfish complex, only a single definition of directed fishing for sablefish is proposed when compared to amounts of flatfish.

Prior to the Council's recommendations, NMFS had calculated that the definition of sablefish directed fishing ought to be at least 20 percent of rockfish and 10 percent of pollock and Pacific cod on the basis of the EA/RIR, using the high end in the data range. However, the recommendations of the Council also reasonably approximate the low end in the data range. The Council's recommendations for lower percentages are intended to reduce economic incentives such that individual vessels would not be encouraged to target on species for which directed fishing is prohibited. The Secretary, on the basis of the EA/RIR, concurs with the Council recommendation and proposes 15 percent to define directed fishing for sablefish when compared to amounts of rockfish on board but proposes a definition of 5 percent of all the other fish and fish products.

For sablefish caught with hook-and-line gear, the retention of sablefish in an amount that constitutes 4 percent or more of all fish and fish products retained during that trip constitutes directed fishing for sablefish. For all other species of groundfish, the retention of a species or species group in an amount that equals or exceeds 20

percent of all fish and fish products retained during the same trip constitutes directed fishing for that species or species group.

Bering Sea and Aleutian Islands Groundfish

The Council reviewed bycatch percentages recommended by NMFS to define directed fishing. Amounts of fish and fish products retained on board that are equal to, or greater than, these percentages would be considered to be directed fishing. With the exception of a sablefish bycatch percentage in rockfish and Greenland turbot fisheries, the Council adopted the recommended percentages. Although NMFS had determined that the sablefish bycatch percentage could be up to 25 percent of Greenland turbot and up to 15 percent of rockfish, the Council adopted 10 percent for both Greenland turbot and rockfish as recommended by the Advisory Panel and public testimony. The higher percentages recommended by NMFS represent the high end of the data range. However, the recommendations of the Council also reasonably approximate the low end of the data range. As with the standard for directed fishing proposed for sablefish caught with trawl gear in the Gulf of Alaska, the Council intends that the percentages be lower to remove economic incentives to target on species closed to directed fishing.

The bycatch percentages in the Bering Sea and Aleutian Islands groundfish fisheries were examined by gear type and by target fishery. The Secretary notes that these percentages vary among areas and seasons fished. Annual variation is likely, too, if stocks of any species vary substantially in abundance. As bycatch species fluctuate in abundance, changes in bycatch rates should show the same trend. For example, when sablefish is abundant, then sablefish bycatch rates would be higher for each gear type. If sablefish is not abundant, then sablefish bycatch rates would be lower.

This variability presents practical problems that must be considered when proposing bycatch rates for the fisheries. Although different bycatch rates for different times of the fishing year and for each area might be observed, the accounting by enforcement officers for discrepancies in apparent catches on board fishing vessels at this level of refinement is not feasible without inordinate management costs. Consequently, the Secretary is proposing percentages that are aggregated, using data from the combined statistical areas 51-54 of the International North Pacific Fishery

Commission. Although percentages were examined for trends, no obvious patterns were detected to warrant regulation of bycatches differently during seasons of the year.

Bycatch rates among the gear types are expected to be independent. Consequently, bycatch percentages for trawl, hook-and-line, and pot gear are summarized and proposed independently.

Monitoring and Enforcement

Compliance with the directed fishing standards would be monitored through the review of catches retained during a trip through a review of the amounts of fish and fish products on board a vessel at the completion of a trip. Part of the latter review would likely be accomplished by reviewing the vessel's catch, production, and offloading records. Although a number of specific percentages are used in the standards for directed fishing, accounting is done the same way. For example, if directed fishing for pollock is prohibited in a particular area, then a boarding officer would calculate the round weight equivalents for all species recorded to have been caught in that area during a trip, other than "other flatfish" Pacific cod, and yellowfin sole, and multiply the sum by 1 percent. Then, the boarding officer would calculate the sum of the round weight of "other flatfish" Pacific cod, and yellowfin sole caught in the same area during the trip and multiply that sum by 20 percent. The sum of the two results would be compared to the amount of pollock retained in that area during the trip. If the amount of pollock exceeded the sum, that vessel would have violated the directed fishing closure for pollock.

Classification

The Assistant Administrator for Fisheries, NOAA, has determined that this rule is necessary for the conservation and management of the groundfish fisheries off Alaska and that it is consistent with the Magnuson Act and other applicable law.

The Alaska Region, NMFS, prepared an environmental assessment for this rule that discusses the environmental, social, and economic impacts on the human environment that will occur as a result of this rule. You may obtain a copy of the EA/RIR/IRFA from the Regional Director at the address above.

The Under Secretary for Oceans and Atmosphere, NOAA, (Under Secretary) determined that this proposed rule is not a "major rule" requiring a regulatory impact analysis under Executive Order 12291. This determination is based on the socioeconomic impacts discussed in

the EA/RIR/IRFA prepared by the Alaska Region, NMFS.

The Alaska Region, NMFS, prepared an initial regulatory flexibility analysis as part of the regulatory impact review, which concludes that this proposed rule, if adopted, could have significant economic impacts on a substantial number of small entities.

Implementation and enforcement of a bycatch definition that is based on a trip basis instead of an individual haul or set basis is better for small entities than the status quo because it will allow fishermen to sort their catch over a period of time to accomplish the objective that the amount of bycatch retained is within the allowable percentage. The reduced percentages are superior to the status quo, because they reflect more accurately amounts of groundfish actually needed as bycatch and will reduce the amount of groundfish discarded at sea as prohibited species.

This rule does not contain a collection of information requirement subject to the Paperwork Reduction Act.

The Under Secretary has determined that this rule will be implemented in a manner that is consistent to the maximum extent practicable with the approved coastal zone management program of the State of Alaska. This determination has been submitted for review by the responsible State agencies under section 307 of the Coastal Zone Management Act.

This proposed rule does not contain policies with federalism implications sufficient to warrant preparation of a Federalism Assessment under Executive Order 12612.

List of Subjects in 50 CFR Parts 611, 672, and 675

Fisheries.

Dated: September 26, 1989.

James E. Douglas, Jr.,
Deputy Assistant Administrator for Fisheries,
National Marine Fisheries Service.

For the reasons set out in the preamble, parts 611, 672, and 675 are amended as follows:

PART 611—FOREIGN FISHING

1. The authority citation for part 611 continues to read as follows:

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

2. In § 611.92, paragraph (j) is added to read as follows:

§ 611.92 Gulf of Alaska Groundfish Fishery.

(j) *Directed fishing.* See 50 CFR part 672, subpart A, for standards for

directed fishing applicable to this section. These standards apply to fishing activities conducted under this section notwithstanding the definition for "directed fishing" under § 611.2 of this part. If the Regional Director determines that the amount of a target species or the "other species" category apportioned to a fishery is likely to be attained, he may establish a directed fishing allowance for that species or species group. The amount of a species or species group apportioned to a fishery is the amount in table 1 of 50 CFR part 672, as revised by inseason adjustments, for that species or species group, as identified by regulatory area or district and as further identified according to any allocation for TALFF and the apportionment for JVP. In establishing a directed fishing allowance, the Regional Director shall consider the amount of that species or species group which will be taken as bycatch in directed fishing for other species in the same regulatory area or district which is attributable to any TALFF allocation or JVP apportionment. If the Regional Director establishes a directed fishing allowance and that allowance is, or will be, reached, he will prohibit directed fishing for that species or species group in the specified regulatory area or district. The fishery closure procedures of § 611.13(c) of this part apply to the closure of an area to directed fishing under this paragraph. No person may engage in directed fishing in violation of an area closure. If directed fishing is prohibited, the amount of any catch of that species or species group equal to or greater than the amount which constitutes directed fishing under the standards in 50 CFR part 672, subpart A, may not be retained and must be treated in the same manner as a prohibited species under § 611.11 of this part.

3. In § 611.93, paragraph (b)(1)(iii) is revised and paragraph (j) is added to read as follows:

§ 611.93 Bering Sea and Aleutian Islands groundfish fishery.

(b)

(1)

(iii) *Directed fishing.* See 50 CFR part 675, subpart A, for standards for directed fishing applicable to this section. These standards apply to fishing activities conducted under this section notwithstanding the definition under § 611.2 of this part. See paragraph (j) of this section for prohibitions on directed fishing.

(j) *Prohibitions on directed fishing and restrictions on the retention of bycatch.* If the Regional Director determines that the amount of a target species or "other species" category apportioned to a fishery is likely to be attained, he may establish a directed fishing allowance for that species or species group. The amount of a species or species group apportioned to a fishery is the amount under table 1 of 50 CFR part 675, as revised by inseason adjustments, for that species or species group, as identified by subarea and as further identified according to any allocation for TALFF and the apportionment for JVP. In establishing a directed fishing allowance, the Regional Director shall consider the amount of that species or species group which will be taken as bycatch in directed fishing for other species in the same subarea which is attributable to any TALFF allocation or JVP apportionment. If the Regional Director establishes a directed fishing allowance and that allowance is, or will be, reached, he will prohibit directed fishing for that species or species group in the specified subarea. The fishery closure procedures of § 611.13 (c) of this part apply to the closure of a subarea to directed fishing under this paragraph. No person may engage in directed fishing in violation of a subarea closure. If directed fishing is prohibited, the amount of any catch of that species or species group equal to or greater than the amount which constitutes directed fishing under the standards in 50 CFR part 675, subpart A, may not be retained and must be treated in the same manner as a prohibited species under § 611.11 of this part.

PART 672—GROUND FISH OF THE GULF OF ALASKA

4. The authority citation for part 672 continues to read as follows:

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

5. In § 672.2, the definition of directed fishing is revised to read as follows:

§ 672.2 Definitions.

Directed fishing means any fishing activity which constitutes directed fishing under the standards specified in § 672.20(g) of this part.

6. In § 672.20, the heading of paragraph (c)(2) is removed, paragraphs (c)(2)(i), (ii), (iii), and (iv) are redesignated as paragraphs (c)(3), (4), (5), and (6), and revised, and new paragraphs (c)(2), (g) and (h) are added to read as follows:

§ 672.20 General limitations.

(c) Notices.

(2) *Notices prohibiting directed fishing.* If the Regional Director determines that amount of a target species or "other species" category apportioned to a fishery is likely to be reached, the Regional Director may establish a directed fishing allowance for that species or species group. The amount of a species or species group apportioned to a fishery is the amount in table 1 or, if applicable, table 2, as these amounts are revised by inseason adjustments, for that species or species group, as identified by regulatory area or district and as further identified according to any allocation for TALFF the apportionment for JVP the apportionment for DAP and, if applicable, as further identified by gear type. In establishing a directed fishing allowance, the Regional Director shall consider the amount of that species or species group which will be taken as bycatch in directed fishing for other species in the same regulatory area or district. If the Regional Director establishes a directed fishing allowance and that allowance is, or will be, reached, he will prohibit directed fishing for that species or species group in the specified regulatory area or district. No person may engage in directed fishing in violation of an applicable notice. If directed fishing is prohibited, the amount of any catch of that species or species group equal to or greater than the amount which constitutes directed fishing may not be retained and must be treated as a prohibited species under paragraph (e) of this section.

(3) *Notices of closure.* If the Regional Director determines that the TAC for any target species or of the "other species" category in a regulatory area or district in Table I has been or will be reached, the Secretary will publish a notice in the **Federal Register** declaring that the species or species group is to be treated as a prohibited species under paragraph (e) of this section in all or part of that area or district. During the time that this notice is in effect, the operator of every vessel regulated by this part must minimize the catch of that species in the area or district, or part thereof where the notice is applicable.

(4) *Notice of prohibitions or limitations.* If, in making a determination under paragraph (c)(3) of this section, the Regional Director also determines that fishing for other target species or species groups in the area, district, or part thereof where the notice applies, may lead to the overfishing of the species or species group for which

the TAC is or will be reached, the Secretary will publish a notice in the **Federal Register** specifying prohibitions or limitations designed to prevent overfishing of the species or species group for which the TAC is or will be reached. These prohibitions and limitations may prohibit the directed fishing for other species or species groups in the area, district, or part thereof where the notice applies, or may limit the time, area, or gear types which may be used in the directed fishing for the other species or species groups.

(5) *Factors to be considered.* In making a determination under paragraph (c) (3) or (4) of this section, the Secretary may allow fishing with certain gear types to continue after taking into account and issuing findings relevant to the following considerations:

(i) The risk of biological harm to a groundfish species or species group for which the TAC is or will be reached;

(ii) The risk of socioeconomic harm to authorized users of the groundfish species or species group for which the TAC is or will be reached; and

(iii) The impact that the continued closure might have on the socioeconomic well-being of other domestic fisheries.

(6) *Prohibition of JVP or TALFF fishing if PSC limit is or will be reached.* If the Regional Director determines that a PSC limit applicable to a directed JVP or TALFF fishery in a regulatory area or district in Table 1 is or will be reached, the Secretary will publish a notice of closure in the **Federal Register** prohibiting all further JVP or TALFF fishing in all or part of the regulatory area or district concerned.

(g) *Standards for directed fishing—(1) Using trawl gear for sablefish.* The operator of a vessel is engaged in the directed fishing for sablefish if at the completion of a trip sablefish caught using trawl gear is retained on the vessel in an amount equal to or greater than:

(i) 15 percent of the amount of rockfish of the genera *sebastes* and *sebastolobus* retained on the vessel during the same trip; plus

(ii) 5 percent of the total amount of all fish species not identified under paragraph (g)(1)(i) of this section retained on the vessel during the same trip.

(2) *Using hook-and-line gear for sablefish.* The operator of a vessel is engaged in the directed fishing for sablefish if at the completion of a trip sablefish caught using hook-and-line gear is retained on the vessel in an amount equal to or greater than 4

percent of the total amount of all fish species retained by the vessel during the same trip.

(3) *Other*. Except as provided under paragraphs (g) (1) and (2) of this section, the operator of a vessel is engaged in the directed fishing for a specific species or species group if at the completion of a trip that species or species group is retained on the vessel in an amount equal to or greater than 20 percent of the amount of all fish species retained on the vessel during the same trip.

(h) *Directed fishing—calculations and determinations*—(1) *Calculations*. In making any determination concerning directed fishing the amount or percentage of any species, species group or any fish or fish products will be calculated in round weight equivalents.

(2) *Trip*. A vessel is engaged in a single fishing trip from the commencement of any fishing activity until any offload or transfer of any fish or fish product from that vessel or until the vessel leaves the regulatory area or district where fishing activities commenced, whichever occurs first.

PART 675—GROUND FISH FISHERY OF THE BERING SEA AND ALEUTIAN ISLANDS AREA

7 The authority citation for part 675 continues to read as follows:

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

8. In § 675.2, the definition of directed fishing is revised to read as follows:

§ 675.2 Definitions.

Directed fishing means any fishing activity which constitutes directed fishing under the standards specified in § 675.20(h) of this part.

9. In § 675.20, paragraph (a)(8) is revised and new paragraphs (h) and (i) are added to read as follows:

§ 675.20 General limitations.

(a)

(8) If the Regional Director determines that the amount of a target species or "other species" category apportioned to a fishery is likely to be reached, the Regional Director may establish a directed fishing allowance for that species or species group. The amount of a species or species group apportioned to a fishery is the amount under table 1, as revised by inseason adjustments, for that species or species group, as identified by subarea and as further identified according to any allocation for TALFF the apportionment for JVP the apportionment for DAP and, if applicable, as further identified by gear type. In establishing a directed fishing

allowance, the Regional Director shall consider the amount of that species or species group which will be taken as bycatch in directed fishing for other species in the same subarea. If the Regional Director establishes a directed fishing allowance and that allowance is, or will be, reached, he will prohibit directed fishing for that species or species group in the specified subarea. No person may engage in directed fishing in violation of an applicable notice. If directed fishing is prohibited, the amount of any catch of that species or species group equal to or greater than the amount which constitutes directed fishing may not be retained and must be treated as a prohibited species under paragraph (c) of this section.

(h) *Standards for directed fishing*—(1) *Using trawl gear for pollock*. The operator of a vessel is engaged in the directed fishing for pollock if at the completion of a trip pollock caught using trawl gear is retained on the vessel in an amount equal to or greater than:

(i) 20 percent of the amount of all "other rockfish" Pacific cod, and yellowfin sole retained on the vessel during the same trip; plus

(ii) 1 percent of the total amount of all fish species not identified under paragraph (h)(1)(i) of this section retained on the vessel during the same trip.

(2) *Using trawl gear for yellowfin sole*. The operator of a vessel is engaged in the directed fishing for yellowfin sole if at the completion of a trip yellowfin sole caught using trawl gear is retained on the vessel in an amount equal to or greater than:

(i) 20 percent of the amount of all "other rockfish" retained on the vessel during the same trip; plus

(ii) 1 percent of the total amount of all fish species not identified under paragraph (h)(2)(i) of this section retained on the vessel during the same trip.

(3) *Using trawl gear for "other flatfish"*. The operator of a vessel is engaged in the directed fishing for "other flatfish" if at the completion of a trip "other flatfish" caught using trawl gear is retained on the vessel in an amount equal to or greater than:

(i) 20 percent of the amount of all yellowfin sole retained by the vessel during the same trip; plus

(ii) 10 percent of the amount of all Pacific cod retained on the vessel during the same trip; plus

(iii) 1 percent of the total amount of all fish species not identified under paragraphs (h)(3) (i) and (ii) of this

section retained on the vessel during the same trip.

(4) *Using trawl gear for Pacific cod*. The operator of a vessel is engaged in the directed fishing for Pacific cod if at the completion of a trip Pacific cod caught using trawl gear is retained on the vessel in an amount equal to or greater than:

(i) 20 percent of the amount of all "other flatfish, yellowfin sole, and pollock retained on the vessel during the same trip; plus

(ii) 1 percent of the total amount of all fish species not identified under paragraph (h)(4)(i) of this section retained on the vessel during the same trip.

(5) *Using trawl gear for sablefish*. The operator of a vessel is engaged in the directed fishing for sablefish if at the completion of a trip sablefish caught using trawl gear is retained on the vessel in an amount equal to or greater than:

(i) 10 percent of the amount of all Greenland turbot and rockfish retained on the vessel during the same trip; plus

(ii) 1 percent of the total amount of all fish species not identified under paragraph (h)(5)(i) of this section retained on the vessel during the same trip.

(6) *Using trawl gear for Greenland turbot*. The operator of a vessel is engaged in the directed fishing for Greenland turbot if at the completion of a trip Greenland turbot caught using trawl gear is retained on the vessel in an amount equal to or greater than:

(i) 10 percent of the total amount of all sablefish retained on the vessel during the same trip; plus

(ii) 1 percent of the total amount of all fish species not identified under paragraph (h)(6)(i) of this section retained on the vessel during the same trip.

(7) *Using trawl gear for rockfish*. The operator of a vessel is engaged in the directed fishing for rockfish if at the completion of a trip rockfish caught using trawl gear is retained on the vessel in an amount equal to or greater than:

(i) 10 percent of the total amount of all sablefish retained on the vessel during the same trip; plus

(ii) 1 percent of the total amount of all fish species not identified under paragraphs (h)(7)(i) of this section retained on the vessel during the same trip.

(8) *Using hook-and-line gear for sablefish*. The operator of a vessel is engaged in the directed fishing for sablefish if at the completion of a trip sablefish caught using hook-and-line

gear is retained on the vessel in an amount equal to or greater than:

(i) 10 percent of the amount of all Greenland turbot and rockfish retained on the vessel during the same trip; plus

(ii) 1 percent of the total amount of all fish species not identified under paragraph (h)(8)(i) of this section retained on the vessel during the same trip.

(9) *Using hook-and-line gear for Pacific cod.* The operator of a vessel is engaged in the directed fishing for Pacific cod if at the completion of a trip Pacific cod caught using hook-and-line gear in an amount equal to or greater than 1 percent of the total amount of all other fish species is retained on the vessel during the same trip.

(10) *Using hook-and-line gear for Greenland turbot.* The operator of a vessel is engaged in the directed fishing for Greenland turbot if at the completion of a trip Greenland turbot caught using hook-and-line gear is retained on the vessel in an amount equal to or greater than:

(i) 20 percent of the amount of all sablefish retained on the vessel during the same trip; plus

(ii) 1 percent of the total amount of all fish species not identified under paragraph (h)(10)(i) of this section retained on the vessel during the same trip.

(11) *Using pot gear for sablefish.* The operator of a vessel is engaged in the directed fishing for sablefish if at the completion of a trip sablefish caught using pot gear is retained on the vessel in an amount equal to or greater than 1 percent of the total amount of all other fish species retained on the vessel during the same trip.

(12) *Using pot gear for Pacific cod.* The operator of a vessel is engaged in the directed fishing for Pacific cod if at the completion of a trip Pacific cod caught using pot gear is retained on the vessel in an amount equal to or greater than 1 percent of the total amount of all other fish species retained on the vessel during the same trip.

(13) *Other.* Except as provided under paragraphs (h) (1) through (12) of this

section the operator of a vessel is engaged in the directed fishing for a specific species or species group if at the completion of a trip that species or species group is retained on the vessel in an amount equal to or greater than 20 percent of the amount of all fish species retained on the vessel during the same trip.

(i) *Directed fishing—calculations and determinations—(1) Calculations.* In making any determination concerning directed fishing the amount or percentage of any species, species group or any fish or fish products will be calculated in round weight equivalents.

(2) *Trip.* A vessel is engaged in a single fishing trip from the commencement of any fishing activity until any offload or transfer of any fish or fish product from that vessel or until the vessel leaves the subarea where fishing activities commenced, whichever occurs first.

[FR Doc. 89-23223 Filed 10-02-89; 8:45 am]

BILLING CODE 3510-22-M

Notices

Federal Register

Vol. 54, No. 190

Tuesday, October 3, 1989

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.

ACTION

Member of Performance Review Board; Meeting

AGENCY: ACTION.

ACTION: Revision of list of Performance Review Board Positions.

SUMMARY: ACTION publishes the revised list of positions which comprise the Performance Review Board established by ACTION under the Civil Service Reform Act.

FOR FURTHER INFORMATION CONTACT: Phyllis D. Beaulieu, Director of Personnel, ACTION, 1100 Vermont Avenue, NW Room 5101, (Washington, DC 20525, (202) 634-9263.

SUPPLEMENTARY INFORMATION: The Civil Service Reform Act of 1978 (CSRA), which created the Senior Executive Service (SES), requires that each agency establish one or more Performance Review Boards to review and evaluate the initial appraisal of a senior executive's performance by the supervisor and to make recommendation to the appointing authority concerning the performance of the senior executive.

The positions listed below will serve as members of the ACTION Performance Review Board:

1. Associate Director, Office of Management and Budget—Chairman
2. Executive Officer—Office of the Director
3. Comptroller

Issued in Washington, DC on September 28, 1989.

Dated: September 28, 1989.

Jane A. Kenny,

Acting Director.

[FR Doc. 89-23266 Filed 10-2-89; 8:45 am]

BILLING CODE 6050-28-M

DEPARTMENT OF AGRICULTURE

Office of the Secretary

Meat Import Limitations; Fourth Quarterly Estimate

Public Law 88-482, enacted August 22, 1964, as amended by Public Law 96-177 Public Law 100-418, and Public Law 100-449 (hereinafter referred to as the "Act"), provides for limiting the quantity of fresh, chilled, or frozen meat of bovine, sheep except lamb, and goats; and processed meat of beef or veal (Harmonized Tariff Schedule of the United States subheadings 020.10.00, 0201.20.20, 0201.20.40, 0201.20.60, 0201.30.20, 0201.30.40, 0201.30.60, 0202.10.00, 0202.20.20, 0202.20.40, 0202.20.60, 0202.30.20, 0202.30.40, 0202.30.60, 0204.21.00, 0204.22.40, 0204.23.40, 0204.41.00, 0204.42.40, 0204.43.60, and 0204.50.00), which may be imported, other than products of Canada, into the United States in any calendar year. Such limitations are to be imposed when the Secretary of Agriculture estimates that imports of articles, other than products of Canada, provided for in Harmonized Tariff Schedule of the United States subheadings 0201.10.00, 0201.20.40, 0201.20.60, 0201.30.40, 0201.30.60, 0202.10.00, 0202.20.40, 0202.20.60, 0202.30.40, 0202.30.60, 0204.21.00, 0204.22.40, 0204.23.40, 0204.41.00, 0204.42.40, 0204.43.40, and 0204.50.00 (hereinafter referred to as "meat articles"), in the absence of limitations under the Act during such calendar year, would equal or exceed 110 percent of the estimated aggregate quantity of meat articles prescribed for calendar year 1989 by subsection 2(c) as adjusted under subsection 2(d) of the Act.

As announced in the Notice published in the *Federal Register* on April 4, 1989 (54 FR 13538), the estimated aggregate quantity of meat articles other than products of Canada prescribed by subsection 2(c) as adjusted by subsection 2(d) of the Act for calendar year 1989 is 1,245.3 million pounds.

In accordance with the requirements of the Act, I have determined that the fourth quarterly estimate of the aggregate quantity of meat articles other than products of Canada which would, in the absence of limitations under the Act, be imported during calendar year 1989 is 1,160 million pounds.

Done at Washington, DC this 27th day of September, 1989.

Secretary of Agriculture.

Clayton Yeutter,

[FR Doc. 89-23334 Filed 10-2-89; 8:45 am]

BILLING CODE 3410-10-M

Determination of the Market Stabilization Price for Sugar for Fiscal Year 1990

AGENCY: Office of the Secretary.

ACTION: Notice.

SUMMARY: This notice sets forth the market stabilization price for sugar for the period October 1, 1989-September 30, 1990 as 21.95 cents per pound, raw value. In market stabilization price is needed to determine bond requirements and maximum liabilities under certain programs authorized by paragraph (ij) of additional U.S. note 3 to chapter 17 of the Harmonized Tariff Schedule of the United States (HTS).

EFFECTIVE DATE: October 1, 1989.

FOR FURTHER INFORMATION CONTACT: John Nuttall, Foreign Agricultural Service, Department of Agriculture, Washington, DC 20250, Telephone: (202) 447-2916.

SUPPLEMENTARY INFORMATION: The market stabilization price is used to determine bond requirements and maximum liabilities under certain programs authorized by paragraph (ij) of additional U.S. note 3 to chapter 17 of the Harmonized Tariff Schedule of the United States (HTS). The calculation of the market stabilization price is provided for in 7 CFR 6.300-6.302 and is the sum of (1) the price support level for the applicable fiscal year, expressed in cents per pound of raw cane sugar; (2) adjusted average transportation costs; (3) interest costs, if applicable; and (4) 0.2 cents per pound. The adjusted average transportation costs are the weighted average costs of handling and transporting domestically produced raw cane sugar from Hawaii to Gulf and Atlantic Coast points, as determined by the Secretary. Interest costs are the amount of interest, as determined and estimated by the Secretary, that would be required to be paid by a recipient of a price support loan for raw cane sugar upon repayment of the loan at full maturity. Interest costs shall only be applicable where, as under the current

sugar price support program, a price support loan recipient is not required to pay interest upon forfeiture of the loan collateral.

The Secretary of Agriculture has announced that the applicable loan rate under the price support program for sugar, expressed in cents per pound for raw cane sugar, will be 18.00 cents per pound for loans disbursed during the period October 1, 1989–September 30, 1990.

Accordingly, after appropriate review, it has been determined that the market stabilization price for fiscal year 1990 shall be 21.95 cents per pound. This consists of the 18.00 cents per pound loan rate; adjusted average transportation costs of 3.04 cents per pound; an interest cost of .71 cent per pound; and 0.2 cent per pound. The transportation further represents estimated costs for 1989 projected forward to 1990 by applying a projected increase in the producer price index (PPI) for finished goods over this time. The interest factor is based on an estimated average interest rate of 7.875 percent over the year, and a six month loan maturity period.

Notice is hereby given that, in conformity with the provisions of 7 CFR 6.300(a), the market stabilization price for sugar for fiscal year 1990 has been determined to be 21.95 cents per pound.

Signed at Washington, DC on September 28, 1989.

Jack C. Parnell,
Acting Secretary of Agriculture.
[FR Doc. 89-23268 Filed 10-2-89; 8:45 am]
BILLING CODE 3410-10-M

Animal and Plant Health Inspection Service

[Docket No. 89-161]

U.S. Veterinary Biological Product and Establishment Licenses Issued, Suspended, Revoked, or Terminated

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Notice.

SUMMARY: The purpose of this notice is to advise the public of the issuance of veterinary biological product and establishment licenses by the Animal and Plant Health Inspection Service during the month of July 1989. These

actions are taken in accordance with the regulations issued pursuant to the Virus-Serum-Toxin Act.

FOR FURTHER INFORMATION CONTACT: Joan Montgomery, Program Assistant, Veterinary Biologics, Biotechnology, Biologics, and Environmental Protection, Animal and Plant Health Inspection Service, U.S. Department of Agriculture, Room 838, Federal Building, 6505 Belcrest Road, Hyattsville, MD 20782, 436-8674.

SUPPLEMENTARY INFORMATION: The regulations in 9 CFR part 102, "Licenses For Biological Products, require that every person who prepares certain biological products that are subject to the Virus-Serum-Toxin Act (21 U.S.C. 151 *se seq.*) shall hold an unexpired, unsuspended, and unrevoked U.S. Veterinary Biological Product License. The regulations set forth the procedures for applying for a license, the criteria for determining whether a license shall be issued, and the form of the license.

Pursuant to these regulations, the Animal and Plant Health Inspection Service (APHIS) issued the following U.S. Veterinary Biological Product Licenses during the month of July 1989:

Product license code	Dated issued	Product	Establishment	Establishment license no.
1485.22	07-19-89	Encephalomyelitis Vaccine, Eastern and Venezuelan, Killed Virus	Coopers Animal Health, Inc	107
1485.23	07-19-89	Encephalomyelitis Vaccine, Eastern, Western, and Venezuelan, Killed Virus	Coopers Animal Health, Inc	107
2101.02	07-17-89	Bordetella Bronchiseptica-Erysipelothrix Rhinopathiae-Pasteurella Multocida Bacterium	Ambico, Inc	281
4637.20	07-14-89	Canine Distemper-Adenovirus Type 2-Parainfluenza-Parvovirus Vaccine—Leptospira Bacterium, Modified Live Virus.	Smithkline Beckman Corporation	189
46J7.20	07-24-89	Canine Distemper-Adenovirus Type 2-Corona-Parainfluenza-Parvovirus Vaccine—Leptospira Bacterium, Modified Live and Killed Virus.	Smithkline Beckman Corporation	189
4835.20	07-19-89	Encephalomyelitis-Influenza Vaccine—Tetanus Toxoid, Eastern and Western, Killed Virus.	Coopers Animal Health, Inc	107
4865.20	07-19-89	Encephalomyelitis Vaccine—Tetanus Toxoid, Eastern and Western, Killed Virus...	Coopers Animal Health, Inc	107
4865.23	07-19-89	Encephalomyelitis Vaccine—Tetanus Toxoid, Eastern, Western, and Venezuelan, Killed Virus.	Coopers Animal Health, Inc	107
5038.00	07-25-89	Feline Immunodeficiency Virus Antigen Test Kit	IDEXX Corporation	313
7423.00	07-21-89	Clostridium Chauvolet-Septicum-Novyi-Sordellii-Perfringens Types C&D-Haemophilus Somnus Bacterium-Toxoid.	Grand Laboratories, Inc	303
B659.00	07-21-89	Haemophilus Somnus Bacterium, For Further Manufacture	Grand Laboratories, Inc	303

Done in Washington, DC, this 28th day of September 1989.

James W. Glosser,
Administrator, Animal and Plant Health Inspection Service.
[FR Doc. 89-23267 Filed 10-2-89; 8:45 am]
BILLING CODE 3410-34-M

Cooperative State Research Service

National Agricultural Research and Extension Users Advisory Board; Meeting

According to the Federal Advisory

Committee Act of October 6, 1972 (Pub. L. 92-463, 86 Stat. 770-776), the Office of Grants and Program Systems, Cooperative State Research Service, announces the following meeting:

Name: National Agricultural Research and Extension Users Advisory Board.

Date: October 29-31, and November 1, 1989.

Time:

1:00 p.m.–5:00 p.m., October 29, 1989,
8:00 a.m.–7:00 p.m., October 30, 1989,
8:00 a.m.–7:00 p.m., October 31, 1989,
8:00 a.m.–9:00 p.m., November 1, 1989.

Place: Embassy Suites Hotel, Baton Rouge, Louisiana.

Type of Meeting: Open to the public. Persons may participate in the meeting and site visits as time and space permit.

Comments: The public may file written comments before or after the meeting with the contact person below.

Purpose: The Board will conduct an orientation session for new UAB members, review local industry operations, hear presentations on Louisiana State University and Southern University research and extension programs, and be briefed, in a joint

session with the Joint Council, on recommendations and actions of the USDA/1890 Institutions Task Force.

Contact Person for Agenda and More Information: Marshall Tarkington, Executive Secretary, National Agricultural Research and Extension Users Advisory Board; Room 432-A, Administration Building, U.S. Department of Agriculture, Washington, DC 20250-2200; telephone (202) 447-3684. Done in Washington, DC this 22nd day of September 1989.

John Patrick Jordan,
Administrator.

[FR Doc. 89-23269 Filed 10-2-89; 8:45 am]
BILLING CODE 3410-22-M

Farmers Home Administration

Submission of Information Collection to the Office of Management and Budget OMB

AGENCY: Farmers Home Administration, USDA.

ACTION: Notice.

SUMMARY: The information collection requirement described below has been submitted on OMB for emergency clearance under 5 CFR 1320.18. The agency solicits comments on subject submission. This action is necessary in order to comply with the Disaster Assistance Act of 1989 (Pub. L. 101-82).

ADDRESS: Interested persons are invited to submit comments regarding this submission. Comments should refer to the proposal by name and should be sent to: Lisa Grove, USDA Desk Officer, Office of Management and Budget, New Executive Office Building, Washington, DC 20503.

FOR FURTHER INFORMATION CONTACT: Beverly I. Craver, FmHA Business and Industry Division, USDA Room 6327-South USDA Building, 14th and Independence Avenue, SW., Washington, DC 20250, 202-475-3805.

SUPPLEMENTARY INFORMATION: The agency has submitted the proposal for collection of information as described below, to OMB for clearance as required by the Paperwork Reduction Act (44 U.S.C. Chapter 35). It is requested that OMB approve this submission within seven days.

The supporting statement shown below delineates the revisions to 7 CFR part 1980, subpart E, Business and Industrial Loan Program.

Authority: Section 3507 of the Paperwork Reduction Act, 44 U.S.C. 3407.

Supporting Statement

Amendments to 7 CFR part 1980, subpart E Implementing "Disaster Assistance for Rural Business Enterprises Guaranteed Loans"

FmHA is requesting OMB clearance of changes in the reporting and record-keeping requirements relating to 7 CFR 1980-E. FmHA seeks to implement a program of loan guarantees mandated by section 4091 of Public Law 101-82 (Disaster Assistance Act of 1989, "the Act") which will result in an increase in reporting and recordkeeping burden.

The Act provides \$200 million from the Rural Development Insurance Fund which FmHA anticipates obligating over approximately 36 months. The Act directs guarantees to rural business entities which have suffered losses or distress as a result of certain natural disasters in 1988 or 1989, which means loans will be made to existing rather than start-up operations. FmHA anticipates approving 900 loans during the 36-month period.

FmHA seeks to operate Disaster Assistance for Rural Business Enterprises or "DARBE" a guaranteed loans through the well-established Business and Industry (B&I) guaranteed loan program. The interim rule implementing the DARBE program will make amendments to subpart E of part 1980.

The DARBE program will require two new forms to be used in processing these loans. The new forms are described as follows:

Form FmHA 1980-71, "Lender's Agreement—Disaster Assistance for Rural Business Enterprises Guaranteed Loans," is used to establish a contract between FmHA and the lender for DARBE Guaranteed Loans.

This form is being used in lieu of Form FmHA 449-35, "Lender's Agreement," and Form FmHA 1980-68, "Lender's Agreement—Drought and Disaster," in order to differentiate between the programs under the Business and Industrial Loan Program. Separate forms will simplify loan processing and reporting.

FmHA estimates 300 respondents will use this form since every lender participating in the DARBE loan program will be required to execute the form. This estimate is based on the number of inquiries received from the general public, congressional offices and FmHA field offices. The estimated number of hours per response is 1.5 hours and is based in the completion time of the existing Lender's Agreements.

Form FmHA 1980-73, "Assignment Guarantee Agreement—Disaster Assistance for Rural Business Enterprises Guaranteed Loans," is used to express the terms of the guarantee and the nature and limits of contractual conditions when a holder buys a guaranteed loan.

This form is being used in lieu of Form FmHA 449-36, Assignment Guarantee Agreement, and Form FmHA 1980-70, Assignment Guarantee Agreement—Drought and Disaster, in order to differentiate between the guaranteed loan programs under the Business and Industrial Loan Program. Separate forms will simplify loan processing and reporting.

FmHA estimates 50 respondents will use this form. This estimate is based upon historical data from loans that have been sold to another holder in the open market. The estimated number of hours per response is 2 hours and is based on the completion time of the existing Assignment Guarantee Agreements.

Two new items of non-form reporting burden are also being added by this action. In appendix K, a statement is required showing the causal connection between a loss/distress and a listed 1988 or 1989 natural disaster. FmHA estimates 300 respondents with a total of 1,200 burden hours. Also, appendix K requires the applicant to furnish evidence of compliance with Sodbuster/Swampbuster requirements. FmHA estimates 50 respondents with a total of 4 burden hours. Estimates are based on historical burden data and information provided from the public and Congressional offices.

The information collected under this program is considered the minimum necessary to conform to the requirements of present program regulations established by law, such as those for intergovernmental consultation and environmental review. The information collected is considered to be the minimum necessary to ensure that the intent of the law is achieved while maintaining consistency with OMB circulars such as A-102, A-110, A-70, and A-129 and other requirements. Collection of information under the provisions of this action are not inconsistent with the guidelines of 5 CFR 1320.6.

This rule is to be published as an interim rule with a 60 day comment period to follow publication. All comments received will be analyzed and considered in finalizing the regulation.

Dated: September 29, 1989.

Neal Sox Johnson,
Acting Administrator, Farmers Home
Administration.

[FR Doc. 89-23494 Filed 10-2-89; 8:45 am]

BILLING CODE 3410-07-M

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

North Pacific Fishery Management Council; Public Meeting

AGENCY: National Marine Fisheries
Service, NOAA, Commerce.

An informal working group, drawn from the two North Pacific Fishery Management Council groundfish fishery management plan (FMP) teams will meet on October 17, 1989, at 8:30 a.m., at the National Marine Fisheries Service, Northwest and Alaska Fisheries Center, 7600 Sand Point Way, N.E., Building 4, Room 2143, Seattle, WA. The group will discuss definitions for overfishing and exchange ideas and information on overfishing to better focus the plan teams' analyses. Newly-published guidelines at 50 CFR 602.11 require that Regional Fishery Management Councils define overfishing in an objective and measurable way. The plan teams agreed at August 1989 meetings that the definition contained in the North Pacific Council's groundfish FMPs needs revision. A plan amendment to review the definition will have to be developed during the North Pacific Council's 1990 amendment cycle.

For more information contact Hal Weeks, North Pacific Fishery Management Council, P.O. Box 103136, Anchorage, AK 99510; telephone: (907) 271-2809.

Dated: September 27, 1989.

David S. Crestin,

Deputy Director, Office of Fisheries
Conservation and Management, National
Marine Fisheries Service.

[FR Doc. 89-23220 Filed 10-2-89; 8:45 am]

BILLING CODE 3510-22-M

Pacific Fishery Management Council; Public Meeting

AGENCY: National Marine Fisheries
Service, NOAA, Commerce.

The Pacific Fishery Management Council's Groundfish Management Team (GMT) will hold a public meeting on October 16-18, 1989, at the Metro Center Building, 2000 S.W. First Avenue, Room 240, Portland, OR. The GMT will

begin meeting at 1 p.m., on October 16 and will adjourn its meeting on October 18 at noon. The proposed agenda will include review of draft stock assessment documents, preparation of the annual groundfish stock assessment document for 1990, analysis of proposed measures to extend the joint venture season for Pacific whiting, and sablefish management. Other issues related to West Coast groundfish fisheries management may also be discussed.

For more information contact Lawrence D. Six, Executive Director, Pacific Fishery Management Council, 2000 S.W. First Avenue, Portland, OR 97201; telephone: (503) 326-6352.

September 27, 1989.

David S. Crestin,

Deputy Director, Office of Fisheries
Conservation and Management, National
Marine Fisheries Service.

[FR Doc. 89-23221 Filed 10-2-89; 8:45 am]

BILLING CODE 3510-22-M

Pacific Fishery Management Council; Public Meeting

AGENCY: National Marine Fisheries
Service, NOAA, Commerce.

The Pacific Fishery Management Council's groundfish fishery management plan (FMP) Rewrite Oversight Group (ROG) will hold a public meeting on October 3-4, 1989. On October 3 the meeting will begin at 10 a.m., at the Metro Center Building, Room 440, 2000 S.W. First Avenue, Portland, OR. On October 4 the meeting will continue in the Pacific Council's Chamber Room, at the same address. The ROG will make final revisions to draft Amendment #4 of the groundfish FMP so that the Pacific Council may review the draft at its November 1989 meeting in Portland, OR.

For more information contact Lawrence D. Six, Executive Director, Pacific Fishery Management Council, 2000 S.W. First Avenue, Portland, OR 97201; telephone: (503) 326-6352.

Dated: September 27, 1989.

David S. Crestin,

Deputy Director, Office of Fisheries
Conservation and Management, National
Marine Fisheries Service.

[FR Doc. 89-23222 Filed 10-2-89; 8:45 am]

BILLING CODE 3510-22-M

DEPARTMENT OF DEFENSE

Defense Logistics Agency

Meeting: Department of Defense Clothing and Textiles Board

AGENCY: Defense Logistics Agency, DoD.

ACTION: Notice of open meeting.

SUMMARY: In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92-463), the Deputy Director for Acquisition Management, Defense Logistics Agency, announces a forthcoming meeting of the Department of Defense Clothing and Textiles Board (DoD C&T Board).

DATE AND TIME: October 24, 1989, 1300-1600.

ADDRESS: Defense Logistics Agency,
Cameron Station, Room 3B247
Alexandria, VA.

FOR FURTHER INFORMATION CONTACT:
Ms. Paula Metcalf, Quality Assurance
Specialist, Product Quality Management
Division, Defense Logistics Agency,
Department of Defense, Cameron
Station, Alexandria, VA, (202) 274-7141.

SUPPLEMENTARY INFORMATION: The
agenda for the meeting will focus on
improvements to DOD acquisition of
clothing and textile products.

MG Charles R. Henry,

USA, Deputy Director, Acquisition
Management.

[FR Doc. 89-23250 Filed 10-2-89; 8:45 am]

BILLING CODE 3620-01-M

DEPARTMENT OF EDUCATION

National Board of the Fund for the Improvement of Postsecondary Education; Meeting

AGENCY: National Board of the Fund for
the Improvement of Postsecondary
Education.

ACTION: Notice of meeting.

SUMMARY: This notice sets forth the
proposed agenda of a forthcoming
meeting of the National Board of the
Fund for the Improvement of
Postsecondary Education. This notice
also describes the functions of the
Board. Notice of this meeting is required
under section 10(a)(2) of the Federal
Advisory Committee Act.

DATE: October 19, 1989, beginning at
11:30 a.m. to October 22, 1989, at 6:00
p.m..

ADDRESS: The Mayflower Hotel, 1127
Connecticut Avenue, NW., Washington,
DC 20036.

FOR FURTHER INFORMATION CONTACT:
Charles Karelis, Director, Fund for the
Improvement of Postsecondary
Education, 7th & D Streets SW
Washington, DC 20202 (202) 732-5750.

SUPPLEMENTARY INFORMATION: The
National Board of the Fund for the
Improvement of Postsecondary
Education is established under section

1001 of the Higher Education Amendments of 1980, Title X (20 U.S.C. 1135a-1). The National Board of the Fund is authorized to recommend to the Director of the Fund and the Assistant Secretary for Postsecondary Education priorities for funding and approval or disapproval of grants of a given kind.

The meeting of the National Board will be open to the public. The proposed agenda includes:

- Recommendations of National Board Subcommittee;
- Recapitulation of FY 1989 competitions;
- First joint meeting of FIPSE and FIRST (Fund for the Improvement and Reform of Schools and Teaching) Boards to provide an overview of FIPSE and FIRST priorities and programs and mutual interests;
- Discussion of proposed jointly-sponsored conference on articulation and sponsorships; and
- Observation and participation in the Fund for the Improvement of Postsecondary Education Annual Project Directors' Meeting.

Records are kept of all Board proceedings, and are available for public inspection at the office of the Fund for the Improvement of Postsecondary Education, Room 3100, Regional Office Building #3, 7th & D Streets SW Washington, DC 20202 from the hours of 8:00 a.m. to 4:30 p.m.

William L. Moran

Acting Assistant Secretary for Postsecondary Education.

[FR Doc. 89-23265 Filed 10-2-89; 8:45 am]

BILLING CODE 4000-01-M

DEPARTMENT OF ENERGY

Morgantown Energy Technology Center, Broad Agency Research Announcement, 1989; Fossil Energy Research and Development

AGENCY: Morgantown Energy Technology Center, DOE.

ACTION: Cancellation notice.

SUMMARY: The Morgantown Energy Technology Center, Department of Energy, published a Broad Agency Research Announcement for Fossil Energy Research and Development in the *Federal Register* on January 18, 1989 (54 FR 1983). That Announcement has been cancelled, effective September 30, 1989. Those proposals which have been received will, upon request of the proposer, be evaluated as unsolicited proposals.

FOR FURTHER INFORMATION CONTACT: Jerome S. Hensley, U.S. Department of Energy, Morgantown Energy Technology

Center, P.O. Box 880, Morgantown, WV 26507-0880.

Dated: September 22, 1989.

Louie L. Calaway,

Director, Acquisition and Assistance Division, Morgantown Energy Technology Center

[FR Doc. 89-23328 Filed 10-2-89; 8:45 am]

BILLING CODE 6450-01-M

Office of Fossil Energy

[FE Docket No. 89-27-NG]

Ocean State Power and Ocean State Power II

AGENCY: Office of Fossil Energy, DOE.

ACTION: Notice of orders amending an authorization to import natural gas granted to Ocean State Power and granting an authorization to import natural gas to Ocean State Power II.

SUMMARY: The Office of Fossil Energy (FE) of the Department of Energy (DOE) gives notice that it has issued two orders in FE Docket No. 89-27-NG. The first order amends DOE Economic Regulatory Administration (ERA) Opinion and Order No. 243-A in ERA Docket No. 86-62-NG, to reduce the import authority granted Ocean State Power from 100,000 Mcf per day to up to 50,000 Mcf per day of natural gas for a 20-year term. The other order grants Ocean State Power II authority to import up to 50,000 Mcf per day of natural gas for a 20-year term beginning on the date of first delivery of the import.

A copy of each order is available for inspection and copying in the Office of Fuels Programs Docket Room, 3F-056, Forrestal Building, 1000 Independence Avenue, SW Washington, DC 20585, (202) 586-9478. The docket room is open between the hours of 8:00 a.m. and 4:30 p.m., Monday through Friday, except Federal holidays.

Issued in Washington, DC, September 27 1989.

Constance L. Buckley,

Deputy Assistant Secretary for Fuels Programs, Office of Fossil Energy.

[FR Doc. 89-23328 Filed 10-2-89; 8:45 am]

BILLING CODE 6450-01-M

[FE Docket No. 89-37-NG]

Vesgas Co., Order Granting Blanket Authorization To Import and Export Natural Gas and Granting Intervention

AGENCY: Office of Fossil Energy, DOE.

ACTION: Notice of order granting blanket authorization to import natural gas from Canada and to export natural gas to Mexico.

SUMMARY: The Office of Fossil Energy (FE) of the Department of Energy gives notice that it has issued an order granting Vesgas Company (Vesgas) blanket authorization to import and export natural gas. The order issued in FE Docket No. 89-37-NG authorizes Vesgas to import up to 36.5 Bcf of Canadian natural gas and to export up to 29.2 Bcf of domestically produced natural gas to Mexico for short-term and spot market sales over separate two-year periods beginning on the dates of the first import and the first export.

A copy of the order is available for inspection and copying in the Office of Fuels Programs Docket Room, 3F-056, Forrestal Building, 1000 Independence Avenue, SW Washington, DC 20585, (202) 586-9478. The docket room is open between the hours of 8:00 a.m. and 4:30 p.m., Monday through Friday, except Federal holidays.

Issued in Washington, DC, September 27 1989.

Constance L. Buckley,

Deputy Assistant Secretary for Fuels Programs, Office of Fossil Energy.

[FR Doc. 89-23327 Filed 10-2-89; 8:45 am]

BILLING CODE 6450-01-M

[Docket No. FE C&E 89-21; Certification Notice-47]

BIO Development Corp; Notice of Filing Certification of Compliance: Coal Capability of New Electric Powerplant

AGENCY: Office of Fossil Energy, Department of Energy.

ACTION: Notice of filing.

SUMMARY: Title II of the Powerplant and Industrial Fuel Use Act of 1978, as amended, ("FUA" or "the Act") (42 U.S.C. 8301 *et seq.*) provides that no new electric powerplant may be constructed or operated as a base load powerplant without the capability to use coal or another alternate fuel as a primary energy source (section 201(a), 42 U.S.C. 8311(a), *supp.* V 1987). In order to meet the requirement of coal capability, the owner or operator of any new electric powerplant to be operated as a base load powerplant proposing to use natural gas or petroleum as its primary energy source may certify, pursuant to section 201(d), to the Secretary of Energy prior to construction, or prior to operation as a base load powerplant, that such powerplant has the capability to use coal or another alternate fuel. Such certification establishes compliance with section 201(a) as of the date it is filed with the Secretary. The Secretary is required to publish in the

Federal Register a notice reciting that the certification has been filed. One owner and operator of a proposed new electric base load powerplant has filed a

self certification in accordance with section 201(d).

Further information is provided in the SUPPLEMENTARY INFORMATION section below.

SUPPLEMENTARY INFORMATION: The following company has filed a self certification:

Name	Date received	Type of facility	Megawatt capacity	Location
Bio Development Corporation, Bedford, NH.....	09-14-89	Combined cycle cogen.....	70-86	Lowell, MA.

Amendments to the FUA on May 21, 1987 (Pub. L. 100-42) altered the general prohibitions to include only new electric base load powerplants and to provide for the self certification procedure.

Copies of this self certification may be reviewed in the Office of Fuels Programs, Fossil Energy, Room 3F-056, FE-52, Forrestal Building, 1000 Independence Avenue, SW Washington, DC 20585, phone number (202) 586-6769.

Issued in Washington, DC on September 27 1989.

Constance L. Buckley,

Deputy Assistant Secretary for Fuels Programs, Office of Fossil Energy.

[FR Doc. 89-23325 Filed 10-2-89; 8:45 am]

BILLING CODE 6450-01-M

Facilities (EPA ICR #947.04), OMB #2050-0036. This is a renewal.

Abstract: Owners and operators of hazardous waste management facilities with RCRA permits must submit and keep a copy of the instrument used to demonstrate their financial ability to pay the costs of corrective actions and closure and post-closure care for their facilities (i.e., trust fund agreement, surety bond, letter of credit, corporate guarantee, or letter from the chief financial officer). EPA will evaluate the submissions for compliance with the regulations.

Burden Statement: The estimated average public reporting and recordkeeping burden for this collection of information is about 6 hours per respondent. This estimate includes all aspects of the information collection including time for reviewing instructions, gathering data, and preparing and submitting the instrument to the Agency.

Respondents: Owners and operators of hazardous waste management facilities.

Estimated No. of Respondents: 5,247

Estimated Total Annual Burden of Respondents: 31,424 hours.

Frequency of Collection: Annually.

Send comments regarding the burden estimate, or any other aspect of these information collections, including suggestions for reducing the burden, to:

Sandy Farmer, U.S. Environmental Protection Agency, Information Policy Branch (PM-223), 401 M Street SW Washington, DC 20460, and

Marcus Peacock, Office of Management and Budget, Office of Information and Regulatory Affairs, 726 Jackson Place NW Washington, DC 20530.

Dated: September 21, 1989.

Paul Lapsley,

Director, Information and Regulatory Systems Division.

[FR Doc. 89-23295 Filed 10-2-89; 8:45 am]

BILLING CODE 6560-50-M

[FRL-3654-8]

Agency Information Collection Activities under OMB Review

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*), this notice announces that the Information Collection Request (ICR) abstracted below has been forwarded to the Office of Management and Budget (OMB) for review and comment. The ICR describes the nature of the information collection and its expected cost and burden.

DATE: Comments must be submitted on or before November 2, 1989.

FOR FURTHER INFORMATION CONTACT: Sandy Farmer at EPA, (202) 382-2740).

SUPPLEMENTARY INFORMATION:

Office of Pesticides and Toxic Substances

Title: AHERA section 210 Asbestos Liability Study (EPA ICR #1453.01). This ICR requests clearance for a new collection.

Abstract: Under section 210 of the Asbestos Hazard Emergency Response Act (AHERA), EPA must study the availability of asbestos liability insurance to local educational agencies (LEAs) and accredited asbestos abatement professionals and submit a final report to Congress by October 1, 1990. To implement this directive, EPA will survey LEAs, providers of asbestos abatement services, current/potential providers of financial assurance, and reinsurers on the changes to the cost, coverage, and availability of liability insurance over time and how these changes have affected development and implementation of management plans and inspections under AHERA.

Burden Statement: The public reporting burden for this collection of information is estimated to average 42 minutes per response for local educational agencies, providers of

ENVIRONMENTAL PROTECTION AGENCY

[FRL-3654-9]

Agency Information Collection Activities Under OMB Review

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*), this notice announces that the Information Collection Request (ICR) abstracted below has been forwarded to the Office of Management and Budget (OMB) for review and comment. The ICR describes the nature of the information collection and its expected cost and burden; where appropriate, it includes the actual data collection instrument.

DATE: Comments must be submitted on or before November 2, 1989.

FOR FURTHER INFORMATION CONTACT: Sandy Farmer at EPA, (202) 382-2740).

SUPPLEMENTARY INFORMATION:

Office of Solid Waste and Emergency Response

Title: Financial Responsibility for Hazardous Waste Management

asbestos abatement services, potential providers of financial assurance, and reinsurers, and 1 hour per response for current providers of financial assurance. These estimates include the time for reviewing instructions, searching existing data sources, gathering the data needed, and completing and reviewing the collection of information.

Respondents: Local educational agencies, providers of asbestos abatement services, potential/current providers of financial assurance, and reinsurers.

Estimated No. of Respondents: 2800.

Estimated Total Annual Burden on Respondents: 1200 hours.

Frequency of Collection: One-time.

Send comments regarding the burden estimates, or any other aspect of this collection of information, including suggestions for reducing the burden, to:

Sandy Farmer, U.S. Environmental Protection Agency, Information Policy Branch (PM-223), 401 M Street SW., Washington, DC 20460,
and

Tim Hunt, Office of Management and Budget, Paperwork Reduction Project, Washington, DC 20530; (Telephone (202) 395-3084).

Dated: September 19, 1989.

Paul Lapsley,
Director, Information and Regulatory Systems Division.

[FR Doc. 89-23296 Filed 10-2-89; 8:45 am]

BILLING CODE 6560-50-M

[FRL-3654-7]

Agency Information Collection Activities Under OMB Review

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*), this notice announces that the Information Collection Requests (ICZR) abstracted below have been forwarded to the Office of Management and Budget (OMB) for review and comment. The ICRs describe the nature of the information collection and their expected costs and burdens; where appropriate, they include the actual data collection instrument.

DATE: Comments must be submitted on or before November 2, 1989.

FOR FURTHER INFORMATION CONTACT: Sandy Farmer at EPA, (202 382-2740).

SUPPLEMENTARY INFORMATION: Office of Solid Waste and Emergency Response

Title: 1989 Hazardous Waste Report System (EPA ICR # 0976.04). This a renewal of a previously approved collection for which approval has expired; OMB # 2050-0024

Abstract: Owners and operators of hazardous waste management facilities must compile a biennial report of information on location, amount and description of hazardous waste handled. EPA uses the information to define the population of the regulated community and to expand its data base of information for rulemaking and compliance with statutory requirements.

Burden Statement: The estimated average public reporting burden for this collection of information is about 10 hours per respondent. This estimate includes all aspects of the information collection including time for reviewing instructions, gathering the data needed, and submitting the form.

Respondents: Generators and Handlers of Hazardous Waste.

Estimated No. of Respondents: 23,300.

Estimated Total Annual Burden on Respondents: 118,900 hours.

Frequency of Collection: biennial.

Title: Uniform Hazardous Waste Manifest for Generators, Transporters, and Disposal Facilities (EPA ICR # 801.07). This is a renewal of a previously approved collection; OMB # 2050-0039.

Abstract: All shipments of hazardous waste made by generators of greater than 100 kg/month must be accompanied by copies of the Uniform Hazardous Waste Manifest form. Copies of the manifest must then be signed and retained by all transporters and the designated disposal facility. The disposal facility must also check the manifest against the shipment and file a discrepancy report if necessary, and return a signed copy of the manifest to the generator.

Burden Statement: Public reporting and recordkeeping burden for this collection of information is estimated to average: 37 minutes for generators, 15 minutes for transporters, and 10 minutes for treatment, storage and disposal facilities. This includes time for reviewing instructions, gathering data, and completing and reviewing the form.

Respondents: Generators and transporters of hazardous waste and owners and operators of hazardous waste facilities.

Estimated No. of Respondents: 139,280.

Estimated Total Annual Burden on Respondents: 911,840 hours.

Frequency of Collection: One manifest per shipment.

Send comments regarding the burden estimates, or any other aspects of these information collections, including suggestions for reducing the burden to both of the following addresses:

Sandy Farmer, U.S. Environmental Protection Agency, Information Policy Branch (PM-223), 401 M Street, SW., Washington, DC 20460.

Marcus Peacock, Office of Management and Budget, Office of Information and Regulatory Affairs, 726 Jackson Place, NW., Washington, DC 20503, (Telephone (202) 395-3084).

Dated: September 21, 1989.

Paul Lapsley,
Director, Information and Regulatory System Division.

[FR Doc. 89-23297 Filed 10-2-89; 8:45 am]

BILLING CODE 6560-50-M

[FRL-3653-9]

National Advisory Council For Environmental Technology Transfer

Under Public Law 92463 (the Federal Advisory Committee Act), EPA gives notice of the second meeting of the National Advisory Council for Environmental Technology Transfer (NACETT) on October 25, 1989, from 9:00 a.m. to 4:30 p.m. in the Board Room of the American Institute of Architects, 1735 New York Avenue, NW., Washington, DC. EPA also gives notice of the meetings on October 24, 1989, of the five standing Committees of NACETT in Washington, DC.

The agenda for the second meeting of NACETT will include reports from NACETT's standing Committees and discussion by the NACETT members of these reports:

1. Environmental Financing Advisory Board
2. Technology Innovation and Economics Committee
3. State and Local Programs Committee
4. Education and Training Committee
5. International Committee.

The locations of the meetings of NACETT's Committees are listed below. The National Press Club, where four of the meetings will be held, is located at 14th and F Street, NW. All meetings will begin at 9:00 a.m. and end at 5:00 p.m..

1. Environmental Financing Advisory Board: National Press Club, Large Conference Room
2. Technology Innovation and Economics Committee: National Press Club, Zenger Room
3. State and Local Programs Committee: National Press Club, Private Dining Room

4. Education and Training Committee: National Press Club, First Amendment Room
5. International Committee: World Bank, 701 18th Street, NW Room J4009 (Attendance notification required—phone 202-475-9744).

Members of the public wishing to make comments to NACETT or any of its committees are invited to submit them in writing to R. Thomas Parker, Designated Federal Official for NACETT, by October 19, 1989. Please send comments to R. Thomas Parker (A-101 F6), EPA, 499 South Capitol Street, SW Washington, DC 20460.

The meetings will be open to the public. Additional information on the meeting may be obtained from R. Thomas Parker by writing to the above address or by calling Mr. Parker at 202-475-9741.

Dated: September 21, 1989.

R. Thomas Parker,
Designated Federal Official, National Advisory Council for Environmental Technology Transfer.

[FR Doc. 89-23233 Filed 10-2-89; 8:45 am]

BILLING CODE 6560-50-M

[OPP-00283; FRL-3654-1]

State FIFRA Issues Research and Evaluation Group (SFIREG) Working Committee on Registration and Classification and Working Committee on Enforcement and Certification; Open Meeting

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The State FIFRA Issues Research and Evaluation Group (SFIREG) Working Committee on Registration and Classification will hold a two day meeting beginning on October 2, 1989 and ending on October 3, 1989. The Working Committee on Enforcement and Certification will hold a two-day meeting beginning on October 5, 1989 and ending on October 6, 1989. This notice announces the location and times for the meetings and sets forth tentative agenda items. The meetings are open to the public.

DATES: The SPIREG Working Committee on Registration and Classification will meet on Monday, October 2, 1989 from 8:30 a.m. to 5:00 p.m. and on Tuesday, October 3, 1989 beginning at 8:30 a.m. and adjourning at approximately noon. The Working Committee on Enforcement and Certification will meet on Thursday, October 5, 1989 from 8:30 a.m. to 5:00 p.m. and on Friday, October

6, 1989 beginning at 8:30 a.m. and adjourning at approximately noon.

ADDRESS: The meeting will be held at: Grantree Inn, 1325 North Seventh Avenue, Bozeman, Montana 59715, (406) 587-5261 or (800) 624-5865.

FOR FURTHER INFORMATION CONTACT:

By mail: Arty Williams, Office of Pesticide Programs (H7506C), Environmental Protection Agency, 401 M St., SW., Washington, DC 20460.

Office location and telephone number: Rm. 1007 Crystal Mall No. 2, 1921 Jefferson Davis Highway, Arlington, VA, (703) 557-3401.

SUPPLEMENTARY INFORMATION: The tentative agenda for the meeting of the Working Committee on Registration and Classification includes the following:

1. Bulk handling policy status report.
2. Channels of trade policy update.
3. Update on the Pesticide Officials Pilot Training program.
4. Status of FIFRA 1988 regulations.
5. Good laboratory practice regulations. Update on statements of practical treatment workgroup.
7. Food Safety.
8. Report on September 11, 1989 meeting with EPA on data management and information sharing.
9. Report on the September 27 1989 chemistry workshop.
10. Status report on efforts to resolve whether nominal or lower limit concentration shall be on pesticide labels.
11. Report on the Termiticide Labeling Taskforce.
12. Enforcement issues resulting from voluntary cancellation of pesticides in response to FIFRA 1988 requirements.
13. Applicability of existing endangered species labeling.
14. EPA position on pesticide labels referring user to additional information for "other accepted uses."
15. Definitions of "low volume" and "minor use for purposes of fee apportionment under FIFRA."
16. Other topics as appropriate.

The tentative agenda for the meeting of the Working Committee on Enforcement and Certification includes the following:

1. Items 1 through 7 of the agenda topics of the Working Committee on Registration and Classification, will also be discussed at the meeting of the Working Committee on Enforcement and Certification.
2. Pesticide inspector training and status on Agency Order 3500.1.
3. National compliance strategies progress report.

4. Fiscal Year 1990 Cooperative Enforcement Agreements progress review.
5. Worker protection regulations status.
6. Enforcement case tracking resolution.
7. Certification and training regulations status.
8. Discussion on new directions for the Working Committee.
9. Update on Pesticide Enforcement Tracking System.
10. Other topics as appropriate.

Dated: September 22, 1989.

Susan H. Wayland,
Acting Director, Office of Pesticide Programs.
[FR Doc. 89-23234 Filed 10-2-89; 8:45 am]
BILLING CODE 6560-50-M

[FRL-3654-4]

National Pollutant Discharge Elimination System General Permit for Construction Related Activities in South Dakota

AGENCY: U.S. Environmental Protection Agency (EPA), Region VIII.

ACTION: Notice of issuance of final general permit.

SUMMARY: On July 28, the Region VIII Office of the Environmental Protection Agency published a Federal Register notice (54 FR 31081) of its intent to reissue a National Pollutant Discharge Elimination System (NPDES) general permit for the Construction Related Activities of Excavation Dewatering and Hydrostatic Testing conducted within the State of South Dakota, NPDES permit Number SDG-070000. This permit contains discharge requirements and standards that are based on technology and water quality consideration, prohibitions, Best Management Practices, and other conditions applicable to the types of Waste waters generated by construction facilities. Persons seeking discharge authorization under the general permit are required to submit a request for discharge approval prior to their commencement of such discharge.

Because the Region received no comments during the 30-day public comment period, the final permit is being reissued with the same conditions as contained in the draft public noticed permit. On behalf of the State of South Dakota, EPA certifies that this permit conforms to all applicable requirements of sections 301, 302, 306, and 307 of the Clean Water Act.

Economic Impact

EPA reviewed the effect of Executive Order 12291 on the general permit and

has determined the permit not to be major under that Order. The proposed permit was submitted to the Office of Management and Budget for review as required by the Executive Order.

Paperwork Reduction Act

EPA reviewed the requirements imposed on regulated facilities by this general NPDES permit under the Paperwork Reduction Act of 1980, 44 U.S.C. 3501 *et seq.* The information collection requirements of this permit have already been approved by the Office of Management and Budget under submissions made for the Clean Water Act's NPDES permit program.

The Regulatory Flexibility Act

After review of the facts presented in the notice of intent printed above, I hereby certify, pursuant to the provisions of 5 U.S.C. 605(b), that this general permit will not have a significant impact on a substantial number of small entities. Moreover, it reduces a significant administrative burden on regulated sources.

DATES: Effective Date. This General Permit shall be effective November 2, 1989.

Expiration Date This General Permit shall expire at 12:00 a.m., midnight, September 30, 1994.

FOR FURTHER INFORMATION CONTACT: Mr. Marshall Fischer, Region VIII, U.S. Environmental Protection Agency, Compliance Branch (8WM-C), 999 18th Street, Suite 500, Denver, Colorado 80202-2405, telephone (303) 293-1592 or FTS 564-1592.

SUPPLEMENTARY INFORMATION:

General Permit to Discharge under the National Pollutant Discharge Elimination System for Construction Activities in South Dakota Including Hydrostatic Testing and Excavation Dewatering—NPDES General Permit Number SDG-070000

In compliance with the provisions of the Clean Water Act, as amended (33 U.S.C. 1251 *et seq.*) (hereinafter referred to as "the Act"), facilities engaged in either construction dewatering of groundwaters and/or hydrostatic testing of fluid vessels are authorized to discharge at locations throughout the State of South Dakota to waters of the United States, in accordance with effluent limitations, monitoring requirements and other conditions set forth in parts I and II, hereof.

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Part I. Effluent Limitations and Monitoring Requirements

A. Coverage Under this Permit

1. Applicability of General Permit— This general permit is potentially applicable to all facilities conducting excavation dewatering in conjunction with construction activities, as well as pipeline hydrostatic testing with the State of South Dakota. The water discharged from any of these activities must be relatively uncontaminated and must not have the potential to contribute non-conventional or toxic pollutant loadings to the receiving stream.

2. Request for Authorization— In order to be considered eligible for authorization to discharge waste water under the terms and conditions of this permit, owner, operator, and/or the

authorized agent of any facility desiring to discharge must submit, the following information by certified letter at least thirty (30) days prior to the first anticipated date of discharge:

- a. Name, address, and descriptive location of the facility;
- b. Name of principal in charge of operation of the facility;
- c. Name of water receiving the discharge and, if known, the beneficial use classification(s) and 10-year, 7-day low flow of the water receiving the discharge;
- d. A brief description of the type of activity resulting in the discharge, including the anticipated date for commencement of the discharge, duration of the discharge, termination date of the discharge, total volume, average and maximum flow rate of the discharge, and the source of water which is to be discharged;
- e. A brief description of the type of water treatment processes employed;
- f. A map and/or schematic diagram showing area of the activity and location of the waste water flow and of any treatment system employed;

In addition for *Hydrostatic Testing Related Discharges*, the following must be included:

- g. The type of vessel being tested (e.g., pipe, tank, etc.);
- h. The type of material from which the vessel is constructed;
 - 1. Whether the vessel has been previously used or is of virgin material; and,
 - j. A description of the fluid material normally contained and/or transported through the vessel.

Such information should be submitted to:

U.S. Environmental Protection Agency, Compliance Branch, Water Management, Denver Place, Suite 500, 999 18th Street, Denver, Colorado 80202-2405, Telephone: (303) 293-1592

South Dakota Department of Water and Natural Resources, Division of Land and Water Quality, Surface Water Quality Program, Joe Foss Building, Pierre, South Dakota 57501, Telephone: (605) 773-5270

The permit issuing authority shall have up to thirty (30) days after receipt of the information to request additional data and/or deny the authorization under this general permit for any particular discharge. If the person proposing a new discharge does not receive a request for additional information or a notification of denial from the permit issuing authority, authorization to discharge in accordance with the conditions of the permit shall be deemed granted. For existing individually authorized discharges,

coverage under the general permit will not be effective unless and until the individual permit is either revoked or inactivated. The permit issuing authority may waive, at its discretion, the thirty (30) day period in special cases.

B. Definitions.

1. The "30-day (and monthly) average, is the arithmetic average of all samples collected during a consecutive 30-day period or calendar month, whichever is applicable. The calendar month shall be used for purposes of reporting self-monitoring data on discharge monitoring report forms.

2. "Daily Maximum" ("Daily Max.") is the maximum value allowable in any single sample or instantaneous measurement.

3. "Composite samples" shall be flow proportioned. The composite sample shall, as a minimum, contain at least four (4) samples collected over the compositing period. Unless otherwise specified, the time between the collection of the first sample and the last sample shall not be less than six (6) hours nor more than 24 hours. Acceptable methods for preparation of composite samples are as follows:

a. Constant time interval between samples, sample volume proportional to flow rate at time of sampling;

b. Constant time interval between samples, sample volume proportional to total flow (volume) since last sample. For the first sample, the flow rate at the time the sample was collected may be used;

c. Constant sample volume, time interval between samples proportional to flow (i.e., sample taken every "X" gallons of flow); and,

d. Continuous collection of sample, with sample collection rate proportional to flow rate.

4. A "grab" sample, for monitoring requirements, is defined as a single "dip and take" sample collected at a representative point in the discharge stream.

5. An "instantaneous" measurement, for monitoring requirements, is defined as a single reading, observation, or measurement.

6. "Upset" means an exceptional incident in which there is unintentional and temporary noncompliance with technology-based permit effluent limitations because of factors beyond the reasonable control of the permittee. An upset does not include noncompliance to the extent caused by operational error, improperly designed treatment facilities, inadequate treatment facilities, lack of preventive

maintenance, or careless or improper operation.

7 "Bypass" means the intentional diversion of waste streams from any portion of a treatment facility.

8. "Severe property damage" means substantial physical damage to property, damage to the treatment facilities which causes them to become inoperable, or substantial and permanent loss of natural resources which can reasonably be expected to occur in the absence of a bypass. Severe property damage does not mean economic loss caused by delays in production.

9. "Director" means Director of the United States Environmental Protection Agency's Water Management Division.

10. "EPA" means the United States Environmental Protection Agency.

11. "Sludge" is any solid, semi-solid or liquid residue that contains materials removed from the wastewater during treatment.

12. "Waters of the United States" means:

a. All other waters such as intrastate lakes, rivers, streams (including intermittent streams), mudflats, sandflats, "wetlands" sloughs, prairie potholes, wet meadows, playa lakes, or natural ponds the use, degradation, or destruction of which would affect or could affect interstate or foreign commerce including any such waters:

(1) Which are or could be used by interstate or foreign travelers for recreational or other purposes;

(2) From which fish or shellfish are or could be taken and sold in interstate or foreign commerce; or,

(3) Which are used or could be used for industrial purposes by industries in interstate commerce.

b. All impoundments of waters otherwise defined as waters of the United States under this definition;

c. Tributaries of waters identified in paragraphs a.-d. of this definition;

d. The territorial sea;

e. "Wetlands" adjacent to waters (other than waters that are themselves "wetlands") identified in paragraphs a.-f. of this definition.

C. Specific Limitations and Self-Monitoring Requirements

1. Effluent Limitations.

a. There shall be no discharge of any process generated waste waters except those waste waters resulting from dewatering of groundwater and/or surface runoff from construction sites and/or hydrostatic testing of pipelines or other fluid vessels.

b. This permit does not authorize discharges from dewatering activities at hazardous waste sites or discharges of toxic materials from any location.

c. There shall be no direct discharge of any solids and/or sludges generated by the treatment of the discharge.

d. There shall be no discharge of sanitary waste waters from toilets or related facilities.

e. There shall be no discharge of floating solids or visible foam in other than trace amounts.

f. No chemicals containing toxic pollutants and/or any priority pollutants listed at 40 CFR Part 401 are to be added to the discharge. No chemical, except lime or aluminum salts specifically added as an aid to the flocculation and settling of solids, may be added to the discharge unless prior permission for the use of the additive is specifically granted by the permit issuing authority.

g. The use of chlorinated water (e.g., potable tap water) for a hydrostatic test fluid shall not be allowed unless it can be demonstrated that the chlorine substantially dissipates prior to discharge and/or possesses no potential for toxic impacts to the receiving waters.

h. The permittee shall take such steps as are necessary to prevent or minimize stream scouring caused by the discharge.

i. The concentration of oil and grease in any single sample shall not exceed 10 mg/L nor shall there be a visible sheen in the discharge.

j. The pH of the discharged waters shall not be less than 6.5 nor more than 9.0 units.

k. Total suspended solids shall be limited as follows:

Parameter	Discharge limitation
Total suspended solids.	90 mg/L in any single grab or composite sample.

2. Monitoring and Reporting

a. Daily Logs. The permittee shall maintain a daily log relating to the authorized discharge(s). The log shall contain:

- (1) flow information and data,
- (2) sample results,
- (3) records of visual observations, and
- (4) notations on any problems relating to treatment of the discharge.

b. Samples shall be taken as often as necessary to provide representative information as to the nature and volume of the discharge(s). At a minimum, samples of each discharge shall be taken as follows:

(1) CONSTRUCTION DEWATERING

Anticipated average discharge rate	Pollutant parameter	Sample frequency	Sample type
Greater than 1 Cubic Foot Per Second (CFS) During the actual period of discharge.....	Flow	Daily	Instantaneous or by continuous recorder.
	pH	Weekly	Instantaneous or by continuous recorder.
	Oil and Grease	Daily	Visual.
	Oil and Grease	Monthly	Grab.
	Total Suspended Solids	Weekly	Grab or Composite.
Less than 1 Cubic Foot Per Second (CFS) During the actual period of discharge.....	Flow	Daily	Instantaneous or by continuous recorder.
	pH	Weekly	Instantaneous or by continuous recorder.
	Oil and Grease	Daily	Visual.
	Oil and Grease	Monthly	Grab.
	Total Suspended Solids	Weekly	Grab or Composite.

(2) HYDROSTATIC TESTING DISCHARGES

Anticipated average discharge rate	Pollutant parameter	Sample frequency	Sample type
Greater than 1 Cubic Foot Per Second (CFS) During the actual period of discharge.....	Flow Rate.....	Daily.....	Instantaneous or by continuous recorder.
	Flow Volume.....	Daily.....	Measure or Calculate.
	pH	Daily	Instantaneous or by continuous recorder.
	Oil and Grease	Daily	Visual.
	Oil and Grease	Monthly	Grab.
Less than 1 Cubic Foot Per Second (CFS) During the actual period of discharge.....	Total Suspended Solids	Daily	Grab or Composite.
	Flow	Daily	Instantaneous or by continuous recorder.
	Flow Volume.....	Daily.....	Measure or Calculate.
	pH	Daily	Instantaneous or by continuous recorder.
	Oil and Grease	Daily	Visual.
Oil and Grease	Monthly	Grab.	
	Total Suspended Solids	Daily	Grab or Composite.

c. If sampling performed by the permittee indicates a violation, the permittee shall notify the permit issuing authority in accordance with the provisions at part II.H. of this permit. The permittee shall also repeat the sampling and analysis and submit the results of the repeat analysis to the permit issuing authority within thirty days after becoming aware of the violation.

Part II. Monitoring Recording and Reporting Requirements

A. Representative Sampling

Samples taken in compliance with the monitoring requirements established under Part I shall be collected from the effluent stream prior to discharge into the receiving waters. Samples and measurements shall be representative of the volume and nature of the monitored discharge. Sludge samples shall be collected at a location representative of the quality of sludge immediately prior to the use-disposal practice.

B. Monitoring Procedures

Monitoring must be conducted according to test procedures approved under 40 CFR Part 136, unless other test procedures have been specified in this permit.

C. Penalties for Tampering

The Act provides that any person who falsifies, tampers with, or knowingly renders inaccurate, any monitoring

device or method required to be maintained under this permit shall, upon conviction, be punished by a fine of not more than \$10,000 per violation, or by imprisonment for not more than two years per violation, or by both.

D. Reporting of Monitoring Results

Effluent monitoring results obtained during the previous 3 months shall be summarized for each month and reported on a Discharge Monitoring Report Form (EPA No. 3320-1), postmarked no later than the 28th day of the month following the completed reporting period. If no discharge occurs during the reporting period, "no discharge" shall be reported. Legible copies of these, and all other reports required herein, shall be signed and certified in accordance with the Signatory Requirements (See part IV) and submitted to the Director, Water Management Division and the State water pollution control agency at the following addresses:

Original to: U.S. Environmental Protection Agency, Region VIII, 999 18th Street, Suite 500, Denver, Colorado 80202-2405. Attention: Water Management Division Compliance Branch (8WM-C)

Copy to: South Dakota Department of Water and Natural Resources, Division of Land and Water Quality, Surface Water Quality Program, Joe Foss Building, Pierre, South Dakota 57501

E. Additional Monitoring by the Permittee

If the permittee monitors any pollutant more frequently than required by this permit, using test procedures approved under 40 CFR 136 or as specified in this permit, the results of this monitoring shall be included in the calculation and reporting of the data submitted in the DMR. Such increased frequency shall also be indicated.

F. Records Contents

Records of monitoring information shall include:

1. The date, exact place, and time of sampling or measurements;
2. The initials or name(s) of the individual(s) who performed the sampling or measurements;
3. The date(s) analyses were performed;
4. The time(s) analyses were initiated;
5. The initials or name(s) of individual(s) who performed the analyses;
6. References and written procedures, when available, for the analytical techniques or methods used; and,
7. The results of such analyses, including the bench sheets, instrument readouts, computer disks or tapes, etc., used to determine these results.

G. Retention of Records

The permittee shall retain records of all monitoring information, including all calibration and maintenance records

and all original strip chart recordings for continuous monitoring instrumentation, copies of all reports required by this permit, and records of all data used to complete the application for this permit, for a period of at least three years from the date of the sample, measurement, report or application. This period may be extended by request of the Director at any time. Data collected on site, copies of Discharge Monitoring Reports, and a copy of this NPDES permit must be maintained on-site during the duration of activity at the permitted location.

H. Twenty-four Hour Notice of Noncompliance Reporting

1. The permittee shall report any noncompliance which may seriously endanger health or the environment as soon as possible, but no later than twenty-four (24) hours from the time the permittee first became aware of the circumstances. The report shall be made to the EPA, Region VIII, Emergency Response Branch at (303) 293-1788 and the State of South Dakota at (605) 773-3231.

2. The following occurrences of noncompliance shall be reported by telephone to the EPA, Region VIII, Compliance Branch at (303) 293-1589 and the State of South Dakota at (605) 773-3151 by the first workday (8:00 a.m.-4:30 p.m. Mountain Time) after the day the permittee became aware of the circumstances:

a. Any unanticipated bypass which exceeds any effluent limitation in the permit (See *part III.G., Bypass of Treatment Facilities.*);

b. Any upset which exceeds any effluent limitation in the permit (See *part III.H., Upset Conditions.*); or,

c. Violation of a maximum daily discharge limitation for any of the pollutants listed in the permit to be reported within 24 hours.

3. A written submission shall also be provided within five days of the time that the permittee becomes aware of the circumstances. The written submission shall contain:

a. A description of the noncompliance and its cause;

b. Period of noncompliance, including exact dates and times;

c. The estimated time noncompliance is expected to continue, if it has not been corrected; and,

d. Steps taken or planned to reduce, eliminate, and prevent reoccurrence of the noncompliance.

4. The Director may waive the written report on a case-by-case basis if the oral report has been received within 24 hours by the Compliance Branch, Water

Management Division, Denver, Colorado, by phone, (303) 293-1589.

5. Reports shall be submitted to the address in *part II.D., Reporting of Monitoring Results.*

I. Other Noncompliance Reporting

Instances of noncompliance not required to be reported within 24 hours shall be reported at the time that monitoring reports for *part II.D.* are submitted. The reports shall contain the information listed in *part II.H.2.*

J. Inspection and Entry

The permittee shall allow the Director, or an authorized representative, upon the presentation of credentials and other documents as may be required by law, to:

1. Enter upon the permittee's premises where a regulated facility or activity is located or conducted, or where records must be kept under the conditions of this permit;

2. Have access to and copy, at reasonable times, any records that must be kept under the conditions of this permit;

3. Inspect at reasonable times any facilities, equipment (including monitoring and control equipment), practices, or operations regulated or required under this permit; and,

4. Sample or monitor at reasonable times, for the purpose of assuring permit compliance or as otherwise authorized by the Act, any substances or parameters at any location.

Part III. Compliance Responsibilities

A. Duty to Comply

The permittee must comply with all conditions of this permit. Any permit noncompliance constitutes a violation of the Act and is grounds for enforcement action; for permit termination, revocation and reissuance, or modification; or for denial of a permit renewal application. The permittee shall give the Director advance notice of any planned changes at the permitted facility or of an activity which may result in permit noncompliance.

B. Penalties for Violations of Permit Conditions

The Act provides that any person who violates a permit condition implementing sections 301, 302, 306, 307, 308, 318, or 405 of the Act is subject to a civil penalty not to exceed \$25,000 per day of such violation. Any person who willfully or negligently violates permit conditions implementing sections 301, 302, 306, 307 or 308 of the Act is subject to a fine of not less than \$5,000, nor more than \$50,000 per day of violation, or by imprisonment for not more than

three (3) years, or both. Except as provided in permit conditions on *part III.G., Bypass of Treatment Facilities* and *part III.H., Upset Conditions*, nothing in this permit shall be construed to relieve the permittee of the civil or criminal penalties for noncompliance.

C. Need to Halt or Reduce Activity Not a Defense

It shall not be a defense for a permittee in an enforcement action that it would have been necessary to halt or reduce the permitted activity in order to maintain compliance with the conditions of this permit.

D. Duty to Mitigate

The permittee shall take all reasonable steps to minimize or prevent any discharge in violation of this permit which has a reasonable likelihood of adversely affecting human health or the environment.

E. Proper Operation and Maintenance

The permittee shall at all times properly operate and maintain all facilities and systems of treatment and control (and related appurtenances) which are installed or used by the permittee to achieve compliance with the conditions of this permit. Proper operation and maintenance also includes adequate laboratory controls and appropriate quality assurance procedures. This provision requires the operation of back-up or auxiliary facilities or similar systems which are installed by a permittee only when the operation is necessary to achieve compliance with the conditions of the permit. However, the permittee shall operate, as a minimum, one complete set of each main line unit treatment process, whether or not this process is needed to achieve permit effluent compliance.

F. Removed Substances

Collected screenings, grit, solids, sludges, or other pollutants removed in the course of treatment shall be buried or disposed of in such a manner so as to prevent any pollutant from entering any waters of the state or creating a health hazard. Sludge/digester supernatant and filter backwash shall not be directly blended with or enter either the final plant discharge and/or waters of the United States.

G. Bypass of Treatment Facilities

1. Bypass Not Exceeding Limitations

The permittee may allow any bypass to occur which does not cause effluent limitations to be exceeded, but only if it also is for essential maintenance to assure efficient operation. These

bypasses are not subject to the provisions of paragraphs 2. and 3. of this section.

2. Notice.

a. *Anticipated bypass.* If the permittee knows in advance of the need for a bypass, it shall submit prior notice, if possible at least 60 days before the date of the bypass.

b. *Unanticipated bypass.* The permittee shall submit notice of an unanticipated bypass as required under *part II.H., Twenty-four Hour Reporting.*

3. Prohibition of Bypass

a. Bypass is prohibited and the Director may take enforcement action against a permittee for a bypass, unless:

(1) The bypass was unavoidable to prevent loss of life, personal injury, or severe property damage;

(2) There were no feasible alternatives to the bypass, such as the use of auxiliary treatment facilities, retention of untreated wastes, or maintenance during normal periods of equipment downtime. This condition is not satisfied if adequate back-up equipment should have been installed in the exercise of reasonable engineering judgement to prevent a bypass which occurred during normal periods of equipment downtime or preventive maintenance; and,

(3) The permittee submitted notices as required under paragraph 2. of this section.

H. Upset Conditions

1. Effect of an Update

An upset constitutes an affirmative defense to an action brought for noncompliance with technology-based permit effluent limitations if the requirements of paragraph 2. of this section are met. No determination made during administrative review of claims that noncompliance was caused by upset, and before an action for noncompliance, is final administrative action subject to judicial review (i.e., Permittees will have the opportunity for a judicial determination on any claim of upset only in an enforcement action brought for noncompliance with technology-based permit effluent limitations).

2. Conditions necessary for a demonstration of upset.

A permittee who wishes to establish the affirmative defense of upset shall demonstrate, through properly signed, contemporaneous operating logs, or other relevant evidence that:

a. An upset occurred and that the permittee can identify the cause(s) of the upset;

b. The permitted facility was at the time being properly operated;

c. The permittee submitted notice of the upset as required under *Part II.H., Twenty-four Hour Notice of Noncompliance Reporting*; and,

d. The permittee complied with any remedial measures required under *part III.D., Duty to Mitigate.*

3. Burden of Proof

In any enforcement proceeding, the permittee seeking to establish the occurrence of an upset has the burden of proof.

I. Toxic Pollutants

The permittee shall comply with effluent standards or prohibitions established under section 307(a) of the Act for toxic pollutants within the time provided in the regulations that establish those standards or prohibitions, even if the permit has not yet been modified to incorporate the requirement.

J. Changes in Discharge of Toxic Substances

Notification shall be provided to the Director as soon as the permittee knows of, or has reason to believe:

1. That any activity has occurred or will occur which would result in the discharge, on a routine or frequent basis, of any toxic pollutant which is not limited in the permit, if that discharge will exceed the highest of the following "notification levels":

a. One hundred micrograms per liter (100 ug/L);

b. Two hundred micrograms per liter (200 ug/L) for acrolein and acrylonitrile; five hundred micrograms per liter (500 ug/L) for 2,4-dinitrophenol and for 2-methyl-4, 6-dinitrophenol; and one milligram per liter (1 mg/L) for antimony;

c. Five (5) times the maximum concentration value reported for that pollutant in the permit application in accordance with 40 CFR 122.21(g)(7); or,

d. The level established by the Director in accordance with 40 CFR 122.44(f).

2. That any activity has occurred or will occur which would result in any discharge, on a non-routine or infrequent basis, of a toxic pollutant which is not limited in the permit, if that discharge will exceed the highest of the following "notification levels":

a. Five hundred micrograms per liter (500 ug/L);

b. One milligram per liter (1 mg/L) for antimony;

c. Ten (10) times the maximum concentration value reported for that

pollutant in the permit application in accordance with 40 CFR 122.21(g)(7); or,

d. The level established by the Director in accordance with 40 CFR 122.44(f).

Part IV General Requirements

A. Planned Changes

The permittee shall give notice to the Director as soon as possible of any planned physical alterations or additions to the permitted facility. Notice is required only when:

1. The alteration or addition to a permitted facility may meet one of the criteria for determining whether a facility is a new source as determined in 40 CFR 122.29(b);

2. The alteration or addition could significantly change the nature or increase the quantity of pollutants discharged. This notification applies to pollutants which are subject neither to effluent limitations in the permit, nor to notification requirements under part IV.A.1., or,

3. There are any planned substantial changes to the existing sewage sludge facilities, the manner of its operation, or to current sewage sludge management practices of storage and disposal. The permittee shall give the Director notice of any planned changes at least 30 days prior to their implementation.

B. Anticipated Noncompliance

The permittee shall give advance notice of any planned changes in the permitted facility or activity which may result in noncompliance with permit requirements.

C. Permit Actions

This permit may be modified, revoked and reissued, or terminated for cause. The filing of a request by the permittee for a permit modification, revocation and reissuance, or termination, or a notification of planned changes or anticipated noncompliance, does not stay any permit condition.

D. Duty to Reapply

If the permittee wishes to continue an activity regulated by this permit after the expiration date of this permit, the permittee must apply for and obtain a new permit. The application should be submitted at least 180 days before the expiration date of this permit.

E. Duty to Provide Information

The permittee shall furnish to the Director, within a reasonable time, any information which the Director may request to determine whether cause exists for modifying, revoking and reissuing, or terminating this permit, or

to determine compliance with this permit. The permittee shall also furnish to the Director, upon request, copies of records required to be kept by this permit.

F. Other Information

When the permittee becomes aware that it failed to submit any relevant facts in a permit application, or submitted incorrect information in a permit application or any report to the Director, it shall promptly submit such facts or information.

G. Signatory Requirements

All applications, reports or information submitted to the Director shall be signed and certified.

1. All permit applications shall be signed as follows:

- a. For a corporation: By a responsible corporate officer;
- b. For a partnership or sole proprietorship: By a general partner or the proprietor, respectively;
- c. For a municipality, State, Federal, or other public agency: By either a principal executive officer or ranking elected official.

2. All reports required by the permit and other information requested by the Director shall be signed by a person described above or by a duly authorized representative of that person.

A person is a duly authorized representative only if:

- a. The authorization is made in writing by a person described above and submitted to the Director, and,
- b. The authorization specified either an individual or a position having responsibility for the overall operation of the regulated facility or activity, such as the position of plant manager, operator of a well or a well field, superintendent, position of equivalent responsibility, or an individual or position having overall responsibility for environmental matters for the company. (A duly authorized representative may thus be either a named individual or any individual occupying a named position.)

3. *Changes to authorization.* If an authorization under paragraph IV.G.2. is no longer accurate because a different individual or position has responsibility for the overall operation of the facility, a new authorization satisfying the requirements of paragraph IV.G.2. must be submitted to the Director prior to or together with any reports, information, or applications to be signed by an authorized representative.

4. *Certification.* Any person signing a document under this section shall make the following certification: attachments were prepared under my direction or supervision in accordance with a system

designed to assure that qualified personnel properly gather and evaluate the information submitted. Based on my inquiry of the person or persons who manage the system, or those persons directly responsible for gathering the information, the information submitted is, to the best of my knowledge and belief, true, accurate, and complete. I am aware that there are significant penalties for submitting false information, including the possibility of fine and imprisonment for knowing violations.

H. Penalties for Falsification of Reports

The Act provides that any person who knowingly makes any false statement, representation, or certification in any record or other document submitted or required to be maintained under this permit, including monitoring reports or reports of compliance or noncompliance shall, upon conviction be punished by a fine of not more than \$10,000 per violation, or by imprisonment for not more than two years per violation, or by both.

I. Availability of Reports

Except for data determined to be confidential under 40 CFR part 2, all reports prepared in accordance with the terms of this permit shall be available for public inspection at the offices of the State water pollution control agency and the Director. As required by the Act, permit applications, permits and effluent data shall not be considered confidential.

J. Oil and Hazardous Substance Liability

Nothing in this permit shall be construed to preclude the institution of any legal action or relieve the permittee from any responsibilities, liabilities, or penalties to which the permittee is or may be subject under Section 311 of the Act.

K. Property Rights

The issuance of this permit does not convey any property rights of any sort, or any exclusive privileges, nor does it authorize any injury to private property or any invasion of personal rights, nor any infringement of federal, state or local laws or regulations.

L. Severability

The provisions of this permit are severable, and if any provision of this permit, or the application of any provision of this permit to any circumstance, is held invalid, the application of such provision to other circumstances, and the remainder of this permit, shall not be affected thereby.

M. Transfers

This permit may be automatically transferred to a new permittee if:

1. The current permittee notifies the Director at least 30 days in advance of the proposed transfer date;
2. The notice includes a written agreement between the existing and new permittees containing a specific date for transfer of permit responsibility, coverage, and liability between them; and,
3. The Director does not notify the existing permittee and the proposed new permittee of his or her intent to modify, or revoke and reissue the permit. If this notice is not received, the transfer is effective on the date specified in the agreement mentioned in paragraph 2. above.

N. State Laws

Nothing in this permit shall be construed to preclude the institution of any legal action or relieve the permittee from any responsibilities, liabilities, or penalties established pursuant to any applicable state law or regulation under authority preserved by section 510 of the Act.

O. Reopener Provision

This permit may be reopened and modified include the appropriate effluent limitations or other appropriate requirements if one or more of the following events occurs:

1. Water Quality Standards

The water quality standards of the receiving water(s) to which the permittee discharges are modified in such a manner as to require different effluent limits than contained in this permit.

2. Wasteload Allocation

A wasteload allocation is developed and approved by the State and/or EPA for incorporation in this permit.

3. Water Quality Management Plan

A revision to the current water quality management plan is approved and adopted which calls for different effluent limitations than contained in this permit.

P. Requiring an Individual NPDES Permit

The Director may require any owner or operator covered under this permit to apply for and obtain an individual NPDES permit if:

1. The discharger is not in compliance with the conditions of this General Permit; or,

2. Conditions or standards have changed so that the discharge no longer qualifies for a General Permit.

The owner or operator must be notified in writing that an application for an individual NPDES permit is required. When an individual NPDES permit is issued to an owner or operator otherwise covered under this General Permit, the applicability of the general permit to that owner or operator is automatically terminated upon the effective date of the individual NPDES Permit.

Q. Requesting an Individual NPDES Permit

Any owner or operator covered by this general permit may request to be excluded from the coverage by applying for an individual NPDES Permit.

R. Requesting Coverage Under the General Permit

The owner or operator of a facility excluded from coverage by this General Permit, solely because that facility already has an individual permit, may request that the individual permit be revoked and that the facility be covered by this General Permit. Upon revocation of the individual permit, this General Permit shall apply to that facility.

Signed this 20th day of September 1989.

Kerrigan Clough,

Acting Regional Administrator, Region VIII.

[FR Doc. 89-23298 Filed 10-2-89; 8:45 am]

BILLING CODE 6560-50-M

FEDERAL MARITIME COMMISSION

Item Submitted for OMB Review

The Federal Maritime Commission hereby gives notice that the following item has been submitted to OMB for review pursuant to the Paperwork Reduction Act of 1980 (44 U.S.C. 3601, et seq.). Requests for information, including copies of the collection of information and supporting documentation, may be obtained from John Robert Ewers, Director, Bureau of Administration, Federal Maritime Commission, 1100 L Street, NW., Room 12211, Washington, DC 20573, telephone number (202) 523-5866. Comments may be submitted to the agency and to the Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, DC 20503, Attention: Desk Officer for the Federal Maritime Commission, within 15 days after the date of the *Federal Register* in which this notice appears.

Summary of Item Submitted for OMB Review 46 CFR part 580 (Definition of a Shipper and Availability of Mixed Commodity Rates—Docket 89-20)

FMC requests clearance of an amendment to 46 CFR part 580 which would (1) amend the definition of "shipper" to clarify the scope of the term, and (2) require that mixed commodity rates be made available only to a "shipper," as proposed, and to "shippers' associations" as presently defined in the Commission rules. A shipper using a mixed commodity rate would be required to furnish the ocean common carrier a listing of commodities. If the shipper is a non-vessel-operating common carrier (NVOCC), it would also have to indicate its FMC tariff number on the ocean carrier's bill of lading and on any service contracts to which it is a party. The Commission estimates a filing burden of 30,000 hours for 2105 carriers to implement the proposed rule's provisions. There will be no additional cost to the Federal Government for this amendment. Estimated cost to respondents for this amendment is \$150,000.

Joseph C. Polking,

Secretary.

[FR Doc. 89-23230 Filed 10-2-89; 8:45 am]

BILLING CODE 6730-01-M

San Francisco Port Commission Terminal Agreement

The Federal Maritime Commission hereby gives notice of the filing of the following agreement(s) pursuant to section 5 of the Shipping Act of 1984.

Interested parties may inspect and obtain a copy of each agreement at the Washington, DC Office of the Federal Maritime Commission, 1100 L Street, NW Room 10220. Interested parties may submit comments on each agreement to the Secretary, Federal Maritime Commission, Washington, DC 20573, within 10 days after the date of the *Federal Register* in which this notice appears. The requirements for comments are found in § 572.603 of title 46 of the Code of Federal Regulations. Interested persons should consult this section before communicating with the Commission regarding a pending agreement.

Agreement No. 224-200289

Title: San Francisco Port Commission Terminal Agreement

Parties: San Francisco Port Commission (Port) American Niugini Shipping (ANS)

Synopsis: The Agreement provides that ANS will make San Francisco its Northern California port of call and will

pay the Port 60% of the Port's tariff charges for all revenue derived from dockage and wharfage at the Port's facilities. The terms of the Agreement is for five years and may be extended for a similar term.

By Order of the Federal Maritime Commission.

Dated: September 27 1989.

Joseph C. Polking,

Secretary.

[FR Doc. 89-23231 Filed 10-2-89; 8:45 am]

BILLING CODE 6730-01-M

FEDERAL RESERVE SYSTEM

A.B.N.—Stichting, et al.—Formulations of, Acquisitions by, and Mergers of Bank Holding Companies; and Acquisitions of Nonbanking Companies

The companies listed in this notice have applied under § 225.14 of the Board's Regulation Y (12 CFR 225.14) for the Board's approval under section 3 of the Bank Holding Company Act (12 U.S.C. 1842) to become a bank holding company or to acquire voting securities of a bank or bank holding company. The listed companies have also applied under § 225.23(a)(2) of Regulation Y (12 CFR 225.23(a)(2)) for the Board's approval under section 4(c)(8) of the Bank Holding Company Act (12 U.S.C. 1843(c)(8)) and § 225.21(a) of Regulation Y (12 CFR 225.21(a)) to acquire or control voting securities or assets of a company engaged in a nonbanking activity that is listed in § 225.25 of Regulation Y as closely related to banking and permissible for bank holding companies, or to engage in such an activity. Unless otherwise noted, these activities will be conducted throughout the United States.

The applications are available for immediate inspection at the Federal Reserve Bank indicated. Once the application has been accepted for processing, it will also be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the question whether consummation of the proposal can "reasonably be expected to produce benefits to the public, such as greater convenience, increased competition, or gains in efficiency, that outweigh possible adverse effects, such as undue concentration of resources, decreased or unfair competition, conflicts of interests, or unsound banking practices. Any request for a hearing on this question must be accompanied by a statement of the reasons a written presentation would

not suffice in lieu of a hearing, identifying specifically any questions of fact that are in dispute, summarizing the evidence that would be presented at a hearing, and indicating how the party commenting would be aggrieved by approval of the proposal.

Unless otherwise noted, comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than October 25, 1989.

A. Federal Reserve Bank of Chicago, (David S. Epstein, Vice President), 230 South LaSalle Street, Chicago, Illinois 60690.

1. *A.B.N.—Stichting*, Amsterdam, The Netherlands; *ABN/LaSalle North America, Inc.*, Chicago, Illinois; *Algemene Bank Nederland N.V.* Amsterdam, The Netherlands; and *LaSalle National Corporation*, Chicago, Illinois; to acquire 100 percent of the voting shares of *Exchange Bancorp., Inc.*, Chicago, Illinois, and thereby indirectly acquire *Exchange National Bank of Chicago*, Chicago, Illinois; *Exchange Bank of DuPage*, Oak Brook, Illinois; *Exchange Bank of River Oaks*, Calumet City, Illinois; and *Exchange Bank of Lake County*, Vernon Hills, Illinois.

In connection with these applications, Applicants also propose to acquire *Exchange Securities Corp.*, Hallandale, Florida, and thereby engage in underwriting and dealing in government obligations and money market instruments pursuant to § 225.25(b)(16); and to expand Company's activities to include engaging in broker activities for stocks, bonds and other securities pursuant to § 225.25(b)(15) of the Board's Regulation Y.

Board of Governors of the Federal Reserve System, September 27 1989.

Jennifer J. Johnson,

Associate Secretary of the Board.

[FR Doc. 89-23252 Filed 10-2-89; 8:45 am]

BILLING CODE 6210-01-M

Huntington Bancshares Inc., et al., Formations of, Acquisitions by and Mergers of Bank Holding Companies

The companies listed in this notice have applied for the Board's approval under section 3 of the Banking Holding Company Act (12 U.S.C. 1842) and § 225.14 of the Board's Regulation Y (12 CFR 225.14) to become a bank holding company or to acquire a bank or bank holding company. The factors that are considered in acting on the applications are set forth in section 3(c) of the Act (12 U.S.C. 1842(c)).

Each application is available for immediate inspection at the Federal Reserve Bank indicated. Once the application has been accepted for processing, it will also be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing to the Reserve Bank or to the offices of the Board of Governors. Any comment on an application that requests a hearing must include a statement of why a written presentation would not suffice in lieu of a hearing, identifying specifically any questions of fact that are in dispute and summarizing the evidence that would be presented at a hearing.

Unless otherwise noted, comments regarding each of these applications must be received not later than October 23, 1989.

A. Federal Reserve Bank of Cleveland, (John J. Wixted, Jr., Vice President), 1455 East Sixth Street, Cleveland, Ohio 44101.

1. *Huntington Bancshares Incorporated*, Columbus, Ohio, and *Huntington Bancshares of West Virginia, Inc.*, Columbus, Ohio; to acquire 100 percent of the voting shares of *First Banc Securities, Inc.*, Morgantown, West Virginia, and thereby indirectly acquire *The First National Bank of Morgantown*, Morgantown, West Virginia; *The Peoples National Bank of Martinsburg*, Martinsburg, West Virginia; and *First Bank, N.A.*, of Uniontown, Pennsylvania. In connection with this application, *Huntington Bancshares of West Virginia, Inc.*, has also applied to become a bank holding company.

B. Federal Reserve Bank of Richmond, (Lloyd W. Bostian, Jr., Vice President), 701 East Byrd Street, Richmond, Virginia 23261.

1. *Allegheny Bankshares Corporation*, Lewisburg, West Virginia; to acquire 100 percent of the voting shares of *First National Bank in Marlinton*, Marlinton, West Virginia.

C. Federal Reserve Bank of St. Louis, (Randall C. Sumner, Vice President), 411 Locust Street, St. Louis, Missouri 63166.

1. *Liberty National Bankcorp, Inc.*, Louisville, Kentucky, and its subsidiary, *KBT Bancshares, Inc.*, Madisonville, Kentucky; to acquire 100 percent of the voting shares of *The Community Bank, Inc.*, Erlanger, Kentucky.

D. Federal Reserve Bank of Minneapolis, (James M. Lyon, Vice President), 250 Marquette Avenue, Minneapolis, Minnesota 55480.

1. *Claremont Financial Services, Inc.*, St. Paul, Minnesota; to become a bank holding company by acquiring 90.88 percent of the voting shares of *Security State Bank*, Claremont, Minnesota.

E. Federal Reserve Bank of Kansas City, (Thomas M. Hoeng, Senior Vice President), 925 Grand Avenue, Kansas City, Missouri 64198.

1. *FirstTier Financial, Inc.*, Lincoln, Nebraska; to acquire 100 percent of the voting shares of *Scottsbluff National Corporation*, Scottsbluff, Nebraska, and thereby indirectly acquire *Scottsbluff National Bank and Trust Company*, Scottsbluff, Nebraska.

2. *Hillsboro Financial Corporation*, Wichita, Kansas; to merge with *Council Grove BancShares, Inc.*, Wichita, Kansas, and thereby indirectly acquire *Council Grove National Bank*, Council Grove, Kansas; *Potwin Financial Corporation*, Wichita, Kansas, and thereby indirectly acquire *Potwin State Bank*, Potwin, Kansas; *K & B Producers, Inc.*, Wichita, Kansas, and thereby indirectly acquire *Allen County Bank & Trust*, Iola, Kansas; *Eureka Financial Corporation*, Wichita, Kansas, and thereby indirectly acquire *Citizens National Bank*, Eureka, Kansas; *Toronto Financial Corporation*, Wichita, Kansas, and thereby indirectly acquire *First National Bank*, Toronto, Kansas; and *Moline Financial Corporation*, Wichita, Kansas, and thereby indirectly acquire *Exchange State Bank*, Moline, Kansas. In connection with this application, Applicant also proposes to acquire 93.33 percent of the voting shares of *Citizens State Bank*, Moran, Kansas.

Board of Governors of the Federal Reserve System, September 27 1989.

Jennifer J. Johnson,

Associate Secretary of the Board.

[FR Doc. 89-23254 Filed 10-2-89; 8:45 am]

BILLING CODE 6210-01-M

MNC Financial, Inc., et al., Acquisition of Company Engaged in Permissible Nonbanking Activities

The organization listed in this notice has applied under § 225.23(a)(2) or (f) of the Board's Regulation Y (12 CFR 225.23(a)(2) or (f)) for the Board's approval under section 4(c)(8) of the Bank Holding Company Act (12 U.S.C. 1843(c)(8)) and § 225.21(a) of Regulation Y (12 CFR 225.21(a)) to acquire or control voting securities or assets of a company engaged in a nonbanking activity that is listed in § 225.25 of Regulation Y as closely related to banking and permissible for bank holding companies. Unless otherwise noted, such activities will be conducted throughout the United States.

The application is available for immediate inspection at the Federal Reserve Bank indicated. Once the application has been accepted for

processing, it will also be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the question whether consummation of the proposal can "reasonably be expected to produce benefits to the public, such as greater convenience, increased competition, or gains in efficiency, that outweigh possible adverse effects, such as undue concentration of resources, decreased or unfair competition, conflicts of interests, or unsound banking practices. Any request for a hearing on this question must be accompanied by a statement of the reasons a written presentation would not suffice in lieu of a hearing, identifying specifically any questions of fact that are in dispute, summarizing the evidence that would be presented at a hearing, and indicating how the party commenting would be aggrieved by approval of the proposal.

Comments regarding the application must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than October 23, 1989.

A. Federal Reserve Bank of Richmond, (Lloyd W. Bostian, Jr., Vice President), 701 East Byrd Street, Richmond, Virginia 23261

1. *MNC Financial, Inc.*, Baltimore, Maryland; to acquire ABTS, Inc., Rock Hill, South Carolina, and thereby engage in making, acquiring, and servicing first, second and third lien position mortgage loans for its own account and the account of others and making, acquiring and servicing secured and unsecured loans, conditional sales contracts and other extensions of credit to individuals for personal, family or household purposes pursuant to § 225.25(b)(1); acting as agent for credit life, accident and disability insurance directly related to an extension of credit by it or its subsidiaries pursuant to § 225.25(b)(8)(i); and acting as agent for credit collateral insurance directly related to extensions of credit by it or its subsidiaries pursuant to § 225.25(b)(8)(ii) of the Board's Regulation Y. Such insurance is limited to insuring the repayment of the outstanding balance in the event of loss or damage to property which is used as collateral for the extension of credit.

Board of Governors of the Federal Reserve System, September 27 1989.

Jennifer J. Johnson,

Associate Secretary of the Board.

[FR Doc. 89-23253 Filed 10-2-89; 8:45 am]

BILLING CODE 6210-01-M

National Westminster Bank PLC; Application To Engage de Novo in Permissible Nonbanking Activities

The company listed in this notice has filed an application under § 225.23(a)(1) of the Board's Regulation Y (12 CFR 225.23(a)(1)) for the Board's approval under section 4(c)(8) of the Bank Holding Company Act (12 U.S.C. 1843(c)(8)) and § 225.21(a) of Regulation Y (12 CFR 225.21(a)) to commence or to engage *de novo*, either directly or through a subsidiary, in a nonbanking activity that is listed in § 225.25 of Regulation Y as closely related to banking and permissible for bank holding companies. Unless otherwise noted, such activities will be conducted throughout the United States.

The application is available for immediate inspection at the Federal Reserve Bank indicated. Once the application has been accepted for processing, it will also be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the question whether consummation of the proposal can "reasonably be expected to produce benefits to the public, such as greater convenience, increased competition, or gains in efficiency, that outweigh possible adverse effects, such as undue concentration of resources, decreased or unfair competition, conflicts of interests, or unsound banking practices. Any request for a hearing on this question must be accompanied by a statement of the reasons a written presentation would not suffice in lieu of a hearing, identifying specifically any questions of fact that are in dispute, summarizing the evidence that would be presented at a hearing, and indicating how the party commenting would be aggrieved by approval of the proposal.

Comments regarding the application must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than October 19, 1989.

A. Federal Reserve Bank of New York, (William L. Rutledge, Vice President), 33 Liberty Street, New York, New York 10045

1. *National Westminster Bank PLC*, London, England; *Natwest Holdings, Inc.*, Wilmington, Delaware; and *National Westminster Bancorp, Inc.*, New York, New York; to engage *de novo* through its subsidiary, *Natwest Leasing Corp.*, New York, New York, in leasing personal or real property or acting as agent, broker, or adviser in leasing such property in accordance with the provisions of § 225.25(b)(5); and making, acquiring, or servicing loans or other

extensions of credit for the subsidiary's own account or for the account of others, such as would be made, acquired or serviced by a commercial finance company pursuant to § 225.25(b)(1) of the Board's Regulation Y

Board of Governors of the Federal Reserve System, September 27 1989.

Jennifer J. Johnson,

Associate Secretary of the Board.

[FR Doc. 89-23255 Filed 10-2-89; 8:45 am]

BILLING CODE 6210-01-M

Change in Bank Control Notices; Acquisitions of Shares of Banks or Bank Holding Companies

The notificants listed below have applied under the Change in Bank Control Act (12 U.S.C. 1817(j)) and § 225.41 of the Board's Regulation Y (12 CFR 225.41) to acquire a bank or bank holding company. The factors that are considered in acting on the notices are set forth in paragraph 7 of the Act (12 U.S.C. 1817(j)(7)).

The notices are available for immediate inspection at the Federal Reserve Bank indicated. Once the notices have been accepted for processing, they will also be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing to the Reserve Bank indicated for that notice or to the offices of the Board of Governors. Comments must be received not later than October 13, 1989.

A. Federal Reserve Bank of New York, (William L., Rutledge, Vice President), 33 Liberty Street, New York, New York 10045

1. *Siggi B. Wilzig, c/o The Trust Company of New Jersey*, Jersey City, New Jersey; to acquire 5.4 percent of the voting shares of *The Trust Company Bancorporation*, Jersey City, New Jersey, and thereby acquire indirectly *The Trust Company of New Jersey*, Jersey City, New Jersey.

B. Federal Reserve Bank of Cleveland, (John J. Wixted, Jr., Vice President), 1455 East Sixth Street, Cleveland, Ohio 44101.

1. *Jack A. Coblenz and Carole A. Coblenz*, New Madison, Ohio; to retain up to 13.51 percent of the voting shares of *FSB Financial Corp.*, New Madison, Ohio, and thereby indirectly control *Farmers State Bank & Trust Co.*, New Madison, Ohio.

C. Federal Reserve Bank of Minneapolis, (James M. Lyon, Vice President), 250 Marquette Avenue, Minneapolis, Minnesota 55480

1. *Barbara Lee Bacich*, Anna Maria, Florida; to acquire an additional 3.45 percent of the voting shares of *Little*

Mountain Bancshares, Inc., Monticello, Minnesota, for a total of 14.03 percent, and thereby indirectly acquire First National Bank of Monticello, Monticello, Minnesota.

D. Federal Reserve Bank of Kansas City, (Thomas M. Hoenig, Senior Vice President), 925 Grand Avenue, Kansas City, Missouri 64198

1. *Robert W Kaplan*, Wichita, Kansas; *Yale J. Kaplan*, Omaha, Nebraska; *Calvin L. McMillan*, Wichita, Kansas; and *Carl Chuzy*, Wichita, Kansas; to each acquire an additional 7.55 percent of the voting shares of Andover Banc Shares, Inc., Andover, Kansas, and thereby indirectly acquire National Bank of Andover, Andover, Kansas.

2. *John F.Y. Stambaugh Living Trust*, *John F.Y. Stambaugh*, trustee, Tulsa, Oklahoma, to acquire 16.27 percent, and *Elizabeth L. Stambaugh Living Trust*, *Elizabeth L. Stambaugh*, trustee, Tulsa, Oklahoma, to acquire 10.05 percent of the voting shares of Security Bancshares, Inc., Tulsa, Oklahoma, and thereby indirectly acquire Security Bank, Tulsa, Oklahoma.

E. Federal Reserve Bank of Dallas, (W. Arthur Tribble, Vice President), 400 South Akard Street, Dallas, Texas 75222.

1. *John W Hancock*, El Campo, Texas, to acquire 2.39 percent of the voting shares of Louise Bancshares, Inc., Louise, Texas, and thereby indirectly acquire The First State Bank, Louise, Texas, and The Wallis State Bank, Wallis Texas.

Board of Governors of the Federal Reserve System, September 27 1989.

Jennifer J. Johnson,

Associate Secretary of the Board.

[FR Doc. 89-23256 Filed 10-2-89; 8:45 am]

BILLING CODE 6210-01-M

FEDERAL RETIREMENT THRIFT INVESTMENT BOARD

Employee Thrift Advisory Council; Open Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92-463), a notice is hereby given of the following committee meeting:

Name: Employee Thrift Advisory Council.
Time and date: 10:00 a.m., October 17, 1989.

Place: Fifth Floor Conference Room, Federal Retirement Thrift Investment Board, 805 Fifteenth Street NW., Washington, D.C.

Status: Open.

Matters to be Considered: Approval of the minutes of the July 12, 1989, meeting; report of the Executive Director on the status of the Thrift Savings Plan; legislation; loan program/process; TSP change of address process; November 15, 1989—January 31, 1990, Open Season; and new business.

Any interested person may attend, appear before, or file statements with the Council. For further information contact John J. O'Meara, Committee Management Officer, on (202) 523-6367

Dated: September 27 1989.

Francis X. Cavanaugh,

Executive Director.

[FR Doc. 89-23242 Filed 10-2-89; 8:45 am]

BILLING CODE 6710-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 89N-0416]

Vitarine Pharmaceuticals, Inc., Proposal To Withdraw Approval of Abbreviated Antibiotic Drug Applications and Abbreviated New Drug Applications; Opportunity for a Hearing

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is proposing to withdraw approval of certain abbreviated antibiotic drug applications (AADA's) and abbreviated new drug applications (ANDA's) held by Vitarine Pharmaceuticals, Inc., 227-15 North Conduit Ave., Springfield Gardens, NY 11413 (hereinafter referred to as Vitarine). The basis for the proposal is that the applications contain untrue statements of material fact and that the drugs covered by these applications lack substantial evidence of effectiveness.

DATES: A hearing request is due on November 2, 1989; data and information in support of the hearing request are due on December 4, 1989.

ADDRESS: Requests for hearing, supporting data, and other comments should be identified with Docket No. 89N-0416, and submitted to the Dockets Management Branch (HFA-305), Rm. 4-62, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857

FOR FURTHER INFORMATION CONTACT: Margaret F. Sharkey, or Walter A. Brown, Division of Regulatory Affairs (HFD-366), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857 301-295-8041.

SUPPLEMENTARY INFORMATION:

Background

Vitarine manufactures antibiotic and nonantibiotic drugs at two manufacturing facilities, Springfield Gardens, NY, and St. Croix, Virgin Islands.

During review of one of Vitarine's ANDA's, FDA questioned whether a pilot batch of product may have been produced in the Springfield Gardens plant and not in the St. Croix plant as claimed in the application. An FDA investigator visited the Springfield Gardens plant on February 14, 1989, to determine the actual manufacturing location of the pilot batch in question.

FDA conducted a followup inspection at the St. Croix plant on April 3, 1989. Based on the information uncovered at the St. Croix plant, FDA investigators returned to the Springfield Gardens plant on May 1, 1989. During these inspections, FDA found evidence that documents such as batch records had been falsified or destroyed. At the end of the inspections, FDA issued Notices of Inspectional Observations (Form FD 483's) at both the St. Croix and the New York facilities. These notices detailed the instances of falsified or missing records relating to certain product approvals. By letters dated June 23, July 5, and July 27 1989, Vitarine responded to the FD-483 observations for the New York facility.

At a meeting on June 28, 1989, between FDA and Vitarine, the firm revealed that the retention samples from bioequivalency testing of its triamterene 50 milligrams (mg) and hydrochlorothiazide 25 mg capsules (covered by ANDA 71-737) were not actually its product. Specifically, the firm's capsules had been filled with material that appeared to be the innovator's product. In bioequivalency testing, the generic product is compared with the innovator's product. Approval of Vitarine's product was withdrawn in a notice published in the **Federal Register** of August 28, 1989 (54 FR 35535). In a letter dated July 19, 1989, Vitarine supplied information pertaining to the falsification of records for several applications not covered by the inspections.

Based on the information obtained from inspections of the Vitarine plants in New York and the Virgin Islands, and information supplied by Vitarine, the Director of the Center for Drug Evaluation and Research has determined that approval of the AADA's and ANDA's listed below should be withdrawn because they contain untrue statements of material fact and because there is a lack of substantial evidence that the drugs will have the effects they purport to have in their labeling. These applications contain false records or records that are presumed to be false concerning batches of product that were used to document that the firm can properly manufacture its products, and

to perform tests necessary for approval (e.g., bioequivalence testing, stability testing, validation studies). A discussion of the evidence that supports the determination that Vitarine's applications contain untrue statements of material fact, and that there is a lack of substantial evidence of effectiveness for these drugs, follows:

AADA 62-910; Clindamycin HCl 75 mg and 150 mg Capsules

In support of AADA 62-910, Vitarine submitted copies of batch records 870501, 870502, 870504 through 870506, and 870416. During the inspection of the New York facility, FDA investigators discovered numerous discrepancies between records at the firm and records submitted to FDA in this AADA. First, based on the raw material receiving records, there was insufficient raw material available to Vitarine to produce the batch sizes reported to FDA. Second, on stability sample containers, original batch numbers were crossed out and new batch numbers applied, raising questions about whether the batches actually tested were those reported to FDA as having been tested. Third, stability records for certain batches show that batches were allegedly put on stability testing programs before their manufacturing dates noted on the batch records. Fourth, entries in a "research and development" notebook at the firm show that the batch sizes for batches 870416 and 870504 were each 5,000 capsules, whereas the batch records for batch 870416 submitted in the AADA report 80,000 capsules as the batch size and the batch records for batch 870504 submitted in the AADA report 150,000 capsules as the batch size. Fifth, the product inventory is much less than would be expected from the yield reported in the batch records submitted to FDA. Sixth, laboratory records for batch 870504 show a greater average capsule fill weight than allowed by the encapsulation specifications; no documentation of this was included in the batch record for 870504 submitted with the AADA. Finally, there are discrepancies between the batch records submitted with the AADA, the firm's analytical findings, and the manufacturer's certificate of analysis concerning the potency of the clindamycin used in the batches.

In response to a number of these discrepancies, Vitarine stated in its July 27 letter to FDA that it appeared that only two batches were actually manufactured, rather than six as reported in the AADA.

These discrepancies show that various statements on the batch records (e.g., manufacturing dates, active

ingredient potencies, batch size, quantities of components used in the batches, all calculations that rely on or utilize quantities of components, all control records that rely on or utilize quantities of components, and representations that the manufacturing steps were conducted in accord with the batch records) and statements on the stability test records (e.g., batch identifiers, number of batches tested) are untrue. These statements are untrue statements of material fact in that they concern matters that could have influenced approval of the application.

Moreover, the discovery of these untrue statements constitutes new information demonstrating that there is a lack of substantial evidence that the drug will have the effect it purports to have under the conditions of use prescribed, recommended, or suggested in its labeling. Without reliable information as to the qualitative and quantitative formula, manufacturing process, and size of the test batches on which the bioequivalence and stability studies were performed, the agency cannot assume that the results of these studies are applicable to the approved, marketed product. In the absence of reliable data demonstrating stability and bioequivalence to the listed drug, there is a lack of substantial evidence of effectiveness.¹

ANDA 71-711; Indomethacin 25 mg Capsules

During the inspection of the New York facility, FDA noted various discrepancies between the records for batch 860608 at the firm and the records for this batch submitted to FDA with the ANDA. No original batch production records exist for 860608. However, copies of the batch production records were found at the firm. These records are not initialed, yet the copies submitted with the ANDA are initialed. There are also discrepancies between

Although ANDA's and AADA's are approved for generic drugs without the submission of adequate and well-controlled clinical efficacy studies, which are required under the substantial evidence standard in 21 U.S.C. 355(d), these approvals are supported by such clinical efficacy studies based on a showing of bioequivalence to the listed, approved drug. The listed drug, to be approved by the agency, must be demonstrated effective based on clinical efficacy studies satisfying the substantial evidence requirement or must be related through bioequivalence data to another drug that has been demonstrated effective based on such studies. In the absence of reliable information showing bioequivalence between the generic drug at issue and the listed drug, and in the absence of information demonstrating stability of the generic drug throughout its labeled shelf-life, there is no basis for assuming that the clinical efficacy studies supporting the approval of the listed drug likewise support the claims of efficacy on the part of the generic drug.

the firm's raw material production inventory and disposition records and the batch records. For example, the batch records show that a certain lot of raw material was in the batch, but the firm's inventory record does not show a transfer of the material to the firm's Research and Development Department (where batch 860608 was produced) until after the reported date of the batch's manufacture. In addition, there exists a significant discrepancy between the amount of product remaining from batch 860608 and the amount claimed to have been produced. The theoretical yield from this batch was 45,000 capsules. The equivalent of only 3,177 capsules was accounted for and there were no records that any capsules had been destroyed.

These discrepancies show that various statements on the batch records are untrue (e.g., batch size, type, and quantities of components used in the batch, all calculations that rely on or utilize quantities of components, all control records that rely on or utilize quantities of components, and representations that the manufacturing steps were conducted in accord with the batch records). These statements are untrue statements of material fact in that they concern matters that could have influenced approval of the application.

Moreover, the discovery of these untrue statements constitutes new information demonstrating that there is a lack of substantial evidence that the drug will have the effect it purports to have under the conditions of use prescribed, recommended, or suggested in its labeling. Without reliable information as to the qualitative and quantitative formula, manufacturing process, and size of the test batches on which the bioequivalence and stability studies were performed, the agency cannot assume that the results of these studies are applicable to the approved, marketed product. In the absence of reliable data demonstrating stability and bioequivalence to the listed drug, there is a lack of substantial evidence of effectiveness.

ANDA 71-712; Indomethacin 50 mg Capsules

During the inspection of the New York facility, FDA noted various discrepancies between the batch production records for lot 860408 and the records for this batch submitted to FDA with the ANDA. No original batch production records exist for lot 860408. However, copies of the records were found at the firm. These copies are not initialed, yet the copies submitted to

FDA are initialed. There are significant discrepancies between the amount of product remaining from batch 860408 and the amount claimed to have been produced. Although the batch production records show a yield of 30,000 capsules, the equivalent of only 1,070 capsules were accounted for and there were no records that any capsules had been destroyed. In addition, the "research and development" notebook for this batch shows a size of 15,000 capsules. There are also discrepancies between the raw material production inventory and disposition records and the batch records.

From the discrepancies it follows that various additional statements on the batch records are untrue (e.g., batch size, quantities of components used in the batch, all calculations that rely on or utilize quantities of components, all control records that rely on or utilize quantities of components, and representations that the manufacturing steps were conducted in accord with the batch records). There are also untrue statements on the stability test records for the batch. Furthermore, batch identifiers on the stability samples at the firm were altered. These statements are untrue statements of material fact in that they concern matters that could have influenced approval of the ANDA.

Moreover, the discovery of these untrue statements constitutes new information demonstrating that there is a lack of substantial evidence that the drug will have the effect it purports to have under the conditions of use prescribed, recommended, or suggested in its labeling. Without reliable information as to the qualitative and quantitative formula, manufacturing process, and size of the test batches on which the bioequivalence and stability studies were performed, the agency cannot assume that the results of these studies are applicable to the approved, marketed product. In the absence of reliable data demonstrating stability and bioequivalence to the listed drug, there is a lack of substantial evidence of effectiveness.

ANDA 71-531; Indomethacin ER (Extended Release) 75 mg Capsules

During the inspection of Vitarine's New York facility, FDA investigators noted discrepancies between the batch and production records at the firm for batch 860511, the batch used for bioequivalence testing, and the full statement of the composition of the drug and the full list of articles used as components of the drug submitted with the ANDA. Thus, ANDA 71-531 contains untrue statements of material fact regarding the composition of the drug

product that could have influenced approval of the ANDA.

Moreover, the discovery of these untrue statements constitutes new information demonstrating that there is a lack of substantial evidence that the drug will have the effect it purports to have under the conditions of use prescribed, recommended, or suggested in its labeling. Without reliable information as to the qualitative and quantitative formula, and manufacturing process on which the bioequivalence and stability studies were performed, the agency cannot assume that the results of these studies are applicable to the approved, marketed product. In the absence of reliable data demonstrating stability and bioequivalence to the listed drug, there is a lack of substantial evidence of effectiveness.

ANDA 72-179; Mefenamic Acid 250 mg Capsules

In support of ANDA 72-179, Vitarine submitted a copy of the batch records for batch 870125. The inspection of Vitarine's New York facility revealed that the firm's receiving records show that there was insufficient raw material available to produce the quantity of product reported for the batch. There were no raw material usage records for this batch at the firm. Vitarine, in its July 27 letter, states that it believes the records were destroyed. In addition, a lab notebook at the firm reported the batch size to be 8,000 capsules whereas the batch records submitted to FDA report the batch size as 35,000 capsules. A significant discrepancy also exists between the amount of product remaining from batch 870125 and the batch record in that only 4,097 capsules remain at the firm and there were no destruction records for this batch.

From these discrepancies it follows that additional statements on the batch records are untrue (e.g., batch size, quantities of components used in the batch, all calculations that rely on or utilize quantities of components, all control records that rely on or utilize quantities of components, and representations that the manufacturing steps were conducted in accord with the batch records). These statements were untrue statements of material fact in that they concern matters that could have influenced approval of the ANDA.

Moreover, the discovery of these untrue statements constitutes new information demonstrating that there is a lack of substantial evidence that the drug will have the effect it purports to have under the conditions of use prescribed, recommended, or suggested in its labeling. Without reliable information as to the qualitative and

quantitative formula, manufacturing process, and size of the test batches on which the bioequivalence and stability studies were performed, the agency cannot assume that the results of these studies are applicable to the approved, marketed product. In the absence of reliable data demonstrating stability and bioequivalence to the listed drug, there is a lack of substantial evidence of effectiveness.

ANDA 71-832, Trimipramine 25 mg Capsules; ANDA 71-833, Trimipramine 50 mg Capsules; and ANDA 71-834; Trimipramine 100 mg Capsules

Various batch records were submitted in support of ANDA's 71-832, 71-833, and 71-834. FDA investigators, during an inspection of Vitarine's New York facilities, discovered records that indicate that the batch records submitted to FDA do not accurately reflect the amounts of active ingredients used in producing the batches. The receiving records for certain materials to be used in the batches and a research notebook entry for one particular batch (861108) show that the batches had to be smaller than reported to FDA. The firm has conceded that the batch records do not accurately state the amount of active ingredients used. In addition, there is a large discrepancy between the amounts of product remaining from the three batches and the amounts claimed to have been produced in the batch records submitted to FDA. There are no records of destruction or distribution of the remainder of these batches.

These discrepancies also show that various additional statements on the batch records are untrue (e.g., batch size, quantities of components used in the batches, all calculations that rely on or utilize quantities of components, all control records that rely on or utilize quantities of components, and representations that the manufacturing steps were conducted in accord with the batch records). These statements are untrue statements of material fact in that they concern matters that could have influenced approval of the ANDA's.

Moreover, the discovery of these untrue statements constitutes new information demonstrating that there is a lack of substantial evidence that the drug will have the effect it purports to have under the conditions of use prescribed, recommended, or suggested in its labeling. Without reliable information as to the qualitative and quantitative formula, manufacturing process, and size of the test batches on which the bioequivalence and stability studies were performed, the agency

cannot assume that the results of these studies are applicable to the approved, marketed product. In the absence of reliable data demonstrating stability and bioequivalence to the listed drug, there is a lack of substantial evidence of effectiveness.

AADA 61-471; Tetracycline Hydrochloride 250 mg and 500 mg Capsules

In support of AADA 61-471, Vitamine submitted records for batches 861006, 861205, and 861207. In its July 19 letter, Vitamine revealed that records at the firm indicate that there was insufficient active ingredient to produce the batch sizes reported in the AADA for batches 861006, 861205, and 861207. The firm also noted, based on the formulator's notebook, that the three batches, represented as separate batches in the AADA, were probably the same batch.

These discrepancies show that various additional statements on the batch records are untrue (e.g., batch identification, batch size, quantities of components used in the batches, all calculations that rely on or utilize quantities of components, all control records that rely on or utilize quantities of components, and representations that the manufacturing steps were conducted in accord with the batch records) and that certain batch records may be complete fabrications. These statements are untrue statements of material fact in that they concern matters that could have influenced approval of the AADA.

Moreover, the discovery of these untrue statements constitutes new information demonstrating that there is a lack of substantial evidence that the drug will have the effect it purports to have under the conditions of use prescribed, recommended, or suggested in its labeling. Without reliable information as to the qualitative and quantitative formula, manufacturing process, and size of the test batches on which the bioequivalence and stability studies were performed, the agency cannot assume that the results of these studies are applicable to the approved, marketed product. In the absence of reliable data demonstrating stability and bioequivalence to the listed drug, there is a lack of substantial evidence of effectiveness.

AADA 62-227; Doxycycline Hyclate 100 mg Capsules

In support of AADA 62-227, Vitamine submitted records for batches 860409, 861209, and 861210. In its July 19 letter, the firm disclosed that records at the firm show that there was insufficient active ingredient to produce the batch sizes reported in the AADA for batches

860409, 861209, and 861210. The firm also disclosed that, based on entries in a formulator's notebook, it appears that all three batches, represented as separate batches in the AADA, were actually one batch.

These discrepancies show that various additional statements on the batch records are untrue (e.g., batch identifiers, batch size, quantities of components used in the batches, all calculations that rely on or utilize quantities of components, all control records that rely on or utilize quantities of components, and representations that the manufacturing steps were conducted in accord with the batch records) and that certain batch records may be complete fabrications. These statements are untrue statements of material fact in that they concern matters that could have influenced approval of the AADA.

Moreover, the discovery of these untrue statements constitutes new information demonstrating that there is a lack of substantial evidence that the drug will have the effect it purports to have under the conditions of use prescribed, recommended, or suggested in its labeling. Without reliable information as to the qualitative and quantitative formula, manufacturing process, and size of the test batches on which the bioequivalence and stability studies were performed, the agency cannot assume that the results of these studies are applicable to the approved, marketed product. In the absence of reliable data demonstrating stability and bioequivalence to the listed drug, there is a lack of substantial evidence of effectiveness.

AADA 62-780; Doxycycline Hyclate 50 Capsules

In support of AADA 62-780, Vitamine submitted records for batches 860605, 861206, and 861208. In its July 19 letter, the firm disclosed that records at the firm show that there was insufficient active ingredient to produce the batch sizes reported in the AADA for batches 860605, 861206, and 861208. The firm also disclosed that, based on entries in a formulator's notebook, it appears that all three batches, represented as separate batches in the AADA, were actually one batch.

These discrepancies show that various additional statements on the batch records are untrue (e.g., batch identifiers, batch size, quantities of components used in the batches, all calculations that rely on or utilize quantities of components, all control records that rely on or utilize quantities of components, and representations that the manufacturing steps were conducted in accord with the batch records) and

that certain batch records may be complete fabrications. These statements are untrue statements of material fact in that they concern matters that could have influenced approval of the AADA.

Moreover, the discovery of these untrue statements constitutes new information demonstrating that there is a lack of substantial evidence that the drug will have the effect it purports to have under the conditions of use prescribed, recommended, or suggested in its labeling. Without reliable information as to the qualitative and quantitative formula, manufacturing process, and size of the test batches on which the bioequivalence and stability studies were performed, the agency cannot assume that the results of these studies are applicable to the approved, marketed product. In the absence of reliable data demonstrating stability and bioequivalence to the listed drug, there is a lack of substantial evidence of effectiveness.

AADA 62-779, Cephalixin for Oral Suspension 125 mg/5 Milliliter (mL) and AADA 62-781, Cephalixin for Oral Suspension 250 mg/5 mL

In support of AADA's 62-779 and 62-781, Vitamine submitted copies of batch records 860611 through 860613 and 870102 through 870109. These batches were purportedly made at the St. Croix facility.

During the inspection of the St. Croix facility, the firm could not produce records demonstrating that the batches were actually produced at the facility. In addition, the employee whose initials were on the records could not state that the initials were his and could not state that he participated in the production of the batches. Moreover, there are no records corroborating that these batches were manufactured in the St. Croix facility (e.g., no raw data to support actual raw material weighings and active ingredient potency calculations, and no shipping records to support movement of raw materials or finished product).

Other discrepancies also exist. A "raw material inventory and disposition record" for an inactive ingredient shows that the inactive ingredient was not used in any batch of Cephalixin for Oral Suspension made at St. Croix; however, the batch of Cephalixin for Oral Suspension made at St. Croix; however, the batch records submitted to FDA show that the inactive ingredient was used.

There is inadequate evidence to demonstrate that the batch records submitted in support of AADA's 62-779 and 62-781 were from batches produced

in St. Croix or whether the batches were ever manufactured. FDA concludes that the batch records in their entirety are untrue statements of material fact.

Moreover, the discovery of these untrue statements constitutes new information demonstrating that there is a lack of substantial evidence that the drug will have the effect it purports to have under the conditions of use prescribed, recommended, or suggested in its labeling. Without reliable information as to the qualitative and quantitative formula, manufacturing process, and size of the test batches on which the bioequivalence and stability studies were performed, the agency cannot assume that the results of these studies are applicable to the approved, marketed product. In the absence of reliable data demonstrating stability and bioequivalence to the listed drug, there is a lack of substantial evidence of effectiveness.

ANDA 71-564; Orphenadrine Compound (Orphenadrine Citrate 25 mg, Aspirin 385 mg, Caffeine 30 mg) Tablets

In support of ANDA 71-564, Vitarine submitted a copy of the batch records for batch 860205. In its July 19 letter, the firm disclosed that the purchasing, receiving, and transfer records for orphenadrine citrate indicate insufficient material to manufacture batch 860205 in the amount specified in the batch record submitted with the ANDA.

These discrepancies show that various statements on the batch records are untrue (e.g., batch size, quantities of components used in the batch, all calculations that rely on or utilize quantities of components, all control records that rely on or utilize quantities of components, and representations that the manufacturing steps were conducted in accord with the batch records). These statements are untrue statements of material fact in that they concern matters that could have affected approval of the ANDA.

Moreover, the discovery of these untrue statements constitutes new information demonstrating that there is a lack of substantial evidence that the drug will have the effect it purports to have under the conditions of use prescribed, recommended, or suggested in its labeling. Without reliable information as to the qualitative and quantitative formula, manufacturing process, and size of the test batches on which the bioequivalence and stability studies were performed, the agency cannot assume that the results of these studies are applicable to the approved, marketed product. In the absence of reliable data demonstrating stability

and bioequivalence to the listed drug, there is a lack of substantial evidence of effectiveness.

ANDA 71-656; Orphenadrine Compound (Orphenadrine Citrate 50 mg, Aspirin 770 mg, Caffeine 60 mg) Tablets

In support of ANDA 71-565, Vitarine submitted a copy of the batch records for batch 860301. In its July 19 letter, the firm disclosed that the purchasing, receiving, and transfer records for orphenadrine citrate indicate insufficient material to manufacture lot 860301 in the amount specified in the batch record submitted with the ANDA.

These discrepancies show that various statements on the batch records are untrue (e.g., batch size, quantities of components used in the batch, all calculations that rely on or utilize quantities of components, all control records that rely on or utilize quantities of components, and representations that the manufacturing steps were conducted in accord with the batch records). These statements are untrue statements of material fact in that they concern matters that could have influenced approval of the ANDA.

Moreover, the discovery of these untrue statements constitutes new information demonstrating that there is a lack of substantial evidence that the drug will have the effect it purports to have under the conditions of use prescribed, recommended, or suggested in its labeling. Without reliable information as to the qualitative and quantitative formula, manufacturing process, and size of the test batches on which the bioequivalence and stability studies were performed, the agency cannot assume that the results of these studies are applicable to the approved marketed product. In the absence of reliable data demonstrating stability and bioequivalence to the listed drug, there is a lack of substantial evidence of effectiveness.

AADA 62-613; Cephadrine 250 mg and 500 mg Capsules

In support of AADA 62-813, Vitarine submitted to FDA copies of batch records for batches 860814, 860815, and 870119 through 870122. These batches were purportedly manufactured at the St. Croix facility. The records show that these batches were produced during August 1986 and January 1987 at a time when the St. Croix facility was reportedly inactive.

In addition, there are no records to corroborate the production of these batches at the St. Croix facility (e.g., no raw material receipts from New York, no finished product receipts from St. Croix to New York, no records to

document preparation and cleaning of the equipment, no raw data on loss-on-drying results, and no documentation to show the final disposition of batches 870119 through 870122). Moreover, one of the St. Croix employees whose initials were on the records could not assure that he actually participated in the manufacture of the batches, and could not state that the records were legitimate documents describing the production activities associated with the batches. He also could not explain how he and one other employee were able to accomplish all the work which the records indicate they performed between January 13 and 17 1987 on these batches using equipment that other records indicate were being used to produce certain batches of another product (Cephalexin tablets).

There is inadequate evidence to demonstrate that the batch records submitted in support of AADA 62-813 were from a batch produced in St. Croix or whether the batch were ever manufactured. FDA concludes that the batch records in these entirety are untrue statements of material fact.

Moreover, the discovery of these untrue statements constitutes new information demonstrating that there is a lack of substantial evidence that the drug will have the effect it purports to have under the conditions of use prescribed, recommended, or suggested in its labeling. Without reliable information as to the qualitative and quantitative formula, manufacturing process, and size of the test batches on which the bioequivalence and stability studies were performed, the agency cannot assume that the results of these studies are applicable to the approved, marketed product. In the absence of reliable data demonstrating stability and bioequivalence to the listed drug, there is a lack of substantial evidence of effectiveness.

AADA 62-863; Cephalexin 250 mg, 500 mg, and 1,000 mg Tablets

Vitarine submitted copies of batch records 870110 through 870118 in support AADA 62-863. These batches were purportedly made at the St. Croix facility. During the inspection of the St. Croix facility, the firm could not demonstrate that the batch records accurately reflect the purported production of these batches in St. Croix. Many records are lacking, incomplete, or contain inconsistencies (e.g., more active ingredient was used than accounted for by receiving records, no temperature chart records for drying ovens and coating machines, no raw data for loss-on-drying results, no

records to document receipt of the necessary tablet punches and dies, no raw data on calculating the amounts of active ingredient needed for each batch, discrepancies and omissions in some of the dates and signatures for some items, and no records for the shipping of most of the finished products). Furthermore, one of the St. Croix employees whose initials were on the records could not assure that he actually participated in the manufacture of the batches, and could not state that the records were legitimate documents describing the production activities associated with the batches. He also could not explain how he and one other employee were able to accomplish all the work, even using some of the same equipment, which the records indicate they performed between January 13 and 17 1987 on six of these batches and certain batches of other products. Moreover, these batches were purportedly made during a time when the St. Croix facility was reportedly inactive.

There is inadequate evidence to demonstrate that the batch records submitted in support of AADA 62-863 were from batches produced in St. Croix or whether the batches were ever manufactured. Thus, FDA concludes that the batch records in their entirety are untrue statements of material fact that invalidate any tests or studies that were represented to have been conducted with the batches.

Moreover, the discovery of these untrue statements constitutes new information demonstrating that there is a lack of substantial evidence that the drug will have the effect it purports to have under the conditions of use prescribed, recommended, or suggested in its labeling. Without reliable information as to the qualitative and quantitative formula, manufacturing process, and size of the test batches on which the bioequivalence and stability studies were performed, the agency cannot assume that the results of these studies are applicable to the approved, marketed product. In the absence of reliable data demonstrating stability and bioequivalence to the listed drug, there is a lack of substantial evidence of effectiveness.

ANDA 71-360; Tramterene 75 mg/ Hydrochlorothiazide 50 mg Tablets

In support of ANDA 71-360, Vitarine submitted a copy of batch record 860106. During the inspection of Vitarine's New York facility, the firm could not produce the original batch record for this batch. There are also discrepancies between other relevant records at the firm and the batch records submitted to FDA. The relevant raw material card for

hydrochlorothiazide shows no usage of this raw material before February 11, 1986 and no usage in batch 860106, whereas the batch record submitted to FDA shows usage of the raw material on February 7 1986. There is no record of the existence of the batch of triamterene that was purportedly used in batch 860106. Furthermore, the amount of product remaining at the firm is inconsistent with the yields reported in the batch records coupled with the number of tablets reported to have been destroyed.

These discrepancies show that various statements on the batch records are untrue (e.g., dates of manufacture, batch size, quantities of components used in the batch, all calculations that rely on or utilize quantities of components, all control records that rely on or utilize quantities of components, and representations that the manufacturing steps were conducted in accord with the batch records). These statements are untrue statements of material fact in that they concern matters that could have influenced approval of the ANDA.

Moreover, the discovery of these untrue statements constitutes new information demonstrating that there is a lack of substantial evidence that the drug will have the effect it purports to have under the conditions of use prescribed, recommended, or suggested in its labeling. Without reliable information as to the qualitative and quantitative formula, manufacturing process, and size of the test batches on which the bioequivalence and stability studies were performed, the agency cannot assume that the results of these studies are applicable to the approved, marketed product. In the absence of reliable data demonstrating stability and bioequivalence to the listed drug, there is a lack of substantial evidence of effectiveness.

ANDA 71-684, Meclofenamate 100 mg Capsules and ANDA 71-710, Meclofenamate 50 mg Capsules

Two batch records submitted in support of ANDA 71-684 (lot 860604) and ANDA 71-710 (lot 860706) were evaluated in FDA's inspection of the firm's New York facility. FDA investigators determined that the finished product yields reported for these batches could not be accurate based on the amount of available meclufenamate noted in Vitarine's receiving or inventory records. The firm has conceded that the amounts of meclufenamate raw material stated to have been used and the reported finished product yields were incorrect for these batches. There was no raw

material inventory and disposition card at the firm covering the meclufenamate raw material used to make the batches. Vitarine believes that the records were deliberately destroyed by or under the supervision of research and development personnel.

The discrepancies noted between the batch records submitted to FDA and the existing records at the firm show that various statements on the batch records are untrue (e.g., batch size, quantities of components used in the batches, all calculations that rely on or utilize quantities of components, all control records that rely on or utilize quantities of components, and representations that the manufacturing steps were conducted in accord with the batch records). These statements are untrue statements of material fact in that they concern matters that could have influenced approval of the ANDA's.

Moreover, the discovery of these untrue statements constitutes new information demonstrating that there is a lack of substantial evidence that the drug will have the effect it purports to have under the conditions of use prescribed, recommended, or suggested in its labeling. Without reliable information as to the qualitative and quantitative formula, manufacturing process, and size of the test batches on which the bioequivalence and stability studies were performed, the agency cannot assume that the results of these studies are applicable to the approved, marketed product. In the absence of reliable data demonstrating stability and bioequivalence to the listed drug, there is a lack of substantial evidence of effectiveness.

ANDA 71-901; Baclofen 10 mg Tablets

In support of ANDA 71-901, vitarine submitted a copy of batch record 860819. An inspection of Vitarine's New York facility revealed missing or incomplete raw material and disposition records for the batch. In a letter dated June 23, 1989, Vitarine stated that these records could have been destroyed deliberately. From the records that were found, however, FDA investigators determined that there was insufficient raw material to make the amount of product reported for batch 860819. In addition, there are no records showing that an excipient purportedly used in the batch was transferred to the department where the batch was produced.

Moreover, there exists a significant discrepancy between the amount of product remaining from batch 860819 and the batch record. The batch record submitted to FDA reports a theoretical yield of 50,000 tablets. The firm's

inventory, however, contains only 480 tablets and there is no destruction record for the batch. In its letter of June 23, 1989, Vitarme told FDA that the amount of baclofen raw material on hand was sufficient to make about 15,000 tablets, not the 50,000 theoretical yield claimed in the batch record submitted in the application.

The discrepancies show that various statements on the batch records are untrue, including batch size, quantities of components used in the batch, all calculations that rely on or utilized quantities of components, all control records that rely on or utilize quantities of components, and representations that the manufacturing steps were conducted in accord with the batch records. These statements are untrue statements of material fact in that the concern matters that could have influenced approval of the ANDA.

Moreover, the discovery of these untrue statements constitutes new information demonstrating that there is a lack of substantial evidence that the drug will have the effect it purports to have under the conditions of use prescribed, recommended, or suggested in its labeling. Without reliable information as to the qualitative and quantitative formula, manufacturing process, and size of the test batches on which the bioequivalence and stability studies were performed, the agency cannot assume that the results of these studies are applicable to the approved, marketed product. In the absence of the listed drug, there is a lack of substantial evidence of effectiveness.

ANDA 71-902; Baclofen 20 mg Tablets

In support of ANDA 71-902, Vitarme submitted a copy of a batch record for batch 860513A. An inspection of Vitarme's New York facility revealed missing or incomplete raw material and disposition records for this batch. From the records that were found, FDA investigators determined and Vitarme has agreed in its letter of June 23, 1989, that there was insufficient raw material to make the amount of product reported for batch 860513A. In addition, there exists a significant discrepancy between the amount of product remaining from batch 860513A and the batch record. The batch record submitted to FDA reports a theoretical yield of 25,000 tablets. The firm's inventory, however, contains only 181 tablets and there is no record of destruction for the batch. Vitarme has concluded in its July 23, 1989, letter that the amount of baclofen raw material on hand was sufficient to make about 17,000 tablets, not the 25,000 theoretical yield claimed in the batch record submitted in the application.

These discrepancies show that various statements on the batch records are untrue, including batch size, quantities of components used in the batch, all calculations that rely on or utilize quantities of components, all control records that rely on or utilize quantities of components, and representations that the manufacturing steps were conducted in accord with the batch records. These statements are untrue statements of material fact in that they concern matters that could have influenced approval of the ANDA.

Moreover, the discovery of these untrue statements constitutes new information demonstrating that there is a lack of substantial evidence that the drug will have the effect it purports to have under the conditions of use prescribed, recommended, or suggested in its labeling. Without reliable information as to the qualitative and quantitative formula, manufacturing process, and size of the test batches on which the bioequivalence and stability studies were performed, the agency cannot assume that the results of these studies are applicable to the approved, marketed product. In the absence of reliable data demonstrating stability and bioequivalence to the listed drug, there is a lack of substantial evidence of effectiveness.

ANDA 72-167; Desipramine Hydrochloride 10 mg Tablets

In support of ANDA 72-167 Vitarme submitted a copy of the batch records for batch 870414. In its July 19 letter, Vitarme disclosed that the raw material inventory and disposition records at the firm are inconsistent with the batch size stated in the batch records submitted with the ANDA.

The discrepancy shows that various statements on the batch records are untrue, including batch size, quantities of components used in the batch, all calculations that rely on or utilize quantities or components, all control records that rely on or utilize quantities of components, and representations that the manufacturing steps were conducted in accord with the batch records. These statements are untrue statements of material fact in that they concern matters that could have influenced approval of the ANDA.

Moreover, the discovery of these untrue statements constitutes new information demonstrating that there is a lack of substantial evidence that the drug will have the effect it purports to have under the conditions of use prescribed, recommended, or suggested in its labeling. Without reliable information as to the qualitative and quantitative formula, manufacturing

process, and size of the test batches on which the bioequivalence and stability studies were performed, the agency cannot assume that the results of these studies are applicable to the approved, marketed product. In the absence of reliable data demonstrating stability and bioequivalence to the listed drug, there is a lack of substantial evidence of effectiveness.

ANDA 72-254; Desipramine Hydrochloride 150 mg Tablets

In support of ANDA 72-254, Vitarme submitted a copy of the batch records for batch 870415. In its July 19 letter, Vitarme disclosed that the raw material inventory and disposition records at the firm are inconsistent with the batch size stated in the batch records submitted with the ANDA.

This discrepancy shows that various statements on the batch records are untrue, including batch size, quantities of components used in the batch, all calculations that rely on or utilize quantities of components, all control records that rely on or utilize quantities of components, and representations that the manufacturing steps were conducted in accord with the batch records. These statements are untrue statements of material fact in that they concern matters that could have influenced approval of the ANDA.

Moreover, the discovery of these untrue statements constitutes new information demonstrating that there is a lack of substantial evidence that the drug will have the effect it purports to have under the conditions of use prescribed, recommended, or suggested in its labeling. Without reliable information as to the qualitative and quantitative formula, manufacturing process, and size of the test batches on which the bioequivalence and stability studies were performed, the agency cannot assume that the results of these studies are applicable to the approved, marketed product. In the absence of reliable data demonstrating stability and bioequivalence to the listed drug, there is a lack of substantial evidence of effectiveness.

AADA 62-159; Cephalexin 250 mg and 500 mg Capsules

Vitarme submitted records associated with batches 860609, 860610, 860915, and 860916 in support of AADA 62-159. These batches were purportedly made at the St. Croix facility. However, upon inspection of the facility, Vitarme was unable to produce any documentation demonstrating that the batches were actually produced in St. Croix. There is inadequate evidence to demonstrate

that the batch records submitted in support of AADA 62-159 were from batches produced in St. Croix or whether the batches were ever manufactured. Thus, the batch records in their entirety are untrue statements of material fact.

Moreover, the discovery of these untrue statements constitutes new information demonstrating that there is a lack of substantial evidence that the drug will have the effect it purports to have under the conditions of use prescribed, recommended, or suggested in its labeling. Without reliable information as to the qualitative and quantitative formula, manufacturing process, and size of the test batches on which the bioequivalence and stability studies were performed, the agency cannot assume that the results of these studies are applicable to the approved, marketed product. In the absence of reliable data demonstrating stability and bioequivalence to the listed drug, there is a lack of substantial evidence of effectiveness.

Proposed Action and Notice of Opportunity for Hearing

The Director of the Center for Drug Evaluation and Research has evaluated the information discussed above concerning the filing of false data by Vitamine and, on the grounds stated, is proposing to withdraw approval of the following AADA's and ANDA's:

AADA 61-471; Tetracycline Hydrochloride 500 mg Capsules
 AADA 62-159; Cephalaxin 250 mg and 500 mg Capsules
 AADA 62-227; Doxycycline Hyclate 100 mg Capsules
 AADA 62-779; Cephalaxin for Oral Suspension, 125 mg/5 mL
 AADA 62-780; Doxycycline Hyclate 50 mg Capsules
 AADA 62-781; Cephalaxin for Oral Suspension, 250 mg/5 mL
 AADA 62-813; Cephadrine 250 mg and 500 mg Capsules
 AADA 62-863; Cephalaxin 250 mg, 500 mg, and 1,000 mg Tablets
 AADA 62-910; Clindamycin HCl 75 mg and 150 mg Capsules
 ANDA 71-360; Tramterene 75 mg/
 Hydrochlorothiazide 50 mg Tablets
 ANDA 71-531; Indomethacin ER 75 mg Capsules
 ANDA 71-564; Orphenadrine Compound Tablets, Single Strength
 ANDA 71-565; Orphenadrine Compound Tablets, Double Strength
 ANDA 71-684; Meclofenamate 100 mg Capsules
 ANDA 71-710; Meclofenamate 50 mg Capsules
 ANDA 71-711; Indomethacin 25 mg Capsules

ANDA 71-712; Indomethacin 50 mg Capsules
 ANDA 71-832; Trimipramine 25 mg Capsules
 ANDA 71-833; Trimipramine 50 mg Capsules
 ANDA 71-834; Trimipramine 100 mg Capsules
 ANDA 71-901; Baclofen 10 mg Tablets
 ANDA 71-902; Baclofen 20 mg Tablets
 ANDA 72-167; Desipramine Hydrochloride 10 mg Tablets
 ANDA 72-179; Mefenamic Acid 250 mg Capsules
 ANDA 72-254; Desipramine Hydrochloride 150 mg Tablets

Notice is hereby given to the holder of the AADA's and ANDA's listed above and to all other interested persons, that the Director of the Center for Drug Evaluation and Research proposes to issue an order under section 505(e) of the Federal Food, Drug and Cosmetic Act (the act), withdrawing approval of the foregoing AADA's, ANDA's, and all amendments and supplements thereto. The Director finds that the applications contain untrue statements of material fact and, on the basis of new information before him with respect to the drugs, evaluated together with the evidence available to him when the applications were approved, that there is a lack of substantial evidence that the drugs will have the effects they purport or are represented to have under the conditions of use prescribed, recommended, or suggested in their labeling.

In accordance with section 505 of the act and 21 CFR Part 314, the applicant is hereby given an opportunity for a hearing to show why approval of the AADA's and ANDA's should not be withdrawn.

An applicant who decides to seek a hearing shall file: (1) on or before November 2, 1989, a written notice of appearance and request for hearing, and (2) on or before December 4, 1989, the data, information, and analyses relied on to demonstrate that there is a genuine issue of material fact to justify a hearing. Any other interested person may also submit comments on this notice. The procedures and requirements governing this notice of opportunity for a hearing, a notice of appearance and request for a hearing, information and analyses to justify a hearing, other comments, and a grant or denial of a hearing are contained in 21 CFR 314.200 (except that the limitations imposed by 21 CFR 314.200(d)(1) and (2) do not apply) and in 21 CFR part 12.

The failure of the applicant to file a timely written notice of appearance and

request for hearing, as required by 21 CFR 314.200, constitutes an election by that person not to use the opportunity for a hearing concerning the action proposed, and a waiver of any contentions concerning the legal status of that person's drug products. Any new drug product marketed without an approved new drug application is subject to regulatory action at any time.

A request for a hearing may not rest upon mere allegations or denials, but must present specific facts showing that there is a genuine and substantial issue of fact that requires a hearing. If it conclusively appears from the face of the data, information, and factual analyses in the request for hearing that there is no genuine and substantial issue of fact which precludes the withdrawal of approval of the applications, or when a request for hearing is not made in the required format or with the required analyses, the Commissioner of Food and Drugs will enter summary judgment against the person(s) who request the hearing, making findings and conclusions, and denying a hearing.

All submissions pursuant to this notice of opportunity for hearing are to be filed in six copies. Except for data and information prohibited from public disclosure under 21 U.S.C. 331(j) or 18 U.S.C. 1905, the submissions may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

Section 505(j)(6)(C) of the act requires that FDA remove from its approved product list (FDA's publication "Approved Drug Products with Therapeutic Equivalence Evaluations") (the list) any drug that was withdrawn for grounds described in the first sentence of section 505(e) of the act. If the agency determines that withdrawal of the drugs subject to this notice is appropriate, FDA will announce their removal from the list in the **Federal Register** notice announcing the withdrawal of approval of the drugs.

This notice is issued under the Federal Food, Drug, and Cosmetic Act (sec. 502, 52 Stat. 1052-1053 as amended (21 U.S.C. 355)) and under authority delegated to the Director of the Center for Drug Evaluation and Research (21 CFR 5.82).

Dated: September 28, 1989.

Carl C. Peck,

Director, Center for Drug Evaluation and Research.

[FR Doc. 89-23374 Filed 10-2-89; 8:45 am]

BILLING CODE 4160-01-M

Public Health Service**National Toxicology Program;
Availability of Technical Report on
Toxicology and Carcinogenesis
Studies of 2,4-Dichlorophenol**

The HHS' National Toxicology Program announces the availability of the NTP Technical Report on the toxicology and carcinogenesis studies of 2,4-dichlorophenol. 2,4-Dichlorophenol is used principally as a chemical intermediate in the manufacture of the herbicide, 2,4-dichlorophenoxyacetic acid (2,4-D).

Toxicology and carcinogenesis studies were conducted by feeding diets containing 0, 5,000 or 10,000 ppm 2,4-dichlorophenol to groups of 50 male rats and 50 male and 50 female mice for 103 weeks. Groups of 50 female rats received diets containing 0, 2,500 or 5,000 ppm.

Under the conditions of these 2-year feed studies, there was no evidence of carcinogenic activity for male F344/N rats fed diets containing 5,000 or 10,000 ppm 2,4-dichlorophenol or for female F344/N rats fed diets containing 2,500 or 5,000 ppm 2,4-dichlorophenol. There was no evidence of carcinogenic activity for male and female B6C3F₁ mice fed diets containing 5,000 or 10,000 ppm 2,4-dichlorophenol.

The study scientist for these studies is Dr. R. Melnick. Questions or comments about the conduct of this Technical Report should be directed to Dr. Melnick at P. O. Box 12233, Research Triangle Park, NC 27709 or telephone (919) 541-4142.

Copies of *Toxicology and Carcinogenesis studies of 2,4-Dichlorophenol in F344/N Rats and B6C3F₁ Mice (Feed Studies)* (TR 353) are available without charge from the NTP Public Information Office, MD B2-04, P. O. Box 12233, Research Triangle Park, NC 27709 or telephone (919) 541-3991; FTS: 629-3991.

Dated: September 27 1989.

David P Rall,

Director.

[FR Doc. 89-23292 Filed 10-2-89; 8:45 am]

BILLING CODE 4140-01-M

The NTP uses five categories of evidence of carcinogenic activity to summarize the strength of the evidence observed in each experiment: Two categories for positive results ("clear evidence" and "some evidence"); one category for uncertain findings ("equivocal evidence"); one category for no observable effects ("no evidence"); and one category for experiments that because of major flaws cannot be evaluated ("inadequate study").

**National Toxicology Program;
Availability of Technical Report on
Toxicology and Carcinogenesis
Studies of Furosemide**

The HHS' National Toxicology Program announces the availability of the NTP Technical Report on the toxicology and carcinogenesis studies of furosemide, a diuretic used in human and veterinary medicine.

Toxicology and carcinogenesis studies were conducted by feeding diets containing 0, 350, or 700 ppm furosemide to groups of F344/N rats for 103 weeks. Groups of 50 mice of each sex were administered diets containing 0, 700 or 1400 ppm furosemide for 104 weeks.

Under the conditions of these 2-year feed studies, there was equivocal evidence of carcinogenic activity of furosemide for male F344/N rats, as shown by marginal increases in uncommon tubular cell neoplasms of the kidney and meningiomas of the brain. There was no evidence of carcinogenic activity of furosemide for female F344/N rats fed diets containing 350 or 700 ppm furosemide for 2 years. There was no evidence of carcinogenic activity for male B6C3F₁ mice fed diets containing 700 or 1400 ppm furosemide for 2 years. There was some evidence of carcinogenic activity of furosemide for female mice, as shown by an increase in malignant tumors of the mammary gland.

The study scientist for these studies is Dr. John R. Bucher. Questions or comments about the conduct of this Technical Report should be directed to Dr. Bucher at P. O. Box 12233, Research Triangle Park, NC 27709 or telephone (919) 541-4532.

Copies of *Toxicology and Carcinogenesis studies of Furosemide in F344/N Rats and B6C3F₁ Mice (Feed Studies)* (TR 356) are available without charge from the NTP Public Information Office, MD B2-04, P. O. Box 12233, Research Triangle Park, NC 27709 or telephone (919) 541-3991; FTS: 629-3991.

Dated: September 27 1989.

David P Rall,

Director.

[FR Doc. 89-23293 Filed 10-2-89; 8:45 am]

BILLING CODE 4140-01-M

The NTP uses five categories of evidence of carcinogenic activity to summarize the strength of the evidence observed in each experiment: Two categories for positive results ("clear evidence" and "some evidence"); one category for uncertain findings ("equivocal evidence"); one category for no observable effects ("no evidence"); and one category for experiments that because of major flaws cannot be evaluated ("inadequate study").

**National Toxicology Program;
Availability of Technical Report on
Toxicology and Carcinogenesis
Studies of Tribromomethane**

The HHS' National Toxicology Program announces the availability of the NTP Technical Report on the toxicology and carcinogenesis studies of tribromomethane, a chemical intermediate and solvent. This chemical has been identified as a drinking water contaminant resulting from water chlorination.

Toxicology and carcinogenesis studies were conducted by administering doses of 0, 100, or 200 mg/kg tribromomethane in corn oil by gavage, 5 days per week for a period of 103 weeks, to groups of 50 rats of each sex and 50 female mice. Groups of 50 male mice were administered 0, 50, or 100 mg/kg tribromomethane on the same schedule.

Under the conditions of these 2-year gavage studies, there was some evidence of carcinogenic activity of tribromomethane for male F344/N rats and clear evidence of carcinogenic activity for female F344/N rats, based on increased incidences of uncommon neoplasms of the large intestine. Reduced survival for male rats given 200 mg/kg tribromomethane lowered the sensitivity of this group to detect a carcinogenic response. Chemically related nonneoplastic lesions included fatty change and active chronic inflammation of the liver in male and female rats, minimal necrosis of the liver in male rats, and mixed cell foci of the liver in female rats. There was no evidence of carcinogenic activity for male B6C3F₁ mice given 50 or 100 mg/kg tribromomethane or for female B6C3F₁ mice given 100 or 200 mg/kg; male mice might have been able to tolerate a higher dose. Survival of the female mice was reduced, partly due to a utero-ovarian infection.

The study scientist for these studies is Dr. Ronald L. Melnick. Questions or comments about the conduct of this Technical Report should be directed to Dr. Melnick at P. O. Box 12233, Research Triangle Park, NC 27709 or telephone (919) 541-4142.

Copies of *Toxicology and Carcinogenesis Studies of Tribromomethane (Bromoform) in F344/*

* The NTP uses five categories of evidence of carcinogenic activity to summarize the strength of the evidence observed in each experiment: Two categories for positive results ("clear evidence" and "some evidence"); one category for uncertain findings ("equivocal evidence"); one category for no observable effects ("no evidence"); and one category for experiments that because of major flaws cannot be evaluated ("inadequate study").

N Rats and B6C3F₁ Mice (Gavage Studies) (TR 350) are available without charge from the NTP Public Information Office, MD B2-04, P. O. Box 12233, Research Triangle Park, NC 27709 or telephone (919) 541-3991; FTS: 629-3991.

Dated: September 27, 1989.

David P. Rall,

Director.

[FR Doc. 89-23294 Filed 10-2-89; 8:45 am]

BILLING CODE 4140-01-M

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

Receipt of Applications for Permits

The following applicants have applied for permits 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.*):

PRT 741901

Applicant: John Gehan, Irving, Texas.

The applicant requests a permit to import the personal sport-hunted trophy of one male bontebok (*Damaliscus dorcas dorcas*), culled from the captive-herd maintained by Mr. M. Greggor of Elandsberg Farms, Hermon, Republic of S. Africa, for the purpose of enhancement of survival of the species.

PRT 741910

Applicant: Gladys Porter Zoo, Brownsville, TX.

The applicant requests a permit to import one male and one female captive-hatched saltwater crocodile (*Crocodylus porosus*) from the Samutprakan Crocodile Farm & Zoo Co., Ltd., Samutprakan, Thailand, for the purpose of captive propagation, zoological exhibition and behavioral research.

PRT 741915

Applicant: Zoological Society of San Diego, San Diego, CA.

The applicant requests a permit to import one captive-born male Persian fallow deer (*Cervus dama mesopotamica*) from Tierpark Berlin, Berlin, East Germany, for the purpose of enhancement of propagation.

PRT 741881

Applicant: Minden Wildlife Sanctuary, Minden, LA.

The applicant requests a permit to purchase in interstate commerce six pairs of adult wild-caught golden parakeets (*Aratinga gaurouba*) imported from Brazil, from Life Fellowship, Seffner, Florida, for enhancement of

propagation through educational display and breeding.

PRT 741785

Applicant: Steve Martin, Acton, CA.

The applicant requests a permit to export and reimport a captive-bred male tiger (*panthera tigris*) to Argentina and return for the purpose of enhancement of propagation through educational display. This tiger will be reexported and reimported to and from other countries in the future.

PRT 741995

Applicant: Cincinnati Zoo, Cincinnati, Ohio.

The applicant requests a permit to import 1.1 Komodo dragons (*Varanus komodoensis*) from Metro Zoo of Jakarta, Jakarta Selatan, Indonesia, for enhancement of propagation through educational display, breeding and research.

PRT 742015

Applicant: Clyde Peeling's Reptiland Ltd., Allenwood, Pa.

The applicant requests a permit to purchase in interstate commerce six (6) Galapagos tortoises (*Geochelone elephantopus*) from Life Fellowship, Seffner Florida, for enhancement of propagation through educational display and breeding.

PRT 741885

Applicant: Avicultural Breeding and Research, Loxahatchee, FL.

The applicant requests a permit to purchase in interstate commerce two female nene geese (*Nesochen sandvicensis*) from St. Louis Zoological Park, St. Louis, MO, for enhancement of propagation through breeding.

PRT 741823

Applicant: International Animal Exchange, Inc., Ferndale, MI.

The applicant requests a permit to purchase one pair of captive born jaguars (*Panthera onca*) from the Cleveland Metroparks Zoo, Cleveland, Ohio, and export them to Yong-In Farmland, Swoul, Korea, for breeding and display purposes.

Documents and other information submitted with these applications are available to the public during normal business hours (7:45 a.m. to 4:15 p.m.) Room 432, 4401 N. Fairfax Dr., Arlington, VA 22203, or by writing to the Director, U.S. Office of Management Authority, P.O. Box 3507 Arlington, Virginia 22203-3507

Interested persons may comment on any of these applications within 30 days of the date of this publication by submitting written views, arguments, or data to the Director at the above address. Please refer to the appropriate

PRT number when submitting comments.

Dated: September 26, 1989.

Susan Lawrence,

Acting Chief, Branch of Permits, U.S. Office of Management Authority.

[FR Doc. 89-23239 Filed 10-2-89; 8:45 am]

BILLING CODE 4310-55-M

Issuance of Permit for Marine Mammals

On August 8, 1989, a notice was published in the *Federal Register* (Vol. 54, No. 151) that an application had been filed with the Fish and Wildlife Service by the Service's Alaska Office of Fish and Wildlife Research, Anchorage, Alaska (PRT-740507) for a permit to take (harass) up to 650 Alaska sea otters for the purpose of scientific research.

Notice is hereby given that on September 18, 1989, as authorized by the provisions of the Marine Mammal Protection Act of 1972, as amended, the Fish and Wildlife Service issued the requested permit subject to certain conditions set forth therein.

The permit, as well as an Environmental Assessment and Finding of No Significant Impact prepared in compliance with the National Environmental Policy Act, are available for public inspection during normal business hours at the Service's Office of Management Authority, Room 432, 4401 North Fairfax Drive, Arlington, Virginia.

Dated: September 26, 1989.

S.M. Lawrence,

Acting Chief, Branch of Permits, Office of Management Authority.

[FR Doc. 89-23238 Filed 10-2-89; 8:45 am]

BILLING CODE 4310-55-M

U.S. Geological Survey

Information Collection Submitted to the Office of Management and Budget for Review Under the Paperwork Reduction Act

The proposal for the collection of information listed below has been submitted to the Office of Management and Budget for approval under the provisions of the Paperwork Reduction Act (44 U.S.C. chapter 35). Copies of the proposed collection of information and related forms and explanatory material may be obtained by contacting the Bureau Clearance Office at the phone number listed below. Comments and suggestions on the requirement should be made directly to the Bureau Clearance Office and to the Office of Management and Budget, Interior

Department, Desk Officer, Paper Reduction Project (1028-0013), Washington, DC 20503, telephone: (202) 395-7340.

Title: Inventory of Hydrologic Data.
OMB Approval Number: 1028-0013.

Abstract: The collection is required to provide a data base for coordination of water-data acquisition activities in compliance with OMB Circular A-67. It is used within all governmental, academic, and private levels of the water-data community for national or regional network design and operation and for water resources and environmental management planning.
Bureau Form Number: 9-1981-1 through 6; 7A.

Frequency: Biennially.

Description of Respondents: Federal, State, County, River Basin, Interstate, Municipality, Local Government.

Estimated Completion Time: .35 hours.

Annual Responses: 1624.

Annual Burden Hours: 284.

Bureau Clearance Officer: Geraldine A. Wilson, (703) 648-7309.

Dated: July 18, 1989.

Philip Cohen,

Chief Hydrologist.

[FR Doc. 89-23321 Filed 10-2-89; 8:45 am]

BILLING CODE 4130-31-M

Bureau of Land Management

[CO-030-09-4410-08]

Availability of Approved Uncompahgre Basin Resource Management Plan/Record of Decision; Colorado

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of Availability of the approved Uncompahgre Basin Resource Management Plan/Record of Decision and notice of four areas designated as Areas of Critical Environmental Concern (ACECs) and as either Research Natural Areas or Outstanding Natural Areas.

SUMMARY: Pursuant to the National Environmental Policy Act of 1969 (NEPA) and the Federal Land Policy and Management Act of 1976 (FLPMA), the Bureau of Land Management has prepared a Record of Decision (ROD) for the Uncompahgre Basin Resource Management Plan (RMP).

EFFECTIVE DATE: The Resource Management Plan/ROD and ACEC designations became effective with the signing of the documents on July 26, 1989, by Neil F. Morck, Colorado State Director.

ADDRESS: Copies of the approved Resource Management Plan/ROD are

available upon request at the Uncompahgre Basin Resource Area Office, Bureau of Land Management, 2505 South Townsend Avenue, Montrose, Colorado 81401.

FOR FURTHER INFORMATION CONTACT: Allen J. Belt, Area Manager, Bureau of Land Management, Uncompahgre Basin Resource Area, 2505 South Townsend Avenue, Montrose, Colorado 81401, Telephone 303-249-7791.

SUPPLEMENTARY INFORMATION: The Uncompahgre Basin RMP is approved. The plan was prepared under the regulations for implementing the Federal Land Policy and Management Act (FLPMA) of 1976 (43 CFR 1600). An environmental impact statement was prepared for this plan in compliance with the National Environmental Policy Act (NEPA) of 1969. The approved RMP is identical to the Proposed RMP published in September 1988.

Decisions: The RMP describes the management objectives and prescriptions for the 16 management units of the Uncompahgre Basin Planning Area. The RMP designates a total of 224,276 acres open to off-road vehicle (ORV) use, 38,600 acres closed to ORV use and 220,201 acres limited either seasonally or year-long to ORV use. The RMP recommends to the Secretary of the Interior the Gunnison Gorge WSA (21,038 acres) as suitable for inclusion into the National Wilderness Preservation System. The RMP designates four areas as ACECs:

A 1,895-acre portion of Escalante Canyon located west of Delta, Colorado, is designated as the Escalante Canyon Area of Critical Environmental Concern. Specifically, this area is located in T. 51 N., R. 13 W sections 19, 20, 21, 22, 27, 28, 29, and 30, New Mexico Principal Meridian. This area contains several federally-listed threatened and endangered plant species and two unique plant associations. The area also receives significant recreational use.

An area comprised of two tracts totalling 377 acres located eight miles east of Montrose, Colorado, is designated as the Fairview Research Natural Area/Area of Critical Environmental Concern. Specifically, this area is located in T. 49 N., R. 8 W sections 18 and 19; T. 48 N., R. 8 W section 6; and T. 48 N., R. 9 W., section 1, New Mexico Principal Meridian. The tracts contain a large population of a listed endangered species and significant populations of a candidate species.

An 80-acre site located northeast of Crawford, Colorado, is designated as the Needle Rock Outstanding Natural Area/Area of Critical Environmental

Concern. Specifically, this area is located in T. 15 S., R. 91 W section 27 Sixth Principal Meridian. This site contains a volcanic geologic structure with high-value scientific, interpretive, and scenic characteristics. A 6,783-acre area located approximately three miles northwest of Delta, Colorado, is designated as the Adobe Badlands Outstanding Natural Area/Area of Critical Environmental Concern. Specifically, this area is located in T. 14 S., R. 96 W sections 8, 9, 10, 14, 15, 16, 21, 22, 23, 24, 25, 26, 27, 28, 33, 34, 35, and 36; and T. 15 S., R. 96 W sections 2, 3, and 4, Sixth Principal Meridian. The area consists of Mancos shale hills and flats which, through wind and water erosion, have formed unique scenic formations. The area's soils are highly erodible and saline, resulting in high sediment loads and very saline runoff.

The area also contains known and potential habitat for several endangered and threatened plant species.

Dated: September 25, 1989.

Tom Walker,

Associate State Director.

[FR Doc. 89-23320 Filed 10-2-89; 8:45 am]

BILLING CODE 4310-3B-M

[AZ-020-09-4213-01]

Phoenix District Advisory Council; Meeting Cancellation

AGENCY: Bureau of Land Management, Interior.

ACTION: Cancellation notice of the Phoenix District Advisory Council.

DATE: Scheduled for October 5-6, 1989, 9:00 a.m.

ADDRESS: 2015 West Deer Valley Road, Phoenix, Arizona 85027

SUMMARY: The above scheduled meeting of the Phoenix District Advisory Council has been canceled. It will be rescheduled at a later date.

Dated: September 25, 1989.

Henri R. Bisson,

District Manager.

[FR Doc. 89-23319 Filed 10-2-89; 8:45 am]

BILLING CODE 4310-32-M

[NM 910-GP9-467; NM NM 55953]

Proposed Reinstatement of Terminated Oil and Gas Lease; New Mexico

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice.

SUMMARY: Under the provisions of 43 CFR 3108.2-3, Southland Royalty Company petitioned for reinstatement of oil and gas lease NM NM 55953 covering the following described lands located in Lea County, New Mexico:

Eddy County, New Mexico

T. 24 S., R. 32 E., NMPM
sec. 7: E½NE¼, SE¼,
sec. 8: N½, NW¼SW¼,
sec. 9: W½, SE¼

Containing 1,080,000 acres.

It has been shown to my satisfaction that failure to make timely payments of rental was due to inadvertence.

No valid lease has been issued effecting the lands. Payment of back rentals and administrative cost of \$500.00 has been paid. Future rentals shall be at the rate of \$5.00 per acre per year and royalties shall be at the rate of 16½ percent, computed on a sliding scale of 4 percentage points greater than the competitive royalty schedule attached to the lease. Reimbursement for cost of the publication of this notice shall be paid by the lessee.

Dated: September 22, 1989.

Martha A. Rivera,

Acting Chief, Adjudication Section.

[FR Doc. 89-23331 Filed 10-2-89; 8:45 am]

BILLING CODE 4310-FB-M

[CA-010-090-4212-13, CA 25913]

Realty Action: Exchange of Public Land in Nevada County, CA

AGENCY: Bureau of Land Management, Interior.

SUMMARY: The following described public land is being considered for exchange under section 206 of the Federal Land Policy and Management Act of 1976 (43 U.S.C. 1716):

Selected Public Land

T.16 N., R. 9 E., MDM, California
Sec. 18: Lots 16, 18 and 19.

Containing 16.67 acres, more or less.

The above described land is hereby segregated from settlement, location and entry under the public land laws and from the mining laws for a period of two years from the date of publication of this notice in the *Federal Register*.

This land is difficult and uneconomic to manage as part of the public lands and is not considered suitable for management by another Federal agency.

The above land is being considered for possible transfer to a nonprofit conservation organization (American

River Land Trust, Trust for Public Land, or The Nature Conservancy). In exchange, the public would receive private land (approximately equal in value) located on either the South Fork of the American River or the Merced River, or wetlands and waterfowl habitat located in the Sacramento Valley. The purpose would be to acquire these lands in order to prevent development and to preserve their natural character for the enjoyment of future generations.

SUPPLEMENTARY INFORMATION: A right-of-way would be reserved to the U.S. on the Federal land being considered for exchange (43 U.S.C. 945); a transfer would also include a protection for and preservation of certain elements of a historic Chinese Cemetery which once occupied the Federal parcel.

All necessary clearances including clearances for archaeology, rare plants and animals would be completed prior to any conveyance of title by the U.S.

FOR ADDITIONAL INFORMATION: Contact Mike Kelley, (916) 985-4474 or at the address listed below.

ADDRESS: For a period of 45 days from publication of this notice in the *Federal Register*, interested parties may submit comments to the District Manager c/o the Area Manager, Folsom Resource Area, 63 Natoma Street, Folsom, CA 95630.

Dated: September 22, 1989.

D. K. Swickard,

Area Manager.

[FR Doc. 89-23322 Filed 10-2-89; 8:45 am]

BILLING CODE 4310-40-M

[MT-020-09-4340-02]

Montana; Intent To Prepare a Resource Management Plan Environmental Impact Statement and Hold Scoping Meetings In the Big Dry Resource Area

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of intent.

SUMMARY: A Resource Management Plan (RMP) will be prepared for the BLM-administered lands within the Big Dry Resource Area, Miles City District, Montana. The RMP will be based upon the existing statutory requirements and will meet the requirements of the Federal Land Policy and Management Act of 1976. The RMP and accompanying Environmental Impact Statement (EIS) will guide management decisions within the Big Dry Resource

Area. The RMP and EIS are scheduled for completion by September 1992.

SUPPLEMENTARY INFORMATION: The RMP geographic area is northeastern Montana and consists of BLM-administered lands in Daniels, Dawson, Fallon, Garfield, McCone, Prairie, Richland, Roosevelt, Sheridan, and Wibaux Counties, the northern tip of Custer County, the northwest tip of Carter County and the northern half of Rosebud County.

The public will assist the BLM in identification of the issues. Examples of potential issues (problems, concerns) are: acquisition of lands with important resource values, access to public lands, off-road vehicle use, identifying areas of special management concerns, rights-of-way, withdrawal review, forage allocation, riparian and wetlands management, land treatment, exploration and development, wildlife expansion and reintroduction, biological and chemical weed control, recreation permits and range improvement funding allocations for improving and maintaining allotments.

BLM is also extending a call for coal resource information and any information regarding resources which may affect the leasing of Federal coal or be affected by the leasing of Federal coal. Resource information pertinent to any other BLM resource management activities is also requested.

The public is also asked to assist BLM in identification of areas of critical and environmental concern (ACECs). An ACEC is an area within the public lands where special management attention is required to protect important historic, cultural or scenic values, fish and wildlife resources or other natural systems, or to protect life and safety from natural hazards. Nominations must meet both the relevance and importance criteria under the Code of Federal Regulations: 43 CFR part 1610.7-2(a) to be considered as a potential ACEC. Four alternatives will be developed to present a range of feasible management actions. The "No Action Alternative" is included in accordance with 43 CFR 1502.14(d) and represents the continuation of current management.

Three alternatives being considered are: the "Resource Production Alternative" favoring the use and development of public land resources over extensive natural and cultural resource protection; the "Resource Protection Alternative" which would go beyond legal mandates of resource protection, allowing the protection of natural and cultural resources to dictate other allowable uses; and management under the "Resource Production—

Protection" Alternative which would balance use of the public land resources with protection of valuable and/or sensitive natural and cultural resources.

Development of this RMP will require involvement of professionals from these disciplines: wildlife management, threatened and endangered species, hydrology, riparian, soil science, range management, land use planning, reactivity, forestry, geology, archaeology, recreation, economics, and sociology. The public will be provided the opportunity to review and comment on issues and ACECs developed by BLM and to identify new issues and potential ACECs. A mailing list is being developed and will be used to communicate with and solicit comments from all local, state and federal agencies, Native American tribes, the Miles City BLM District Advisory Council, the Miles City BLM Grazing Advisory Board, and the public at large which may be affected by the plan. As the planning process proceeds, these publics will be encouraged to participate.

Public information and scoping meetings for this RMP will be held at Baker, Circle Forsyth, Glendive, Jordan, Miles City, Sidney, Terry and Wolf Point, Montana, from January 8 through the 24, 1990 (exact places and dates to be provided later).

Recommendations for issues, ACECs and/or other public concerns should be submitted to BLM on or before February 1, 1990.

FOR FURTHER INFORMATION CONTACT: Area Manager, Big Dry Resource Area, Miles City Plaza, Miles City, Montana 59301 or telephone (406) 232-7000.

Darrel G. Pistorius,
Acting District Manager.

[FR Doc. 89-23217 Filed 10-2-89; 8:45 am]
BILLING CODE 4310-DN-M

National Park Service

Availability of Plan of Operations and Environmental Assessment Plugging and Abandonment of Four Wells; Big Thicket National Preserve, Lance Rosier Unit, Hardin County, Texas

Notice is hereby given in accordance with § 9.52(b) of title 36 of the Code of Federal Regulations that the National Park Service has received from Mobil Exploration and Producing U.S., Inc., a Plan of Operations for plugging and abandonment of four wells located within the Lance Rosier Unit of Big Thicket National Preserve, Hardin County, Texas.

The Plan of Operations and Environmental Assessment are available for public review and comment for a period of 30 days from the publication date of this notice in the Office of the Superintendent, Big Thicket National Preserve, 3785 Milam, Beaumont, Texas; and the Southwest Regional Office, National Park Service, 1220 South St. Francis Drive, Room 347 Santa Fe, New Mexico. Copies are available from the Southwest Regional Office, Post Office Box 728, Santa Fe, New Mexico 87504-0728, and will be sent upon request.

Dated: September 18, 1989.

Richard W. Marks,
Acting Regional Director, Southwest Region.
[FR Doc. 89-23208 Filed 10-2-89; 8:45 am]
BILLING CODE 4310-10-M

National Register of Historic Places; Notification of Pending Nominations

Nominations for the following properties being considered for listing in the National Register were received by the National Park Service before September 23, 1989. Pursuant to § 60.13 of 36 CFR part 60 written comments concerning the significance of these properties under the National Register criteria for evaluation may be forwarded to the National Register, National Park Service, P.O. Box 37127 Washington, DC 20013-7127. Written comments should be submitted by October 18, 1989.

Carol D. Shull,
Chief of Registration, National Register.

COLORADO

Alamosa County
Superintendent's Residence, Great Sand Dunes National Monument, CO 150, SW of Mosca, Mosca vicinity, 89001761

Delta County

Curtis Hardware Store, 228 Grand Ave., Paonia, 89001746

Denver County

Field Officer's Quarters, Fort Logan, 3742 W. Princeton Cir., Denver, 89001745

DISTRICT OF COLUMBIA

District of Columbia

Mayfair Mansions Apartments, 3819 Jay St., NE., Washington, 89001735
Park Tower, 2440 Sixteenth St., NW., Washington, 89001744
Sheridan—Kalamazoo Historic District,
• *Roughly bounded by Rock Creek Park, Connecticut Ave., NW., Florida Ave., NW., 22nd St., NW., and P St., NW., Sheridan, 89001743*

FLORIDA

Pinellas County

Pass-a-Grille Historic District, Roughly bounded by 12th Ave., Gulf Blvd., 4th Ave., and Gulf Ave., St. Petersburg Beach, 89001734

ILLINOIS

Champaign County

Farm House, 1403 E. Lorado Taft Dr., Urbana, 89001728
Inman Hotel, 17 E. University Ave., Champaign, 89001732

Cook County

Crow Island School, 1112 Willow Rd., Winnetka, 89001730
West Jackson Historic District (Boundary Increase), 1513 W. Adams St., Chicago, 89001729

Du Page County

Whitney, William, House, 142 E. First St., Hinsdale, 89001731

Warren County

Stewart, Minnie, House, 1015 E. Euclid Ave., Monmouth, 89001733

MASSACHUSETTS

Suffolk County

Mission Hill Triangle Historic District, Roughly bounded by Smith St., Worthington St., Tremont St., and Huntington Ave., Boston, 89001747

NORTH DAKOTA

Adams County

US Post Office—Hettinger (US Post Offices in North Dakota, 1900-1940 MPS), Lake St. and Adams Ave., Hettinger, 89001751

Barnes County

US Post Office—Valley City (US Post Offices in North Dakota, 1900-1940 MPS), 149 NE. Third St., Valley City, 89001758

Cavalier County

US Post Office—Langdon (US Post Offices in North Dakota, 1900-1940 MPS), 323 Eighth Ave., Langdon, 89001752

Dickey County

US Post Office—Oakes (US Post Offices in North Dakota, 1900-1940 MPS), 611 Main Ave., Oakes, 89001753

Eddy County

US Post Office—New Rockford (US Post Offices in North Dakota, 1900-1940 MPS), 821 N. First Ave., New Rockford, 89001750

Foster County

US Post Office—Carrington (US Post Offices in North Dakota, 1900-1940 MPS), 87 N. Ninth Ave., Carrington, 89001754

Pembina County

US Customs House and Post Office—Pembina (US Post Offices in North Dakota, 1900-1940 MPS), 125 S. Cavalier St., Pembina, 89001755

Pierce County

US Post Office—Rugby (US Post Offices in North Dakota, 1900–1940 MPS), 205 SE. Second St., Rugby, 89001748

Ransom County

US Post Office—Lisbon (US Post Offices in North Dakota, 1900–1940 MPS), 17 W. Fourth Ave., Lisbon, 89001749

Richland County

US Post Office—Wahpeton (US Post Offices in North Dakota, 1900–1940 MPS), 620 Dakota Ave., Wahpeton, 89001759

Stark County

US Post Office—Dickinson (US Post Offices in North Dakota, 1900–1940 MPS), 15 E. First St., Dickinson, 89001757

Walsh County

US Post Office—Grafton (US Post Offices in North Dakota, 1900–1940 MPS), 506 S. Griggs Ave., Grafton, 89001756

SOUTH DAKOTA**Bon Homme County**

Greenfield, Dr. John C., Houseq, 307 W. First St., Avon, 89001717

Brookings County

Sterling Methodist Church, US 77 5 mi. E of Bruce, Bruce vicinity, 89001723

Brown County

Bickelhaupt, William G., House, 1003 S. Jay, Aberdeen, 89001727

Clark County

Telemarken Lutheran Church, NW of Wallace, Wallace vicinity, 89001720

Codington County

Reeve's Resort, 6 mi. S. of Florence, Florence vicinity, 89001728

Davison County

Welch, L.J., House, 608 E. 4th Ave., Mitchell, 89001722

Hughes County

McDonald, Henry M., House, 1906 E. Erskine, Pierre, 89001718

Lake County

Chicago, Milwaukee, St. Paul, and Pacific Railroad Depot, 315 S. Egan, Madison, 89001719

Minnehaha County

Daniels, E.J. and Alice, House, 3901 S. Hawthorne, Sioux Falls, 89001724

Moody County

Flandreau Masonic Temple, 300 E. Second Ave., Flandreau, 89001725

Potter County

Holland, George, House, 314 N. Exene St., Gettysburg, 89001721

TENNESSEE**Hickman County**

Shelby Bend Archeological District, Address Restricted, Greenfield Bend vicinity, 89001760

UTAH**Salt Lake County**

Armista Apartments (Salt Lake City MPS), 555 E. 100 South, Salt Lake City, 89001736

Cluff Apartments (Salt Lake City MPS), 1270—1280 E. 200 South, Salt Lake City, 89001739

Cornell Apartments (Salt Lake City MPS), 101 S. 600 East, Salt Lake City, 89001741

Corona Apartments (Salt Lake City MPS), 335 S. 200 East, Salt Lake City, 89001742

Ivanhoe Apartments (Salt Lake City MPS), 417 E. 300 South, Salt Lake City, 89001738

Lincoln Arms Apartments (Salt Lake City MPS), 242 E. 100 South, Salt Lake City, 89001737

Smith Apartments (Salt Lake City MPS), 228 S. 300 East, Salt Lake City, 89001740

The following property is also being considered for listing in the National Register:

ALASKA**Anchorage Borough**

Indian Valley Mine, Address Restricted, Indian vicinity 89001762

[FR Doc. 89-23288 Filed 10-2-89; 8:45 am]

BILLING CODE 4310-70-M

INTERSTATE COMMERCE COMMISSION

[ICC Order No. P-106]

Passenger Train Operation; Chicago Central and Pacific Railroad Co.

The National Railroad Passenger Corporation (AMTRAK) has established through passenger train service between Chicago, Illinois and Seattle, Washington, Train Nos. 7 & 8, the Empire Builder. These train operations require the use of tracks and other facilities of the Soo Line Railroad Company (SL). A portion of the SL tracks near Tunnel City, Wisconsin will be out of service because of scheduled track work and tunnel repair on September 18th and 19th. An alternate route is available via the Burlington Northern Railroad that requires the use of the Chicago & Central Pacific Railroad Company tracks between East Cabin and Portage, Illinois.

It is the opinion of the Commission that such an operation is necessary in the interest of the public and the commerce of the people; that notice and public procedure are impracticable and contrary to the public interest; and that good cause exists for making this order effective upon less than thirty days' notice.

It is ordered, (a) Pursuant to authority vested in me by order of the Commission decided January 13, 1986, and of the authority vested in the Commission by section 402(c) of the Rail

Passenger Service Act of 1970 (45 U.S.C. 562(c)), Chicago & Central Pacific Railroad Company is directed to operate trains of the National Railroad Passenger Corporation between East Cabin and Portage, Illinois in order to permit a rerouting utilizing the Burlington Northern Railroad.

(b) In executing the provisions of this order, the common carriers involved shall proceed even if no agreements or arrangements may now exist between them with reference to the compensation terms and conditions applicable to said questions. The compensation terms and conditions shall be, during the time this order remains in force, those which are voluntarily agreed upon by and between said carriers; or upon failure of the carriers to so agree, the compensation terms and conditions shall be as hereafter fixed by the Commission upon petition of any or all of said carriers in accordance with pertinent authority conferred upon it by the Interstate Commerce Act and by the Rail Passenger Service Act of 1970, as amended.

(c) *Application.* The provisions of this order shall apply to intrastate, interstate, and foreign commerce.

(d) *Effective date.* This order shall become effective at 12:01 a.m., (C.D.T.), September 18, 1989.

(e) *Expiration date.* The provisions of this order shall expire at 11:59 p.m., (C.D.T.), September 19, 1989, unless otherwise modified, amended, or vacated by order of this Commission.

This order shall be served upon the Chicago Central & Pacific Railroad Company and the National Railroad Passenger Corporation, and a copy of this order shall be filed with the Director, Office of the Federal Register.

Issued at Washington, DC, September 11, 1989, Heber P Hardy, Agent

Noreta R. McGee,

Secretary.

[FR Doc. 89-23291 Filed 10-2-89; 8:45 am]

BILLING CODE 7035-01-M

[ICC Order No. P-105]

Passenger Train Operation; Wisconsin Central Ltd.

The National Railroad Passenger Corporation (AMTRAK) has established through passenger train service between Chicago, Illinois and Seattle, Washington, Train Nos. 7 & 8, the Empire Builder. These train operations require the use of tracks and other facilities of the Soo Line Railroad Company (SL). A portion of the SL

tracks near Deerfield, Illinois are temporarily out of service because of a derailment. An alternate route is available via the Wisconsin Central Ltd. (WC) between Columbus, Wisconsin and Chicago, Illinois via Duplainville, Wisconsin.

It is the opinion of the Commission that such an operation is necessary in the interest of the public and the commerce of the people; that notice and public procedure are impracticable and contrary to the public interest; and that good cause exists for making this order effective upon less than thirty days' notice.

It is ordered, (a) Pursuant to authority vested in me by order of the Commission decided January 13, 1986, and of the authority vested in the Commission by section 402(c) of the Rail Passenger Service Act of 1970 (45 U.S.C. 562(c)), Wisconsin Central Ltd. (WC) is directed to operate trains of the National Railroad Passenger Corporation (AMTRAK) between Columbus, Wisconsin, via Duplainville, Wisconsin, and Chicago, Illinois.

(b) In executing the provisions of this order, the common carriers involved shall proceed even if no agreements or arrangements may now exist between them with reference to the compensation terms and conditions applicable to said operations. The compensation terms and conditions shall be, during the time this order remains in force, those which are voluntarily agreed upon by and between said carriers; or upon failure of the carriers to so agree, the compensation terms and conditions shall be as hereafter fixed by the Commission upon petition of any or all of said carriers in accordance with pertinent authority conferred upon it by the Interstate Commerce Act and by the Rail Passenger Service Act of 1970, as amended.

(c) *Application.* The provisions of this order shall apply to intrastate, interstate, and foreign commerce.

(d) *Effective date.* This order shall become effective at 1:00 p.m., (e.d.t.), September 4, 1989.

(e) *Expiration date.* The provisions of this order shall expire at 1:00 p.m., (c.d.t.), September 5, 1989, unless otherwise modified, amended, or vacated by order of this Commission.

This order shall be served upon Wisconsin Central Ltd., and upon the National Railroad Passenger Corporation (AMTRAK); and a copy of this order shall be filed with the Director, Office of the Federal Register.

Issued at Washington, DC, September 4, 1989, Bernard Gaillard, Agent.

Noreta R. McGee,

Secretary.

[FR Doc. 89-23289 Filed 10-2-89; 8:45 am]

BILLING CODE 7035-01-M

DEPARTMENT OF JUSTICE

Lodging of Consent Decree Pursuant to the Clean Water Act

In accordance with Departmental Policy, 28 CFR 50.7 notice is hereby given that a consent decree in *United States v. Associated Materials, Inc., et al.*, Civil Action No. 89-2511 (D.N.J.) was lodged with the United States District Court for the District of New Jersey on June 20, 1989.

The proposed consent decree concerns alleged violations of the Clean Water Act, 33 U.S.C. 1311 and 1344, as a result of dredging and the discharge of fill material into portions of Pompton Lake, NJ., and onto wetlands adjacent to the lake, without authorization from the U.S. Army Corps of Engineers. The consent decree requires Associated Materials, Inc. to restore Pompton Lake by removing all fill material placed into the lake by them, to a depth of seven feet, and by removing all access roads, berms, dikes and unconsolidated sidecast fill material. The decree further requires Associated Materials, Inc. to acquire suitable wetlands property in Northern New Jersey, valued at a minimum of \$50,000.00, and convey that property to the State Office of Natural Lands Management, or, in the alternative, to the U.S. Fish and Wildlife Service.

The Department of Justice will receive until October 25, 1989, written comments relating to the consent decree. Comments should be addressed to the Assistant Attorney General, Land and Natural Resources Division, U.S. Department of Justice, Attention: Robert LeFevre, Road 7130, 10th St. & Constitution Avenue, NW Washington, DC 20530 and should refer to *United States v. Associated Materials, Inc.*, DJ Reference No. 90-5-1-1-3356.

The consent decree may be examined at the Clerk's Office, United States District Court, U.S. Post Office and Courthouse Building, Newark, NJ 07101.

Richard B. Stewart,

Assistant Attorney General, Land and Natural Resources Division.

[FR Do. 89-23317 Filed 10-2-89; 8:45 am]

BILLING CODE 4410-01-M

DEPARTMENT OF LABOR

Employment and Training Administration

Determinations Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with section 223 of the Trade Act of 1974 (19 U.S.C. 2273) the Department of Labor herein presents summaries of determinations regarding eligibility to apply for adjustment assistance issued during the period of September 1989.

In order for an affirmative determination to be made and a certification of eligibility to apply for adjustment assistance to be issued, each of the group eligibility requirements of section 222 of the Act must be met.

(1) That a significant number or proportion of the workers in the workers' firm, or an appropriate subdivision thereof, have become totally or partially separated,

(2) That sales or production, or both, of the firm or subdivision have decreased absolutely, and

(3) That increases of imports of articles like or directly competitive with articles produced by the firm or appropriate subdivision have contributed importantly to the separations, or threat thereof, and to the absolute decline in sales or production.

Negative Determinations

In each of the following cases the investigation revealed that criterion (3) has not been met. A survey of customers indicated that increased imports did not contribute importantly to worker separations at the firm.

TA-W-22,795; *Textron Lycoming Div., Avco Corp., Stratford, CT*

TA-W-23,134; *Babcock & Wilcox Co., Bryan, TX*

TA-W-23,140; *Designers Workshop, Phoenix, AZ*

TA-W-23,181; *Laird & Co., Scobeyville, NJ*

TA-W-23,210; *Shadyside Stamping Corp of Ohio, Shadyside, OH*

TA-W-23,157; *Schaevitz Engineering Co., Aerospace Div Pennsauken, NJ*

TA-W-23,138; *DeBari Fashions Finishing Corp., Middle Village, NY*

TA-W-23,096; *Albert Forte Neckwear, Paulsboro, NJ*

TA-W-23,193; *Trasco, Inc., South Paris, ME*

TA-W-23,126; *Universal Resources Corp., Oklahoma City, OK*

TA-W-23,144; *Globe Motors Div. Of LCS, Dayton, OH*

TA-W-23,175; *Dover Weaver Corp., Paris, KY*

TA-W-23,119; *R.S.P Industries, Inc., Brooklyn, NY*

TA-W-23,102; *Demetrious Designs, New York, NY*

TA-W-23,135; *Burlington Industries, Inc., Rockly Mount, NC*

TA-W-23,159; *Teleflex, Inc., Marine Div Limerick, PA*

In the following cases, the investigation revealed that criterion (3) has not been met for the reasons specified.

TA-W-23,194; *United Auto Workers, Local #558, Willow Springs, IL*

The workers' firm does not produce an article as required for certification under Section 222 of the Trade Act of 1974.

TA-W-23,205; *Murphy/Hennessee, Inc., Owensboro, KY*

The workers' firm does not produce an article as required for certification under Section 222 of the Trade Act of 1974.

TA-W-23,156; *Phoenix Geoscience, Inc., Denver, CO*

The investigation revealed that criterion (2) has not been met. Sales or production did not decline during the relevant period as required for certification.

TA-W-23,148; *Kline Hydraulic, Inc., Westerville, OH*

Increased imports did not contribute importantly to workers separations at the firm.

TA-W-23,122; *Santa Fe Energy Co., Amarillo, TX*

Increased imports did not contribute importantly to workers separations at the firm.

TA-W-23,202; *Control Data Corp., Grey Fox Component Technology Center, St. Paul, MN*

The workers' firm does not produce an article as required for certification under Section 222 of the Trade Act of 1974.

TA-W-23,219; *Delta Chemicals, Inc., Searsport, ME*

Increased imports did not contribute importantly to workers separations at the firm.

TA-W-23,154; *Philips Medical System N.A., Shelton, CT*

Increased imports did not contribute importantly to workers separations at the firm.

TA-W-23,182; *Mercury Manufacturing Corp, Hancock, MI*

Increased imports did not contribute importantly to workers separations at the firm.

TA-W-23,186; *Peter Stewart, Inc., Pleasantville, NJ*

Increased imports did not contribute importantly to workers separations at the firm.

TA-W-23,151; *Nelson Oil & Gas, Inc., Shreveport, LA*

The workers' firm does not produce an article as required for certification under Section 222 of the Trade Act of 1974.

TA-W-23,187; *Petroleum Management, Inc., Corpus Christi, TX*

The workers' firm does not produce an article as required for certification under Section 222 of the Trade Act of 1974.

TA-W-23,195; *Wycoff Steel, Inc., Plymouth, MI*

Increased imports did not contribute importantly to workers separations at the firm.

TA-W-23,206; *Newan Crosby Steel, Inc., Pawtucket, RI*

Increased imports did not contribute importantly to workers separations at the firm.

TA-W-23,172; *Alside, Div. of Associated Materials, Inc., Cuyahoga Falls, OH*

Increased imports did not contribute importantly to workers separations at the firm.

TA-W-23,188; *Petrorentas Internacionals, Inc., McAllen, TX*

The workers' firm does not produce an article as required for certification under Section 222 of the Trade Act of 1974.

Affirmative Determination

TA-W-23,196; *American Stratigraphic Co., Denver, CO*

A certification was issued covering all workers separated on or after July 5, 1988.

TA-W-23,204; *Depoister Drilling Co., Effingham, IL*

A certification was issued covering all workers separated on or after June 26, 1988 and before July 1, 1989.

TA-W-23,152; *Paris Manufacturing Corp., South Paris, ME*

A certification was issued covering all workers separated on or after June 22, 1988 and before July 31, 1989.

TA-W-23,155; *Philips Park-Norelco, Essex, CT*

A certification was issued covering all workers separated on or after June 21, 1988.

TA-W-23,139; *Delta Apparel, Inc., Knoxville, TX*

A certification was issued covering all workers separated on or after June 29, 1988 and before September 12, 1989.

TA-W-23,105; *Datronix, Inc., Elk River, MN*

A certification was issued covering all workers separated on or after July 21, 1988.

TA-W-23,131; *A-1 Bit & Tool Co. Service Center, Lafayette, LA*

A certification was issued covering all workers separated on or after June 26, 1988.

TA-W-23,184; *Paterson Shade Co., Paterson, NJ*

A certification was issued covering all workers separated on or after July 8, 1988.

TA-W-23,113; *Lasmo Energy Corp., Great Bend, KS*

A certification was issued covering all workers separated on or after June 12, 1988.

TA-W-23,185; *Pecten International, Houston, TX*

A certification was issued covering all workers separated on or after July 5, 1988.

TA-W-23,177; *Fox Testing Co., Inc., Dodge City, KS*

A certification was issued covering all workers separated on or after June 6, 1988 and before January 1, 1989.

TA-W-23,190; *Shell Offshore, Inc., New Orleans, LA*

A certification was issued covering all workers separated on or after July 5, 1988.

TA-W-23,191; *Shell Oil Co., Houston, TX*

A certification was issued covering all workers separated on or after July 5, 1988.

TA-W-23,192; *Shell Western E & P Inc., Houston, TX and At Various Locations in California*

A certification was issued covering all workers separated on or after July 5, 1988.

TA-W-23,150; *Montgomery Drilling, Bakersfield, CA*

A certification was issued covering all workers separated on or after June 26, 1988 and before September 1, 1989.

TA-W-23,150A; *Montgomery Drilling, Roosevelt, UT*

A certification was issued covering all workers separated on or after June 26, 1988 and before September 1, 1989.

TA-W-23,147; *Houston Processors, Inc., Houston, TX*

A certification was issued covering all workers separated on or after June 23, 1988.

TA-W-23,133; BTK Industries, Inc., El Paso, TX

A certification was issued covering all workers separated on or after November 1, 1988.

TA-W-23,132; Alert Shoe Corp., New York, NY

A certification was issued covering all workers separated on or after June 27 1988.

TA-W-23,129; Atlas Cased Hole Div. of Western Atlas International, Pampa, TX

A certification was issued covering all workers separated on or after June 8, 1988.

TA-W-23,091; St. Clair-Pakwell, Wilsonville, OR

A certification was issued covering all workers separated on or after May 19, 1988.

TA-W-23,200; C.N. Burman Co., Paterson, NJ

A certification was issued covering all workers separated on or after July 8, 1988.

TA-W-23,180; Knox Corder Drilling Co., Devine, TX

A certification was issued covering all workers separated on or after July 10, 1988 and before July 1, 1989.

TA-W-23,143; General Electric Co., Holland, MI

A certification was issued covering all workers engaged in employment related to the production of cables for hermetic motors at area 58 of subassembly operations at the Holland, Michigan plant of General Electric Manufacturing Dept. separated on or after June 28, 1988.

TA-W-23,001; Getter Trucking, Inc., Corp. Headquarters, Billings, MT and At Various Locations In The Following States

TA-W-23,001A MT

TA-W-23,001B ND

TA-W-23,001C OK

TA-W-23,001D TX

TA-W-23,001E WY

A certification was issued covering all workers separated on or after May 12, 1988.

I hereby certify that the aforementioned determinations were issued during the month of September 1989. Copies of these determinations are available for inspection in Room 6434, U.S. Department of Labor, 601 D Street, NW Washington, DC 20213 during normal business hours or will be mailed

to persons who write to the above address.

Marvin M. Fooks,

Director, Office of Trade Adjustment Assistance.

[FR Doc. 89-23310 Filed 10-2-89; 8:45 am]

BILLING CODE 4510-30-M

[TA-W-23, 024]

Bison Drilling, Inc., Wakeeney, KS; Negative Determination Regarding Application for Reconsideration

By an application dated September 5, 1989 the petitioners requested administrative reconsideration of the Department's negative determination on the subject petition for trade adjustment assistance. The denial notice was issued on August 9, 1989 and published in the **Federal Register** on September 6, 1989 (54 FR 37031).

Pursuant to 29 CFR 90.18(c) reconsideration may be granted under the following circumstances:

(1) If it appears on the basis of facts not previously considered that the determination complained of was erroneous;

(2) If it appears that the determination complained of was based on a mistake in the determination of facts not previously considered; or

(3) if, in the opinion of the Certifying Officer, a misinterpretation of facts or of the law justified reconsideration of the decision.

Investigation findings show that Bison Drilling is a producer and markets its oil to independent distributors.

In order for a worker group to be certified eligible to apply for adjustment assistance, it must meet all three of the Group Eligibility Requirements of the Trade Act—a significant decrease in employment, an absolute decrease in sales or production and an increase in imports "contributing importantly" to worker separations. In the subject case the "contributed importantly" test was not met.

The Department's denial was based on the fact that the "contributed importantly" test of the Group Eligibility Requirements of the Trade Act was not met. The "contributed importantly" test is generally demonstrated by a survey of the customers of the workers' firm. The Department's survey of Bison Drilling's customers showed that the customers either reduced their import purchases of crude oil or did not purchase imported crude oil during the period under investigation.

The claim, that the price of crude oil paid to Bison Drilling by its customers is largely the result of the price of

imported crude oil, would not form a basis for certification. Price is not one of the Group Eligibility Requirements for certification. Also, the investigation findings show that none of the customers of Bison Drilling had increased purchases of imported crude oil at the expense of Bison Drilling during the relevant time period.

Conclusion

After review of the application and investigation findings, I conclude that there has been no error or misinterpretation of the law or of the facts which would justify reconsideration of the Department of Labor's prior decision. Accordingly, the application is denied.

Signed at Washington, DC, this 20th day of September 1989.

Mary Ann Wyrach,

Director, Office of Unemployment Insurance Service, UIS.

[FR Doc. 89-23311 Filed 10-2-89; 8:45 am]

BILLING CODE 4510-30-M

[TA-W-23,032]

Chrysler Corp., Kenosha, WI; Negative Determination Regarding Application for Reconsideration

By a letter of September 6, 1989, counsel for the United Auto Workers of America (UAW) requested administrative reconsideration of the Department's negative determination for trade adjustment assistance specifically for those workers engaged in the production of "L" body models (Omni/Horizon) at the Chrysler Corporation plant in Kenosha, Wisconsin. The denial notice was issued on August 4, 1989 and published in the **Federal Register** on September 6, 1989 (54 FR 37032).

Pursuant to 29 CFR 90.18(c) reconsideration may be granted under the following circumstances:

(1) If it appears on the basis of facts not previously considered that the determination complained of was erroneous;

(2) if it appears that the determination complained of was based on a mistake in the determination of facts not previously considered; or

(3) if, in the opinion of the Certifying Officer, a misinterpretation of facts or of the law justified reconsideration of the decision.

Counsel for the union states that the Department should have used a broader comparison of the production data on "L" bodies, the Omni/Horizon models, by collecting production data from September 1986 to the transfer of

production operations to Detroit, Michigan, instead of comparing the production in the 1st quarter of model year (MY) 1989 with the same quarter of MY 1988.

The union's petition dated May 24, 1989 was filed for approximately 5,000 workers laid off at Kenosha in December 1988. The earliest coverage possible based on the petition is May 24, 1988.

The Department's denial of trade adjustment assistance to workers at Kenosha producing Omni/Horizon autos noted that production and sales were higher in the third quarter of calendar year 1988—(1st quarter of (MY) 1989) when Chrysler Corporation decided to transfer. That decision and the actual transfer of production was the dominant cause of the cessation of production and unemployment of workers at Kenosha. The transfer of production from Kenosha to Detroit was so dominant a cause that worker separations would have occurred regardless of the level of imports of small automobiles. Production in Detroit of the Omni/Horizon models began in the 2nd quarter of MY 1989.

Conclusion

After review of the application and investigative findings, I conclude that there has been no error or misinterpretation of the law or of the facts which would justify reconsideration of the Department of Labor's decision. Accordingly, the application is denied.

Signed at Washington, DC, this 25th day of September 1989.

Stephen A. Wandner,

Deputy Director, Office of Legislation and Actuarial Services, UIS.

[FR Doc. 89-23314 Filed 10-2-89; 8:45 am]

BILLING CODE 4510-30-M

[TA-W-22,214]

Conoco, Inc., Production Engineering and Research (Formerly Production Engineering Services), Houston, TX., Negative Determination Regarding Eligibility To Apply for Worker Adjustment Assistance; Correction

The notice corrects the location of the workers' firm for the subject petition published on March 3, 1989 in the *Federal Register* on page 9099 of FR Document 89-5035.

Under Negative Determinations, in column 2 lines 22 and 23 on page 9099 the location of the workers' firm is corrected to read "Houston, TEX. instead of Denver, CO.

Signed at Washington, DC, this 25th day of September, 1989.

Marvin M. Fooks,

Director, Office of Trade Adjustment Assistance.

[FR Doc. 89-23312 Filed 10-2-89; 8:45 am]

BILLING CODE 4510-30-M

[TA-W-23,058]

Keystone Lamp Mfg. Corp., Slatington, PA; Amended Certification Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with section 223 of the Trade Act of 1974 (19 U.S.C. 2273) the Department of Labor issued a Certification of Eligibility To Apply for Worker Adjustment Assistance on August 17 1989 applicable to all workers of Keystone Lamp Manufacturing Corporation, Slatington, Pennsylvania. The notice was published in the *Federal Register* on September 6, 1989 (54 FR 37033).

The Department also issued a certification, TA-W-17,893, for the same worker group on November 19, 1988 which expired on November 19, 1988.

The Department, on its own motion, is amending TA-W-23,058 by deleting the May 31, 1988 impact date and inserting a new impact date of November 19, 1988 in order to delete the overlap period for coverage in the two certifications. The amended notice applicable to TA-W-23,058 is hereby issued as follows:

All workers of Keystone Lamp Mfg. Corp., Slatington, Pennsylvania who became totally or partially separated from employment on or after November 19, 1988 are eligible to apply for adjustment assistance under section 222 of the Trade Act of 1974.

Signed at Washington, DC, this 22nd day of September 1989.

Robert O. Deslongchamps,

Director, Office of Legislation and Actuarial Services, UIS.

[FR Doc. 89-23313 Filed 10-2-89; 8:45 am]

BILLING CODE 4510-30-M

[TA-W-18,731]

Linden Apparel Corp., Linden TN; Notice of Negative Determination on Reconsideration

Pursuant to a remand by the U.S. Court of International Trade, dated June 6, 1989, in *Former Employees of Linden Apparel Corporation v. Secretary of Labor* (USCIT 87-04-00625) the Department makes the following negative determination on reconsideration for workers of Linden Apparel Corporation, Linden, Tennessee.

The workers at Linden Apparel produced men's and boys' painter pants in 1985 and 1986. Overalls were produced at Linden from 1979 to 1985. The investigation findings show increased production in the last quarter of 1985, and for the first five months of 1986 compared to the respective periods in 1984 and 1985. A small pressing and packing operation started at Linden Apparel after painter pants production ceased in June 1986.

The Department's initial denial was based on the fact that the "contributed importantly" test of the Group Eligibility Requirements of the Trade Act of 1974 was not met. Linden Apparel was a contractor who worked exclusively for one apparel manufacturer—the Washington Manufacturing Company. The Washington Manufacturing Company did not import men's and boys' painter pants and overalls or use any foreign contractors during the period applicable to the petition. Also, during the period applicable to the petition, Washington Manufacturing increased its reliance on other domestic contractors and experienced increased sales of men's and boys' painter pants and overalls. No customer survey was conducted since it would have been difficult to show adverse impact when the company had increased sales of painter pants and overalls in 1986.

The USCIT's remand directed the Department to conduct a customer survey in order to determine whether the shift in purchases by Washington's customers from the articles Linden produced to imports "contributed importantly" to the worker separations at Linden Apparel. The USCIT also directed the Department to inquire into the corporate structure of Washington Industries as it affects Linden Apparel.

On remand, the Department surveyed Washington Manufacturing Company's customers and found that none imported painter pants in the period applicable to the petition. Most of the customers indicated that painter pants were a fad which ended abruptly in 1986.

Other findings on remand show that Washington Industries was the holding company for several corporations including Washington Manufacturing—the apparel arm of Washington Industries. Linden Apparel Corporation, a pants contractor, was owned by Washington Manufacturing.

New findings on remand show that Haywood Male was merged into Washington Industries sometime in early 1987. Haywood had started a plant in Haiti in late 1985; however, there was no corporate relationship between Haywood Male and Washington

Industries at that time. Production of painter pants at Linden ceased in June 1986 before any corporate relationship between Haywood and Washington Industries existed. Further, at the time applicable to the petition, the Haitian plant produced men's jackets and western shirts—articles not produced at Linden. The Haitian plant did not produce painter pants during the period applicable to the petition.

In October 1986, BNHH Properties purchased Washington Industries through a leveraged buy out. Prior to this transaction, there had been no relationship between Haywood Male and Washington Industries except that since October 1, 1986, both had been owned by BNHH Properties, Inc. In March 1988 Washington Manufacturing filed for bankruptcy and most of its records were conveyed to the Washington Apparel Group in Franklin, Kentucky or discarded by the trustee. Officials at the Washington Apparel Group reported no records of the Washington Manufacturing Company.

Counsel for the petitioners submitted several affidavits for the Department to consider. Some of the affiants indicated that after the closure of Linden in 1986 they were transferred to another company plant in Hohenwald, Tennessee whose workers subsequently became eligible to apply for trade adjustment assistance benefits (TA-W-20,972).

On September 30, 1988, the Department issued certifications to workers at several plants of the Washington Manufacturing Company. These certifications were based on increased company imports of tops and bottoms with tops consisting between 85 to 90 percent of the company imports in 1987. One of these certifications was for workers at the Hohenwald plant which was part of an integrated production operation at Washington Manufacturing. The Hohenwald certification had an impact date of August 15, 1987, one year prior to its petition date.

The Department's certifications, mentioned above, would not provide a basis for certifying the workers at Linden since they are based on a much later petition dated August 15, 1988. The Linden petition was dated November 21, 1986. Further, the Linden plant produced mainly painter pants in 1986 whose cycle as a fad came to an end when customers did not reorder. According to company officials, the finishing and packing operation at Linden was transferred to other domestic company plants. These Linden workers cannot be reached for coverage under the August 15, 1988 petition.

Conclusion

After reconsideration, I affirm the original notice of negative determination of eligibility to apply for adjustment assistance to workers of Linden Apparel Corporation, Linden, Tennessee.

Signed at Washington, DC, this 22nd day of September 1989.

Robert O. Deslongchamps,
Director, Office of Legislation and Actuarial Services, UIS.

[FR Doc. 89-23309 Filed 10-2-89; 8:45 am]

BILLING CODE 4510-30-M

Job Training Partnership Act (JTPA): JTPA Native American Programs' Advisory Committee; Renewal

In accordance with the provisions of the Federal Advisory Committee Act, and after consultation with the General Services Administration, the Secretary of Labor has determined that the renewal of the Job Training Partnership Act (JTPA) Native American Programs' Advisory Committee is in the public interest in regard to the consultation responsibilities imposed on the Department under title IV, section 401 of JTPA.

The Committee will provide advice to the Assistant Secretary for Employment and Training on rules, regulations and performance standards, specifically and solely for Native American programs authorized under title IV section 401 of JTPA. The Assistant Secretary seeks this advice, as one of several means of consultation with the Native American community, in order to develop such rules, regulations and performance standards. The Committee will provide the Assistant Secretary with a summary report of the advice offered on these matters within 30 days of its scheduled meetings.

As paragraph 401(h)(1) of JTPA directs, the Committee shall be comprised of representatives of the Native American community. The Committee will include, but not be limited to, representatives of JTPA, section 401 grantees and national organizations representing the Native American community. An equitable geographic distribution will be sought in addition to appropriate representations of both tribes and non-tribal organizations. The members shall not be compensated and shall not be deemed to be employees of the United States.

The Committee will function solely as an advisory body, and in compliance with the provisions of the Federal Advisory Committee Act. Its charter has been filed under the Act concurrently with this publication.

Interested persons are invited to submit comments regarding the renewal of the JTPA Native American Programs' Advisory Committee. Such comments should be addressed to: Mr. Paul A. Mayrand, Director, Office of Special Targeted Programs, U.S. Department of Labor, Employment and Training Administration, Room N-4641, 200 Constitution Ave., N.W., Washington, DC 20210, Telephone: (202) 535-0500.

Signed at Washington, DC, this 27th day of Sept., 1989.

Elizabeth Dole,
Secretary of Labor.

[FR Doc. 89-23307 Filed 10-2-89; 8:45 am]

BILLING CODE 5410-30-M

NATIONAL FOUNDATION ON THE ARTS AND HUMANITIES

National Endowment for the Humanities

Agency Information Collection Activities Under OMB Review

AGENCY: National Endowment for the Humanities.

ACTION: Notice.

SUMMARY: The National Endowment for the Humanities (NEH) has sent to the Office of Management and Budget (OMB) the following proposals for the collection of information under the provisions of the Paperwork Reduction Act (44 U.S.C. chapter 35).

DATES: Comments on this information collection must be submitted on or before November 2, 1989.

ADDRESSES: Send comments to Ms. Susan Daisey, Assistant Director, National Endowment for the Humanities, Grants Office, Room 310, 1100 Pennsylvania Avenue, NW Washington, DC 20506 (202-786-0494) and Mr. Jim Houser, Office of Management and Budget, New Executive Office Building, 726 Jackson Place, NW Room 3208, Washington, DC 20503 (202-395-73167).

FOR FURTHER INFORMATION CONTACT: Ms. Susan Daisey, National Endowment for the Humanities, Grants Office, Room 310, 1100 Pennsylvania Avenue, NW Washington, DC 20506 (202-786-0494) from whom copies of forms and supporting documents are available.

SUPPLEMENTARY INFORMATION: All of the entries are grouped into new forms, revisions, or extensions. Each entry is issued by NEH and contains the following information: (1) The title of the form; (2) the agency form number, if applicable; (3) how often the form must

be filled out; (4) who will be required or asked to report; (5) what the form will be used for; (6) an estimate of the number of responses; (7) an estimate of the total number of hours needed to fill out the form. None of these entries are subject to 44 U.S.C. 3504 (h).

Category: Revisions

Title: General Programs: Humanities Projects in Museums and Historical Organizations/Guidelines and Application Instructions.

Form Number: Not Applicable.

Frequency of Collection: Twice a year at each deadline.

Respondents: Museums and historical organizations.

Use: Application for funding.

Estimated Number of Respondents: 280.

Frequency of Response: Once.

Estimated Hours for Respondents to Provide Information: 40 per respondent.

Estimated Total Annual Reporting and Recording Burden: 11,200 hours.

Thomas Kingston,

Assistant Chairman for Operations.

[FR Doc. 89-23226 Filed 10-2-89; 8:45 am]

BILLING CODE 7530-01-M

Meeting; Music Advisory Panel

Pursuant to section 10(a)(2) of the Federal Advisory Committee Act (Public Law 92-463), as amended, notice is hereby given that a meeting of the Music Advisory Panel (Chorus Section) to the National Council on the Arts will be held on October 24-26, 1989, from 9:00 a.m.-6:00 p.m. in Room M14 of the Nancy Hanks Center, 1100 Pennsylvania Avenue, NW Washington, DC 20506.

A portion of this meeting will be open to the public on October 26, 1989, from 4:00 p.m.-6:00 p.m. The topic for discussion will be guidelines and policy issues.

The remaining portions of this meeting on October 24-25, 1989, from 9:00 a.m.-6:00 p.m. and on October 26, 1989, from 9:00 a.m.-4:00 p.m. are for the purpose of Panel review, discussion, evaluation, and recommendation on applications for financial assistance under the National Foundation on the Arts and the Humanities Act of 1965, as amended, including information given in confidence to the agency by grant applicants. In accordance with the determination of the Chairman published in the Federal Register of February 13, 1980, these sessions will be closed to the public pursuant to subsection (c)(4) (6) and (9)(B) of

section 552b of title 5, United States Code.

If you need special accommodations due to a disability, please contact the Office for Special Constituencies, National Endowment for the Arts, 1100 Pennsylvania Avenue, NW Washington, DC 20506, 202/682-5532, TTY 202/682-5496 at least seven (7) days prior to the meeting.

Further information with reference to this meeting can be obtained from Ms. Yvonne M. Sabine, Advisory Committee Management Officer, National Endowment for the Arts, Washington, DC 20506, or call 202/682-5433.

Dated: September 26, 1989.

Yvonne M. Sabine,

Director, Council and Panel Operations,
National Endowment for the Arts.

[FR Doc. 89-23318 Filed 10-2-89; 8:45 am]

BILLING CODE 7537-01-M

NUCLEAR REGULATORY COMMISSION

Power Authority of the State of New York; Environmental Assessment and Findings of no Significant Impact

[Docket No. 50-333]

The U.S. Nuclear Regulatory Commission (NRC/the Commission) is considering issuance of an exemption from the requirements of appendix J of 10 CFR part 50 to the Power Authority of the State of New York (PASNY/the licensee), for the James A. FitzPatrick Nuclear Power Plant located in Oswego County, New York.

Environmental Assessment

Identification of Proposed Action

The licensee would be exempted from the requirements of section IV.A. of appendix J to 10 CFR part 50 to the extent that a Type A, Type B, or Type C Leak Rate Test would not have to be performed following repair of Weld Number 10-14-884A in the "B" Core Spray System full flow test return piping to the suppression chamber (Pipe No. 10"-W23-152-9B) prior to startup from the current maintenance outage. The weld would be subject to a Type A Primary Containment Leak Rate Test prior to startup from the next refueling outage, which is scheduled to start in March 1990.

The Need for the Proposed Action

In accordance with section IV.A. of appendix J, a Type A, Type B or Type C Test (as applicable) is required to be performed following any major modification or replacement of a component which is part of the primary

containment boundary. An inservice inspection conducted during the current mid-cycle maintenance outage has revealed the presence of a slag inclusion within Weld Number 10-14-884A, which has been repaired in accordance with ASME Section XI and ANSI B-31.1-1967. In order to comply with the intent of appendix J, the licensee has determined that the Type A, Type B, or Type C Leak Rate Test criteria are applicable. However, the licensee has also determined that, because of the location of the weld repair, an isolatable volume cannot be attained. Therefore, pressure testing can only be accomplished by performing a Type A primary containment integrated leak rate test. Further, the licensee has determined that performance of a Type A test is not feasible at this time since it would seriously delay plant startup from the current maintenance outage. Therefore, the licensee has requested an exemption from section IV.A. of appendix J to 10 CFR part 50.

In lieu of a Type A, Type B, or Type C Test, the licensee has proposed 100 percent radiography, surface examination of the affected weld repair, and an inservice flow test. This will ensure that the intent of section IV.A. (the identification of any potential leakage paths resulting from repair of a component which is part of the primary containment boundary) is met.

Environmental Impact of the Proposed Action

The alternate proposals would ensure that excessive leakage from the primary containment via the weld repair does not exist and would provide a level of safety at least equivalent to that attained by compliance with section IV.A. of appendix J to 10 CFR part 50. On this basis, the Commission concludes that there are no significant radiological environmental impacts associated with this proposed exemption.

With regard to potential nonradiological impacts, the proposed exemption involves features located entirely within the restricted areas as defined in 10 CFR part 20. It does not affect nonradiological plant effluents and has no other environmental impact. Therefore, the Commission concludes that there are no significant nonradiological environmental impacts associated with the proposed exemption.

Alternative to the Proposed Action

It has been concluded that there is no measurable impact associated with the proposed exemption and associated

license amendment; any alternative to the exemption will have either no environmental impact or greater environmental impact.

Alternative Use of Resources

This action involves no use of resources not previously considered in the Final Environmental Statement (construction permit and operating license) for the James A. FitzPatrick Nuclear Power Plant.

Agencies and Persons Consulted

The NRC staff reviewed the licensee's request and did not consult other agencies or persons.

Finding of No Significant Impact

The Commission has determined not to prepare an environmental impact statement for the proposed exemption.

Based on the foregoing environmental assessment, we conclude that the proposed action will not have a significant effect on the quality of the human environment.

For further details with respect to this action, see the request for exemption dated September 28, 1989, which is available for public inspection at the Commission's Public Document Room, Gelman Building, 2120 L Street, N.W. Washington, D.C., and at the Penfield Library, State University College of Oswego, Oswego, New York.

Dated at Rockville, Maryland, this
For the Nuclear Regulatory Commission.

Scott A. McNeil,

*Acting Director, Project Directorate I-1,
Division of Reactor Projects—1/II, Office of
Nuclear Reactor Regulation.*

[FR Doc. 89-23397 Filed 9-29-89; 12:11 pm]

BILLING CODE 7590-01-M

OFFICE OF PERSONNEL MANAGEMENT

Director's Task Force on Pay Reform

AGENCY: Office of Personnel Management.

ACTION: Notice of meeting.

SUMMARY: According to provisions of section 10 of the Federal Advisory Committee Act (Pub. L. 92-463), notice is hereby given that a meeting of the OPM Director's Task Force on Pay Reform will be held on:

DATE: October 18, 1989, 11:00 a.m., Office of Personnel Management, Room 1350, 1900 E Street, NW., Washington, DC.

AGENDA: The Task Force is considering various alternatives for reforming the Federal white collar pay system and

developing options for the Director's consideration.

FOR FURTHER INFORMATION CONTACT: Vernon B. Parker, Counselor to the Director, Room 5524, Office of Personnel Management, 1900 E Street, NW., 20415.

SUPPLEMENTARY INFORMATION: As time permits, an opportunity will be provided for members of the public in attendance at the meeting to provide their views.

Office of Personnel Management.

Constance Berry Newman,

Director.

[FR Doc. 89-23495 Filed 10-2-89; 8:45 am]

BILLING CODE 6325-01-M

PACIFIC NORTHWEST ELECTRIC POWER AND CONSERVATION PLANNING COUNCIL

Northwest Conservation and Electric Power Plan; Amendments to the Commercial Model Conservation Standards

AGENCY: Pacific Northwest Electric Power and Conservation Planning Council (Northwest Power Planning Council).

ACTION: Notice of amendment to the 1986 Northwest Power Plan model conservation standards for new commercial buildings, conversions, and utility residential and commercial conservation programs; and surcharge methodology.

SUMMARY: At its April 12, 1989 meeting, the Council voted to distribute for public comment a draft revision of the Model Conservation Standards (MCS) for new commercial buildings. The Council then held public hearings in each of the four Northwest states, as required by the Pacific Northwest Electric Power Planning and Conservation Act (16 U.S.C. 839 *et seq.*, the Act). At its meeting of August 9, 1989 in Portland, Oregon the Council adopted the final amendments.

SUPPLEMENTARY INFORMATION: As directed by the Act, the Council developed and adopted a regional conservation and electric power plan shortly after its formation. The Power Plan includes an energy conservation program, including, but not limited to, Model Conservation Standards for new commercial buildings.

In implementing the Power Plan, the Council has developed a practice of reviewing and updating various elements of the Plan on an ongoing basis. The frequency with which an element is updated often depends on the availability of new information or changed circumstances. While some

proposed amendments are taken up on the Council's own initiative, others are the result of informal suggestions or recommendations from outside parties. In addition, the Council has adopted specific procedures that allow any person to petition for an amendment to the Plan at any time. In the case of the commercial MCS, the Northwest Conservation Act Coalition (NCAC) and the Natural Resources Defense Council (NRDC) petitioned the Council to amend the MCS on the ground that potentially economically feasible and regionally cost-effective savings remained beyond the Council's existing MCS. The Council, based on its own analysis, on public comments received and on information obtained from consultations with interested parties, has now adopted revisions to the MCS for new commercial buildings so that the standards capture all electricity savings that are cost effective for the region and economically feasible for consumers, taking into account financial assistance from Bonneville. At its September 13-14, 1989 meeting in Coeur d'Alene, Idaho, the Council approved a response to comments thus concluding this amendment proceeding.

FOR FURTHER INFORMATION CONTACT: If you would like a copy of these amendments and the response to comments, please contact Judi Hertz in the Council's Office of Public Information and Involvement. The Council's address is: 851 S.W. 6th Avenue, Suite 1100, Portland, Oregon 97204. The Council's telephone numbers are: (503) 222-5161 and (toll free) (800) 222-3355 in Idaho, Montana, and Washington or (800) 452-2324 in Oregon. Edward Sheets,

Executive Director.

[FR Doc. 89-23251 Filed 10-2-89; 8:45 am]

BILLING CODE 0800-00-M

SECURITIES AND EXCHANGE COMMISSION

[Corp. Reorg. Rel. No. 384, Rel. No. 34-27300; File No. 4-351]

Request for Public Comments on the Role of the Securities and Exchange Commission in Reorganization Cases Under Chapter 11 of the Bankruptcy Code

AGENCY: Securities and Exchange Commission.

ACTION: Notice; request for comments.

SUMMARY: The Commission is soliciting comments on the scope of its participation in federal court

reorganizations of publicly-held companies under the Bankruptcy Code. The results of this inquiry will assist the Commission in its reassessment of its role in reorganization cases with a view to determining whether that role should be modified.

The Commission will hold a public hearing during the course of this review. Interested individuals and organizations will have an opportunity to present their views on the topics covered in this release.

DATES: Comments are due by November 15, 1989. The public hearing is tentatively scheduled for December 11, 1989, 10:00 a.m. in the Public Meeting Room (Room 1C30) of the Securities and Exchange Commission in Washington, DC, 450 Fifth Street, N.W. Individuals or organizations who wish to participate in the public hearing should contact the Commission's Secretary by November 17, 1989.

ADDRESS: Persons wishing to submit comments should file three copies with Jonathan G. Katz, Secretary, Securities and Exchange Commission, 450 Fifth Street, NW, Washington, DC 20549. All comments should refer to File No. 4-351 and will be available for inspection at the Commission's Public Reference Room.

FOR FURTHER INFORMATION CONTACT: Michael A. Berman, Esq. (202) 272-2493, Office of the General Counsel, Securities and Exchange Commission, 450 Fifth St., NW, Washington, DC 20549.

SUPPLEMENTARY INFORMATION:

I. Summary

Chapter 11 of the Bankruptcy Code, 11 U.S.C. 101, *et seq.*, which became effective October 1, 1979, provides three roles for the Commission:

First, 11 U.S.C. 1109(a) accords the Commission the right to "raise and appear and be heard on any issue in a case.

Second, 11 U.S.C. 1125(d) authorizes the Commission to comment on the adequacy of the information contained in disclosure statements—the functional substitute for securities law registration and proxy statement—relating to plans of reorganization, under which new securities often are issued.

Third, 11 U.S.C. 1129(d) authorizes the Commission to object to confirmation of a reorganization plan if the principal purpose of the plan is to avoid the application of the registration provisions of the Securities Act of 1933.

On June 8, 1989, the Commission voted to review its role under section 1109(a) in bankruptcy reorganization cases involving publicly-held debtor corporations. The review seeks to determine the impact of Commission

participation in the reorganization process and to determine the most appropriate role for the Commission's bankruptcy program. The object of this review is to help to provide an informed basis upon which to reassess the Commission's role in such proceedings and also to consider whether there is a need for legislation.

In this release, the Commission seeks comments on specific questions relating to the appropriate scope and nature of the Commission's participation in Chapter 11 reorganizations. In particular, the Commission invites the views of the bankruptcy bench and bar and others concerning whether or not Commission section 1109(a) participation aids in the fair and efficient resolution of chapter 11 cases. In that connection, interested persons are asked to address the impact of that participation on public investors and also how it affects other parties to chapter 11 reorganization cases, such as nonpublic creditors, employees, and others. A related area of inquiry is the extent to which the interests of public investors are sufficiently protected in reorganization cases through the activities of U.S. Trustees, official investor committees, indenture trustees, institutional investors, or other entities. Finally, the Commission invites public comment on the desirability of legislative change with respect to its section 1109(a) role in bankruptcy reorganization, and with respect to other mechanisms for the protection of public security holders. The Commission anticipates that the responses to these questions will be helpful in framing its future role under section 1109(a).

II. Background

Commission Role in Corporate Reorganization Proceedings

1. The Chandler Act of 1938

The Commission's participation in reorganization cases began in 1938 with passage of the Chandler Bankruptcy Act.¹ Under that Act, a financially troubled business seeking to reorganize its affairs while continuing operations could file for reorganization generally under chapter X or chapter XI. Reorganizations under chapter X affected both secured and unsecured creditors as well as stockholders. A chapter XI arrangement could affect

¹ The Chandler Act was passed following a congressionally directed study conducted by the Commission into the abuses of protective and reorganization committees. "Report of the Securities and Exchange Commission on the Study and Investigation of the Work, Activities, Personnel and Functions of Protective and Reorganization Committees" (1937).

only the claims of unsecured creditors.² Congress required prior court approval of a chapter X reorganization plan as to its fairness³ and feasibility before permitting solicitation of acceptances from affected classes of creditors and stockholders. In contrast, the formulation of a plan of arrangement under chapter XI was in the control of the debtor; and a plan was confirmed unless it failed to meet the "best interest of creditors" standard, *i.e.*, that creditors receive more under the plan than they would in a liquidation.

The Commission's responsibilities under the Chandler Act in chapter X cases were two-fold.⁴ First, the Commission furnished advice to the court and investors by examining and reporting on the fairness and feasibility of reorganization plans (the "Advisory Report"). Under section 172 of chapter C, the judge, before confirming a plan, was required to submit to the Commission, for examination and an advisory report, all plans "worthy of consideration" involving a debtor with liabilities in excess of \$3 million. Second, the Commission was granted general authority to participate on behalf of public investors in all matters.⁵

2. The Bankruptcy Code of 1978

The Bankruptcy Code, which became effective October 1, 1979, consolidated the various reorganization provisions of the old Bankruptcy Act, including chapters X and XI, into chapter 11. Chapter 11 encourages negotiation of a consensual plan of reorganization between a debtor and those creditors and stockholders whose claims and

² In enacting Chapter X, Congress sought "to afford greater protection to creditors and stockholders by providing greater judicial control over the entire proceedings and impartial and expert administrative assistance in corporate reorganizations through appointment of a disinterested trustee and the active participation of the SEC." *Securities and Exchange Commission v. American Trailer Rentals Co.*, 379 U.S. 594, 604 (1965).

³ The requirement that a reorganization plan could not be confirmed by the court unless it was found to be "fair and equitable" incorporated the so-called strict priority standard, under which creditors and stockholders participated in the plan strictly in accordance with their legal priorities. Stockholders could not participate at all unless the claims of creditors were satisfied in full with interest.

The Commission reviewed cases filed under chapter XI to ensure that the investor protections found in chapter X were not circumvented by a debtor filing under chapter XI of the Act. Section 328 of former chapter XI specifically authorized the Commission to make application to the court to transfer a chapter XI proceeding to chapter X.

Pursuant to section 208 of chapter X, the Commission was deemed to be a party in interest, but could not initiate an appeal.

interests are to be compromised. Unlike the procedure under old chapter X, where an independent trustee was appointed to be the focal point of the reorganization, in new chapter 11 the debtor (*i.e.*, existing management) typically remains in possession during the pendency of the reorganization proceeding and is granted a period of time during which it exclusively may propose a plan. Interested parties negotiate with the debtor through official committees. Once a plan is proposed, approval is solicited through a "disclosure statement, which substitutes in effect for a Securities Act registration statement and Exchange Act proxy statement if securities are issued under the plan.⁶ Under chapter 11, a plan need not be "fair" in the absolute priority sense, if each class affected (or "impaired") by the plan votes to approve it.⁷ According to Congress, the premise underlying the chapter 11 standard for confirmation is "the same as the premise of the Federal securities law:" that once parties are given adequate disclosure of all relevant information they should be able to make an informed decision as to whether to accept a proposed reorganization plan.⁸

One of the major changes effected by the Bankruptcy Code was the advent of official committees, whose expenses and professional fees are paid as an administrative expense of the estate, to represent the various constituent interests. The Code mandates the appointment of an official committee to represent the interests of unsecured creditors; other committees may, in the discretion of the court, be appointed to represent the interests of equity holders or other constituencies.⁹ Representation by an official committee was deemed essential to participation in the formulation of a plan in light of the emphasis on the formulation of a consensual plan in lieu of adherence to the absolute priority standard.

⁶ 11 U.S.C. 1125(d), 1145. Where the solicitation involves bad faith or fraud, the anti-fraud provisions of the securities laws would be applicable.

A "fairness" concept, similar to the "fair and equitable" rule of chapter X, is preserved under the present statute only in those situations where at least one class has voted to accept the plan and another class rejects it. In that instance, the plan proponent may invoke the so-called "cramdown" provision (section 1129(b)) to seek court approval of the plan notwithstanding the objection of the rejecting class.

H.R. Rep. No. 595, 95th Cong., 1st Sess. 224 (1977).

Under old chapter X, committees were unofficial and responsible for their own expenses and professional fees unless they could demonstrate a benefit to the administration of the case. Committees actively representing equity interests were rare.

The Bankruptcy Code abolished the requirement that the court submit reorganization plans to the Commission for examination and an advisory report in order to expedite the reorganization process. Section 1109(a) maintained the Commission's general authority to participate in corporate reorganizations, granting the Commission the right to "raise and appear and be heard on any issue in a case. Additionally, the Bankruptcy Code no longer requires, as chapter X did, a request for or leave of court for the Commission to address an issue in a case.

3. Commission practice in corporate reorganization cases

a. *Commission participation prior to 1984.* Under chapter X of the prior Bankruptcy Act, the Commission usually participated only in cases involving large public companies. The Commission viewed the filing of an appearance as imposing a responsibility actively to participate in a case. In implementing this policy, Commission counsel attended committee meetings, key court hearings and informational meetings held by the trustee, and participated in discussions and negotiations about matters arising in the case. The premise underlying these activities was that, by understanding the dynamics of a case, the debtor's prospects for reorganization, and the business problems that caused its failure, the staff could react knowledgeably and expeditiously to issues as they arose. In addition, the Commission usually participated in the process of making an adequate record in court as to the debtor's financial fitness and its prospects for reorganization so that it could later render an advisory report on proposed plans of reorganization on an informed basis. The Commission's presence in these cases served as an invitation to the parties informally to seek the staff's views before matters were formally submitted to the bankruptcy court. Responses to these requests frequently led to consensual resolution.

Under old chapter X, the Commission did not participate on every key question, but focused primarily on protecting the rights of public investors and attempting to secure uniformity in judicial construction of the statute. The Commission was also active in advising the courts concerning the compensation of court appointees.

From the effective date of the new Code in 1979 until the end of 1983, the Commission continued to perform its general participatory role in much the same way as it had under the prior law.

During the first four years in which the Code was in effect, approximately 250 debtors with publicly issued securities outstanding filed chapter 11 petitions. The Commission actively participated in 79, or about 32%, of the filed cases.¹⁰ In those proceedings the Commission participated on a wide range of issues, including the appointment of trustees and examiners, interim compensation, employment of professionals, use of property, appointment of shareholder and creditor committees, administrative expenses, and confirmation issues.

b. *The Commission's current program.* In 1983, Commissioner Bevis Longstreth conducted a study of the Commission's participation in reorganization cases in light of the comprehensive changes under the Bankruptcy Code. The study concluded that the Commission should alter then existing practices by curtailing its active participation in reorganization cases. The report interpreted the Code's silence regarding the manner in which the Commission was to perform its section 1109(a) role as conferring on the Commission discretion in defining its participation in reorganization cases.¹¹ It recommended that the Commission focus on legal questions of precedential significance to public investors generally and respond to judicial requests for assistance.¹²

The conclusion that the program should be significantly curtailed was based in part on the belief that the Commission could reduce its own resource commitment in the reorganization area and rely on the combined efforts of the (then new) U.S. Trustees and of official shareholder committees to protect the interests of the investing public. Accordingly, the study recommended that the Commission restructure its existing program, using the Commission's participation as *amicus curiae* in private securities litigation as a model for its general participatory role in reorganization proceedings. The Commission adopted this recommendation in December 1983.

¹⁰ Commission Annual Reports 1980-1983 and the staff's public company list.

¹¹ The report concluded that "the SEC has an optional, rather than a mandatory, role to play in bankruptcy proceedings. Report at 3. Thus, the report asserted that the Commission "should depend upon its own informed sense of the benefits to be derived" from its participation in determining how to perform its section 1109(a) role. *Id.* at 4.

¹² The report also concluded that the Commission should no longer review and comment on the appropriate amount of fees to be awarded to parties to a reorganization case. Such fact intensive issues require substantial resources and, the report said, are better left to the courts and to the U.S. Trustees who exercise direct oversight on such matters.

Subsequently, the staff has administered the bankruptcy program in accordance with a series of staff guidelines¹³ that emphasize participation on significant legal issues of precedential value to investors generally.¹⁴

Since January 1984, the Commission has participated in the resolution of such issues in 32 cases at all court levels, including the United States Supreme Court. To identify significant legal issues, the Commission files notices of appearance in most public company cases in order to receive mailed copies of pleadings. The Commission's legal staff does not actively participate (*i.e.*, does not attend informational meetings, committee meetings, or key court hearings) in reorganization cases and ordinarily takes no position on issues significant only to the particular case. However, the Commission has sought the appointment of an equity holder committee in cases in which it believed such a committee necessary to assure the adequate representation of public investors.¹⁵

¹³ See Corporate Reorganization Release No. 331 (Feb. 2, 1984) 29 SEC Docket 1181.

¹⁴ The 1983 revision left unchanged the manner in which the Commission comments on plan disclosure statements and reviews reorganization plans to assure compliance with Securities Act registration provisions.

The Commission staff reviews disclosure statements to determine whether the issuance of securities under a plan is consistent with the exemption from registration in the Bankruptcy Code or otherwise in compliance with the federal securities laws. The Commission also reviews disclosure statements to determine whether there is adequate disclosure concerning the proposed plan. Generally, the Commission seeks to resolve questions concerning bankruptcy disclosure through staff comments to the plan proponent. If questions cannot be resolved through this process, the Commission may file objections to the disclosure statement with the bankruptcy court.

During fiscal year 1988, the Commission commented on disclosure statements in 83 cases and objected to disclosure statements in two cases. The Commission also acts to assure that public investors are given an adequate opportunity to be heard on disclosure-related questions.

¹⁵ Since January 1984, the Commission sought or supported the appointment of investor committees in 33 cases, or about 12% of the cases in which the Commission filed a notice of appearance. The Commission does not seek the appointment of an investor committee in every case involving a public company. Generally, the Commission takes the position that separate stockholder representation is not appropriate in cases in which the debtor is so hopelessly insolvent that liquidation appears likely or where the assets of the debtor are completely pledged and investor interests are likely to be extinguished. Among the factors that the Commission considers in determining whether to seek the appointment of an official committee are the value of the equity as publicly reported by the issuer, the going concern or inherent value (if realistically higher), the likelihood of reorganization, the extent of management holdings of common stock, the degree to which incumbent management can be relied on to represent adequately investor interests, and the asset size of the debtor.

The Commission's participation with respect to legal issues of general significance has played a role in the development of bankruptcy law. For example, the Commission has successfully supported stockholders' rights to corporate governance,¹⁶ rights of securities fraud claimants to adequate notice of the claims bar date,¹⁷ and the ability of class representatives to file claims in bankruptcy on behalf of similarly situated claimants.¹⁸ The Commission's participation on these legal issues has generally been at the appellate rather than the bankruptcy court level.

III. Request for Comment

The Commission is again reviewing its section 1109(a) role in Chapter 11 reorganization cases and is also studying the functioning and nature of public investor protections under that chapter. The Commission seeks public comment on three general subject areas:

- To what extent would the Commission's more active participation contribute to a fair, efficient, and effective resolution of chapter 11 proceedings, and to what extent would participation by the Commission affect the rights of non-investors or impede the resolution of cases by adding delay and costs to the process?
- Should the Commission play a more active section 1109(a) role on behalf of investors in reorganization cases, rather than limit its involvement to its present amicus-type role?
- Should the Commission propose legislative changes concerning its section 1109(a) role in reorganizations or in the statutory protections for public investors?

The Commission requests that commentators be as specific as possible and, where appropriate, that they provide quantitative data and cite to the source of the data. The Commission also invites commentators to address any

¹⁶ *In re Johns-Manville Corp.*, Corporate Reorganization Release No. 356 (May 28, 1986), 35 SEC Docket 1402 and 801 F.2d 60 (2d Cir. 1986) (adopting Commission position); *In re Allegheny International, Inc.*, Corporate Reorganization Release No. 376 (July 20, 1988), 41 SEC Docket 770.

¹⁷ *In re Standard Metals Corp.*, Corporate Reorganization Release No. 365 (May 22, 1987), 38 SEC Docket 827 and 839 F.2d 1383 (10th Cir. 1987) (adopting Commission position).

¹⁸ See, e.g., *In re The Charter Co.*, Corporate Reorganization Release No. 375 (July 1, 1988), 41 SEC Docket 566 and 876 F.2d 866 (11th Cir. 1985) (adopting Commission position); *In re American Reserve Corp.*, Corporate Reorganization Release No. 366 (May 22, 1987), 38 SEC Docket 829 and 840 F.2d 487 (7th Cir. 1988) (adopting Commission position); but see *In re Standard Metals Corp.*, Corporate Reorganization Release No. 348 (Aug. 14, 1985), 33 SEC Docket 1425 and 817 F.2d 625 (10th Cir.) (rejecting Commission position), *vacated and reversed on other grounds*, 839 F.2d 1383 (10th Cir. 1987), *cert. dismissed*, 109 S. Ct. 201 (1989).

other matters that they believe relevant to the study.

A. To what extent would the Commission's more active participation contribute to a fair, efficient, and effective resolution of chapter 11 proceedings, and to what extent would participation by the Commission affect the rights of non-investors or impede the resolution of cases by adding delay and costs to the process?

The Commission recognizes that its active participation may have an impact on the bargaining positions of competing claimants in a chapter 11 case, especially in strengthening the position of public investors. Indeed, depending on the issue, the Commission's involvement may have the effect of increasing the ultimate distribution received by public investors at the expense of other parties to the case. Is such participation on behalf of investors unfair to other parties to the case, such as employees, commercial lenders, trade creditors, tort claimants, and others with claims against the debtor? If so, how should this consideration enter into the Commission's determination whether to participate in a proceeding?

Participation may also have the effect of protracting the proceedings or requiring the payment of fees for professional services or the expenditure of other monies that might otherwise be available to satisfy claims of creditors. On the other hand, Commission participation may result in an increase in the value of the estate available for distribution among all claimants.¹⁹ The Commission requests that commentators address whether active Commission participation contributes to a fair and effective resolution of chapter 11 proceedings: Does such participation tend to benefit general creditor interests? Or does it impede the resolution of the case, adding time and costs to the process? Does such participation tend to increase or decrease the size of the estate or to reallocate the estate to public investor classes? How should the Commission take these factors into consideration in deciding whether and how to participate?

Companies that have filed for reorganization will occasionally have classes of public securityholders with adverse interests. For example, holders of publicly traded debt instruments may have interests adverse to those of preferred stockholders, and both those

¹⁹ For example, Commission participation on applications by debtors to sell substantial assets of the estate may increase the value of the estate.

constituencies may have interests adverse to those of the company's common stockholders. How should the Commission's participation be influenced, if at all, by the potential for conflict among the holders of various types of publicly traded securities? Under which circumstances should the Commission seek the appointment of separate committees for holders of different types of publicly traded securities?

B. Should the Commission play a more active section 1109(a) role on behalf of investors in reorganization cases, rather than limit its involvement to its present amicus type role?

As described above, in 1983 the Commission significantly curtailed its general participatory role in reorganization cases under chapter 11. This change had the effect of shifting the Commission's participation away from an active bankruptcy court practice on a wide range of factual and legal issues that affect the rights of public investors or the reorganization process itself. Under the current program, the Commission's practice in this area is limited to *amicus* type participation on significant legal issues.

In assessing the direction the program should take in the future, the Commission invites commentators to address whether or not there presently is a need for greater Commission participation in bankruptcy cases. In this connection, the Commission requests information and data on whether other participants in a chapter 11 case provide adequate representation to shareholder and other public investor interests, thereby obviating the need for a more active Commission presence. Certain participants that may fulfill this role in whole or in part are discussed below. The Code specifically provides for some of these participants. Others, drawn to the process by economic self-interest, may provide indirect representation for or advance the interests of public investors, by virtue of actions taken in their own interests.

1. Investor Committees

As noted, one of the major changes under the Bankruptcy Code was the creation of the official committee system. An official committee for unsecured creditors is mandated in all Chapter 11 cases, and additional committees may be appointed to represent other constituencies, such as bondholders or shareholders. The U.S. Trustee is granted authority to appoint additional committees. In cases in which the U.S. Trustee determines not to appoint an additional committee, the

bankruptcy court has authority to direct the U.S. Trustee to do so. Actual committee membership is left to the discretion of the U.S. Trustee.

According to the drafters of the Code, committees are to serve as "the primary negotiating bodies for the formulation of the plan of reorganization."²⁰ Congress intended that committees represent and protect the interests of the various classes of creditors and equity security holders from which they are selected and provide supervision of the debtor in possession.²¹

The Commission's observations of investor committee practices do not provide clear evidence of whether the committee structure is effective in protecting the interests of public securities holders. In some cases, it appears that committees are not formed or are unable, either because of internal conflicts or delays in organizing or for other reasons, to deal appropriately with critical issues. In other cases, multiple committees are active and appear to participate meaningfully. The Commission invites commentators to address the value of the committee system in protecting investors. In cases in which investor committees are formed, do they function effectively?

The Commission also seeks information on whether committees representing public investors' interests are appointed where appropriate. As noted above, U.S. Trustees have the authority, on their own initiative, to appoint committees to represent the interests of public investors. In practice, do the U.S. Trustees appoint committees to represent those interests in appropriate cases?

In certain cases in which it appears to the Commission staff that shareholders may have an economic interest in the reorganization, no one has sought appointment of an equity committee. The Commission wishes to explore the reason why committees are not formed in some cases where certain evidence suggests that equity holders may have a meaningful economic stake in the debtor. Are investors generally aware of their right to seek formation of an official committee to represent their interests? The Commission staff has informed the Commission that frequently there is an absence of publicly available financial information about corporations undergoing reorganization. Does this lack of current financial information deter persons from seeking formation of a committee, or are other factors predominately responsible

for that decision? Alternatively, investors may have determined that the costs of seeking committee formation and participating in committee activities are not justified by the likely rewards. Does the failure of investors to seek a committee represent an informed decision of this nature?

As pointed out above, the Commission has moved or supported motions for the appointment of investor committees in about 12% of the cases where it has appeared. But the Commission has not sought a committee in every case meeting its criteria for appointment (see footnote 15, page 12 above). Are the Commission's general standards for determining whether to seek the appointment of additional investor committees appropriate? Should the Commission become more active by seeking the formation of investor committees? In contrast, the Commission recognizes that its efforts to encourage committee formation in cases in which no equity investor has sought a committee may have imposed costs on the estate which could otherwise have been avoided. Are such costs justified by increased returns to public investors? If so, are those returns obtained at the expense of other constituencies involved in the proceeding, or do they reflect an increase in value resulting from the Commission's participation? Accordingly, should the Commission be less active in seeking formation of investor committees?

The Commission staff reports that in some cases, even when an investor committee is authorized early in the case, there are significant delays in the actual appointment of the committee's members, thus delaying the functioning of the committee in the case. The Commission solicits comments on the reasons for this phenomenon and what steps, if any, the Commission should take to remedy this problem. Is the delay in part caused by a difficulty in finding investors willing to serve on a committee or a reluctance by investors to serve on committees? Should the U.S. Trustee, or the Commission, take some action to speed the process of committee formation? The staff has observed in some cases that investors refrain from accepting membership on a committee because of a concern that such membership would result in access to nonpublic information which, in turn, would inhibit the investors' ability to trade in the debtor's securities. Are potential securities trading restrictions for committee members considered a significant impediment to accepting membership on an official committee? To what extent, if any, can or should the

²⁰ H.R. Rep. No. 595, 95th Cong., 1st Sess. 401 (1977).

²¹ *Id.*

Commission change its own rules or procedures to address those concerns?

2. Management (the debtor in possession)

Unlike prior Chapter X, under which a trustee was appointed automatically in all large cases, Chapter 11 leaves debtor's current management in control of the proceedings with an initial exclusive right to file a reorganization plan.²² One commentator has noted that the Code has made stockholders much more dependent on management to negotiate a plan that protects their interests, because a Chapter 11 plan can modify, dilute or even cancel their interests without their consent.²³ The staff has observed that in some cases management is more likely to look after the interests of shareholders when management owns a substantial amount of the outstanding common stock. On the other hand, the staff has found that management may have a potential conflict of interest in that it may also seek to negotiate for its own continued services after reorganization. Under what circumstances can shareholders rely on management to represent their interests? Of course, levels of management equity ownership vary widely among public companies. Should the percentage of equity owned by management influence the Commission in determining whether to participate in a particular proceeding? If so, how and why?²⁴

3. Indenture Trustees

The Bankruptcy Code grants indenture trustees party-in-interest status and the right to file claims on behalf of all debtholders. In practice, indenture trustees sit on the mandatory unsecured creditors committee either as

a full voting member or in an *ex-officio* status (non-voting). Indenture trustees do not have a clearly defined role in chapter 11 cases but rather, pursuant to the Trust Indenture Act of 1939, must exercise the same degree of care and skill as a "prudent person" would exercise in the conduct of the person's own affairs.²⁵ The Commission requests that commentators address whether they believe indenture trustees effectively represent the interests of debtholders in reorganization cases.

Under the Bankruptcy Code, as carried forward from prior chapter X, indenture trustees may receive payment for fees and expenses directly out of the assets of the debtor's estate; if they can demonstrate that their services made a "substantial contribution" to the estate. In some cases, however, indenture trustees have found it difficult to establish that their services, under the legal test employed, made a substantial contribution to the estate.²⁶ In such situations, it is the bondholder who ultimately pays for the indenture trustee's services, pursuant to standard provisions of trust indentures qualified under the Trust Indenture Act of 1939. Is this "substantial contribution" standard of compensation an impediment to useful participation of indenture trustees in chapter 11 cases?

In many chapter 11 cases there is more than one outstanding issue of publicly held debt. Often these issues are subordinated to senior bank debt, or one public debt issue is subordinated to another. Under what circumstances should a separate official committee be appointed to represent a class of publicly held debt? Should indenture trustees or the Commission seek to form separate public debtholder committees?

4. U.S. Trustees

The U.S. Trustee program represents a major modification of pre-Code reorganization practice. The U.S. Trustees perform a variety of functions previously assumed by the bankruptcy court. What role do the U.S. Trustees play in protecting the interests of public

investors in chapter 11 reorganization proceedings?

5. Institutional Investors

Institutional investors, including both private and public pension funds, frequently hold large quantities of stocks or bonds of companies that have filed for reorganization. While historically such institutions often sold their securities when the companies filed for bankruptcy, recently some have chosen to hold their securities and to become active participants in the reorganization process through service on equity security holders' committees or unsecured creditors' committees. How active are institutional investors in reorganization cases? When institutional investors are active, does their participation operate to protect the interests of other (non-institutional) public investors?

Last year, the Commission's staff met with representatives of the Council of Institutional Investors ("Council") to discuss a problem that the Council believed tended to discourage pension funds from actively participating in chapter 11 cases. The Council expressed concern that the Commission's insider trading rules effectively prevent pension funds from serving on an equity committee because they may become privy to material non-public information about the reorganization, inhibiting institutions from engaging in ordinary trading strategies in derivative securities that may include the debtor's stock. To address this problem, the Council suggested that the Commission consider adopting a rule or release extending Commission Rule 14e-3(b), 17 CFR 240.14e-3(b), in order to approve the use of "Chinese walls" to avoid potential liability for securities trading decisions made by an institution's trading department while the institution is participating on a committee and has access to non-public information. Would promulgation of such a rule or release by the Commission encourage greater institutional participation on committees? Should the Commission consider other measures to address the concern identified by the Council? If so, which measures should be considered?

6. Funds specializing in securities of distressed companies

It has been reported that, in the past year, funds specializing in securities of distressed companies, generally known as "recovery" or "vulture" funds, have raised from \$300 million to \$500 million to invest primarily in debt but also to a limited extent in equity securities of corporations undergoing

²² Section 1121 of the Bankruptcy Code grants the debtor in possession an initial 120-day period of exclusivity, but bankruptcy courts, especially in cases involving large public companies, routinely grant extensions of the period of exclusivity. See 5 *Collier on Bankruptcy* ¶ 1121.04 at 121-13 (15th ed. 1989).

²³ Gerber, *The Election of Directors and Chapter 11—The Second Circuit Tells Stockholders To Walk Softly And Carry A Big Lever*, 53 Brooklyn L. Rev. 295 (1987).

²⁴ Recently, in a number of cases, shareholders, dissatisfied with management's efforts at negotiating favorable reorganization plan, have sought, through state-law procedure, to replace management by compelling an annual meeting for the election of directors; courts have long recognized the right of shareholders to do so unless the exercise of such function is likely to threaten the reorganization. See *In re Johns-Manville Corp.*, 52 B.R. 879 (Bankr. S.D.N.Y. 1985); *aff'd*, 60 B.R. 842 (S.D.N.Y. 1986), *rev'd and remanded*, 801 F.2d 80 (2d Cir. 1986); *Saxon Industries v. NKFV Partners*, 488 A.2d 1298 (Del. 1984); *In re Lifeguard Industries, Inc.*, 37 B.R. 3 (Bankr. S.D. Ohio 1983); *In re Lionel Corp.*, 30 B.R. 327 (Bankr. S.D.N.Y. 1983); *In re Bush Terminal Co.*, 78 F.2d 662, 664-65 (2d Cir. 1935).

²⁵ See Dunham & Borowitz, *The Role of the Indenture Trustee in Reorganization Cases Under the Bankruptcy Code*, 102 Banking L.J. 436 (1985).

²⁶ See, e.g., *In re Flight Transportation Corp. Securities Litigation*, 874 F.2d 576 (8th Cir. 1989); *In re Multiponics, Inc.*, 622 F.2d 731 (5th Cir. 1980); *In re Baldwin-United Corp.*, 79 B.R. 321 (Bankr. S.D. Ohio 1987). In an appeal to the district court in *Baldwin*, the Commission set forth its views as to the appropriate legal standard for testing whether an indenture trustee has made "substantial contribution" in a Chapter 11 case. See Corporate Reorganization Release No. 370 (Feb. 22, 1988), 40 SEC Docket 565. The district court did not decide the issue; the appeal was dismissed after a settlement provided that the indenture trustee would receive payment of its entire fee request.

reorganization.²⁷ One commentator has referred to a \$3 billion "pool" available for investment in securities of companies in bankruptcy.²⁸ The evolution of funds that specialize in the securities of distressed enterprises has attracted supporters and critics. Supporters claim that, with substantial funds now available for the purchase of distressed securities, the discount from face value has narrowed substantially, resulting in a more efficient market with higher stock and bond prices. If so, the small public investor may benefit from the participation of these funds because their presence helps support the price of securities issued by debtor firms.²⁹ Critics complain, however, that, if the bankruptcy process were more effective in representing the interests of public security holders to begin with, the price of securities might not decline as steeply in the wake of bankruptcy and that the profit opportunities for funds specializing in distressed enterprises would not be as great.³⁰ They complain that it is the small investor who typically sells his securities early in the bankruptcy process and who loses money as a result of the steep decline in the price of the securities.³¹

The Commission is interested in learning about the impact of these funds on the reorganization process. How do the recovery funds affect the interests of public securityholders? Do such funds participate in the committee process or propose or back reorganization plans that might advance the interests of some or all public investors? The literature tends to suggest that the recovery funds are interested primarily in the larger bankruptcy cases. Are such funds also active in the medium or small size public-company Chapter 11 case? On what basis do such funds decide to participate in specific proceedings?

C. Should the Commission propose legislative changes concerning its section 1109(a) role in reorganizations or in the statutory protections for public investors?

As noted above, chapter 11 of the Bankruptcy Code grants the Commission the right to "raise and appear and be heard on any issue in a case." The

Code does not, however, specify the kind of role the Commission should play, but appears to leave to the Commission discretion to determine how best to foster investor protection through its participation in corporate reorganizations. Is a legislative amendment clarifying the Commission's section 1109(a) role necessary or desirable?

With regard to the Code's official committee structure, only the general unsecured creditors' committee is mandatory. Other official committees can be appointed to represent public investor classes—senior debentureholders, subordinated debentureholders, preferred shareholders, common shareholders—in the discretion of the U.S. Trustee or the bankruptcy court. The standard used to determine whether other official committees will be formed looks to whether those committees are needed to assure adequate representation. Does this legal standard—i.e., the need to assure adequate representation—provide sufficient protection for public investors? Should, under certain criteria, there be an automatic appointment of a shareholder committee or a presumption that a shareholder committee is needed in all public company cases? If so, under what criteria? Should committees also be automatically established for holders of non-equity securities? Should there be presumptions in favor of the formation of such committees?

As noted above, the Code intends for indenture trustees to play an active role in the reorganization process on behalf of the debtholders. Indenture trustees and their counsel are required to establish, before receiving reasonable compensation for their services, that their activities made a "substantial contribution" to the case (see section 503(b)(3)(D)). Official participants in a chapter 11 case—a trustee, counsel for a trustee, the debtor, an official committee and professionals retained by a trustee, debtor or an official committee—on the other hand, are paid reasonable compensation for their services that are "actual and necessary" without the need to demonstrate that their activities made a substantial contribution to the case (see section 330). An alternative would be for Congress to permit payment of compensation to indenture trustees on the same basis as payment to official participants in the case. Is the stricter standard of compensation applicable to indenture trustees appropriate or should the Commission formulate a modification? Is it appropriate to require indenture trustees to recoup some or all

of their expenses from the debtholders themselves?

IV Conclusion

For more than 50 years the Commission has participated, on behalf of public investors, in corporate reorganization proceedings under the bankruptcy laws. Over the years, the nature and scope of the Commission's participation in bankruptcy reorganization has undergone change, both as a result of statutory revision and as a result of changes in the Commission's own view as to its proper role. The Commission is currently revisiting the question of its role in reorganization cases under section 1109(a) and the possible need for legislative change. To this end, the Commission invites comments on the subjects covered by this release.

Dated: September 27 1989.

By the Commission.

Jonathan G. Katz,
Secretary.

[FR Doc. 89-23306 Filed 10-2-89; 8:45 am]

BILLING CODE 8010-01-M

Release No. 34-27295; File No. SR-PSE-88-01]

Self-Regulatory Organizations; Pacific Stock Exchange, Inc., Order Approving Proposed Rule Change Relating to Changes to the Constitution

On March 7 1988, the Pacific Stock Exchange, Inc. ("PSE" or "Exchange") filed with the Securities and Exchange Commission ("Commission"), pursuant to section 19(b) of the Securities Exchange Act of 1934 ("Act") and Rule 19b-4 thereunder,¹ a proposed rule change to amend the PSE's Certificate of Incorporation in order to eliminate, under limited circumstances, the personal liability of a member of the PSE's Board of Governor for monetary damages arising from a breach of his or her fiduciary duty as a Governor to the Exchange or its members. Additionally, the proposal sought to make five technical amendments to the PSE Constitution.²

¹ 15 U.S.C. 78s(b) (1982) and 17 CFR 240.19b-4 (1989).

² The proposed PSE rule change was noticed in Securities Exchange Act Release No. 25549 (April 6, 1988), 53 FR 12488. No comments were received on this proposal. On October 3, 1988, the PSE submitted Amendment No. 1 to File No. SR-PSE-88-01. Amendment No. 1 added language that provides that the proposed exemption from monetary damages for breach of fiduciary duty by members of the PSE's Board of Governors would not be available if the liability arose, directly or indirectly, as a result of a violation of Federal securities laws.

²⁷ See *Preying on the Busted*, Economist at 86, 88, May 13, 1989; Rohrer, *Jumping on the Bankruptcy Bandwagon*, 23 Institutional Investors at 84, July 1989.

²⁸ *Preying on the Busted*, supra note 27, at 86.

²⁹ *Id.* at 88.

³⁰ Lunden, *The Big Money in Busted Bonds*, Fortune at 100-104, Feb. 15, 1988. A similar phenomenon has been reported with regard to the purchase of trade claims. See Fanning, *A Stacked Deck?* Forbes at 126, June 12, 1989.

³¹ *The Big Money in Busted Bonds*, supra note 30.

On September 5, 1989, the PSE submitted Amendment No. 2 to File No. SR-PSE-88-01 which narrows the above proposed rule change by deleting all references to the Certificate of Incorporation, while maintaining the five proposed changes to the PSE Constitution as the proposal's sole focus. The PSE explicitly stated that it plans to file a separate rule change containing an amendment to its Certificate of Incorporation regarding Board of Governor liability.³

The proposed rule change would adopt five technical amendments to the PSE Constitution. The proposal will delete an obsolete transition provision in Article II, section 7 that was drafted to govern the timing of the election and the duties of the Chairman and Vice Chairman of the Exchange's Board of Governors for the period immediately following the effectiveness of amendments to the Constitution adopted in 1979. The proposal will also amend Article V section 1, to reflect an increase in the number of authorized memberships from the current level of 516 by stating that it shall "not exceed 552. This increase in the number of memberships was approved by the Commission in April 1982.⁴ The proposal will amend Article VI, section 2, to clarify that an application for membership must be made in accordance with Rule IX of the PSE Board of Governors and that, upon approval, the name of the applicant will be posted with members of the Exchange. The proposal will also amend Article VII, section 4, so that the payment of the purchase price for a PSE membership will only have to be made to the Exchange prior to the effective date for admission to membership rather than four days prior to admission. Finally, the proposal will amend Article VIII, section 4, to specify that the membership of every member of the Exchange who has conferred his membership privileges on any firm shall be deemed to be an asset of such firm only to the extent necessary to protect claimants under Article VII of the PSE Constitution as to the disposition of such proceeds.

The Commission believes the proposed amendments to the PSE's Constitution are consistent with the requirements of the Act and the rules and regulations applicable to a national securities exchange and, in particular, with the requirements of section 6(b)(5)

of the Act.⁵ The Commission believes that the five proposed amendments to the PSE Constitution are not substantive and simply eliminate obsolete provisions, update other provisions, and simplify and clarify various membership application and payment procedures. In view of this, the Commission believes these changes should be approved.

It Is Therefore Ordered, pursuant to section 19(b)(2) of the Act,⁶ that the proposed rule change be, and hereby is, approved.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.⁷

Dated: September 26, 1989.

Jonathan G. Katz,

Secretary.

[FR Doc. 89-23305 Filed 10-2-89; 8:45 am].

BILLING CODE 8010-01-M

[Release No. IC-17154; No. 812-7363]

Sun Life Assurance Co. of Canada (U.S.), et al.

September 25, 1989.

AGENCY: Securities and Exchange Commission ("SEC").

ACTION: Notice of Application for Exemption under the Investment Company Act of 1940 (the "Act").

APPLICANTS: Sun Life Assurance Company of Canada (U.S.) (the "Company"); Sun Life of Canada (U.S.) Variable Account F (the "Variable Account" or the "Account"); and Clarendon Insurance Agency, Inc. ("Clarendon").

RELEVANT 1940 ACT SECTION: Exemptions requested under section 6(c) from sections 2(a)(35), 26(a)(2) and 27(c)(2) of the 1940 Act.

SUMMARY OF APPLICATION: Applicants seek an order to permit the Company to deduct from the assets of the Variable Account the mortality and expense risk charge and distribution expense charge assessed under the variable portion of certain combination fixed/variable annuity contracts ("Contracts") issued in connection with the Variable Account.

FILING: The application was filed on July 27, 1989 and amended on September 22, 1989.

HEARING OR NOTIFICATION OF HEARING: If no hearing is ordered, the application will be granted. Any interested person may request a hearing on this application, or ask to be notified if a

hearing is ordered. Any requests must be received by the SEC by 5:30 p.m. on October 19, 1989. Request a hearing in writing, giving the nature of your interest, the reason for the request, and the issues you contest. Serve the Applicants with the request, either personally or by mail, and also send it to the Secretary of the SEC, along with proof of service by affidavit, or, for lawyers, by certificate. Request notification of the date of a hearing by writing the Secretary of the SEC.

ADDRESSES: Secretary, SEC, 450 Fifth Street, NW., Washington, DC 20549. The Company and the Variable Account, One Sun Life Executive Park, Wellesley Hills Massachusetts 02181, and Clarendon, 500 Boylston Street, Boston, Massachusetts 02116.

FOR FURTHER INFORMATION CONTACT: Michael V. Wible, Staff Attorney, (202) 272-2026 or Clifford E. Kirsch, Acting Assistant Director, (202) 272-2061 (Division of Investment Management).

SUPPLEMENTARY INFORMATION:

Following is a summary of the Application. The complete Application is available for a fee from the SEC's Public Reference Branch in person or the SEC's commercial copier (800) 231-3282 (in Maryland (301) 258-4300).

Applicant's Representations:

1. The Company is a stock life insurance corporation incorporated under the laws of Delaware on January 12, 1970, which issues life insurance policies and individual and group annuities. The Company is a wholly-owned subsidiary of Sun Life Assurance Company of Canada, a mutual life insurance company incorporated pursuant to an Act Parliament of Canada in 1865.

2. The Company established the Variable Account as a separate account to act as the funding medium for the variable portion of the Contracts. The Variable Account is registered under the Act as a unit investment trust. The assets of the Variable Account are divided into Sub-Accounts, each of which invests exclusively in shares of one of seven designated series of MFS/Sun Life Series Trust (the "Series Fund"), an open-end management investment company registered under the Act. Massachusetts Financial Services Company ("MFS"), a wholly-owned subsidiary of Sun Life (U.S.), is the investment adviser to the Series Fund.

3. The Contracts will be distributed by Clarendon, a wholly-owned subsidiary of MFS, and sold by insurance agents licensed in those states where the

³ See Amendment No. 2 to File No. SR-PSE-88-01.

⁴ See File No. SR-PSE-87-5, approved in Securities Exchange Act Release No. 24401 (April 29, 1987), 52 FR 16470.

⁵ 15 U.S.C. 78f(b)(5) (1982).

⁶ 15 U.S.C. 78s(b)(2) (1982);

⁷ 17 C.R.R. 200.30-3(a)(12) (1989).

Contracts may lawfully be sold. Such agents will be registered representatives of broker-dealers registered under the Securities Exchange Act of 1934 who are members of the National Association of Securities Dealers, Inc.

4. The assets of the Variable Account will be derived from the Contracts any may in the future be derived from other contracts providing for investment in a Sub-account of the Variable Account. The Contracts are deferred combination fixed/variable group annuities which provide that annuity payments will begin on a selected future date.

5. Sun Life (U.S.) will establish a Participant's Account for each Participant under a Contract. Only one purchase payment may be made per Certificate. The net purchase payment will be credited to a Participant's Account in the form of variable accumulation units of one or more of the Sub-Accounts and/or allocated to Sun Life (U.S.)'s general account (the "Fixed Account"). The value of the variable portion of a Participant's Account will vary with the investment performance of the respective Sub-Account(s).

6. No sales charge is deducted from a purchase payment. However, a withdrawal charge (contingent deferred sales charge), when applicable, will be assessed in the event of a full or partial withdrawal of Participant's Account value, and a market value adjustment, when applicable, will be applied to withdrawals from the fixed account. During the first seven account years, up to 10% of the net purchase payment may be withdrawn in each account year on a non-cumulative basis without the imposition of a withdrawal charge. Amounts withdrawn from a Participant's Account in excess of such amount (adjusted by an applicable market value adjustment) are subject to a withdrawal charge assessed against such excess amount as follows:

Number of contract year	Withdrawal charge—percent
1-2.....	6
3-4.....	5
5-6.....	4
7.....	3
Thereafter.....	0

No withdrawal charge is imposed after the end of the seventh account year, upon payment of the death benefit, or upon annuitization.

7. The Company assumes the risk that the withdrawal charges may be insufficient to compensate it for the costs of distributing the Contracts. For

assuming such risk, the Company makes a deduction from the Variable Account at the end of each valuation period for the first seven account years (during both the accumulation period and, if applicable, after annuity payments begin) at an effective annual rate of 0.15% of the assets of the Variable Account (the "Distribution Expense Charge"). No deduction is made after the seventh account anniversary. Applicants represent that the distribution expense charges and the withdrawal charges assessed against a Participant's Account will not exceed 9% of the purchase payment and that Sun Life (U.S.) will monitor each Participant's Account for the purpose of ensuring that this limitation is not exceeded.

8. On each account anniversary and upon surrender of a Participant's Account for full value on other than the account anniversary, the Company deducts from each Participant's Account an account administration fee ("Account Fee") equal to the lesser of \$30.00 or 2% of the Participant's Account value to reimburse it for administrative expenses relating to the issuance and maintenance of the Contract and the Participant's Account. This charge is designed not to exceed the Company's current estimates of the administrative costs attributable to the Contracts and Certificates over their expected lifetime, and is not designed or expected to generate a profit. The Contract provides that Sun Life (U.S.) may modify the Account Fee provided that such modification shall apply only with respect to Participant's Accounts established after the effective date of such modification. Applicants propose to rely on Rule 26a-1 under the Act for the exemptive relief necessary to charge such fees.

9. The Company assumes certain mortality and expense risks under the Contracts. For assuming these risks, the Company will make a deduction from the Variable Account at the end of each valuation period at an effective annual rate of 1.25%.

10. Applicants state that the mortality risk assumed by the Company arises from the contractual obligation under some annuity options available under the Contract to continue to make annuity payments to each annuitant regardless of how long the annuitant lives and regardless of how long all annuitants as a group live. The expense risk assumed by the Company is the risk that the administrative charges assessed under the Contract may be insufficient to cover the actual administrative expenses incurred by the Company. The

Company does not believe it feasible to identify precisely that portion of the deduction applicable to either the mortality risk or expense risk, but estimates that a reasonable allocation would be 0.80% for the assumption of the mortality risk, and 0.45% for the assumption of the administrative expense risk. If the mortality and expense risk charges are insufficient to cover the actual cost of the mortality and expense risk undertaking, the Company will bear the loss. Conversely, if the deduction proves more than sufficient, any excess will be profit to the Company and would be available for any proper corporate purpose including, among other things, payment of distribution expenses.

11. Applicants represent that the mortality and expense risk charge is within the range of industry practice for comparable variable annuity products. This representation is based on the Company's analysis of publicly available information about comparable annuity products, in light of such product's particular annuity features, taking into consideration such factors as annuity rate guarantees, current charge levels, charge guarantees, and sales loads. The Company undertakes to maintain and make available to the Commission upon request a memorandum setting forth the basis for its representations.

12. Applicants represent that the company has concluded that there is a reasonable likelihood that the Variable Account's distribution financing arrangements will benefit the Variable Account and Participants, and that the Company will maintain and make available to the Commission upon request a memorandum setting forth the basis for this conclusion. The Variable Account will invest only in open-end management companies which have undertaken to have a Board of Directors, a majority of whom are not interested persons of the open-end management company, formulate and approve any plan adopted under Rule 12b-1 of the Act to finance distribution expenses.

13. Based upon the foregoing reasons, Applicants request exemptions from sections 26(a)(2) and 27(c)(2) to the extent deemed necessary or appropriate to permit imposition of the mortality and expense risk charge and from sections 2(a)(35), 26(a)(2) and 27(c)(2) to the extent deemed necessary or appropriate to permit imposition of the distribution expense charge.

For the Commission, by the Division of Investment Management, pursuant to delegated authority.

Jonathan G. Katz,
Secretary.

[FR Doc. 89-23304 Filed 10-2-89; 8:45 am]

BILLING CODE 8010-01-M

OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE

[Docket No. 301-65]

Determinations Under Section 304 of the Trade Act of 1974, as Amended, Regarding the Republic of Korea's Restrictions on Imports of Beef

AGENCY: Office of the United States Trade Representative.

ACTION: Notice of determinations under section 304 of the Trade Act of 1974 (the "Trade Act"), as amended, 19 U.S.C. 2414.

SUMMARY: Pursuant to section 304(a)(2) of the Trade Act, 19 U.S.C. 2414, as amended by section 1301 of the Omnibus Trade and Competitiveness Act of 1988, the United States Trade Representative (USTR) has determined that rights to which the United States is entitled under a trade agreement are being denied by Korea's restrictions on the import of beef and that the appropriate action to be taken under section 301 of the Trade Act is to suspend the application of tariff concessions on products of interest to Korea. The USTR has further determined that a delay in implementation of such action is necessary and desirable to obtain U.S. rights under the General Agreement on Tariffs and Trade.

EFFECTIVE DATE: September 28, 1989.

FOR FURTHER INFORMATION CONTACT: Gordana Earp, (202) 395-6813, Office of the U.S. USTR, 600 17th Street, NW Washington, DC 20506.

SUPPLEMENTARY INFORMATION: On February 16, 1988, the American Meat Institute (AMI) filed a petition under section 302(a) of the Trade Act of 1974, as amended, 19 U.S.C. 2412(a), alleging that the Government of the Republic of Korea maintains a restrictive import licensing system covering all bovine meat, including high-quality beef, and noting that on May 21, 1985, the Korean Government had banned the importation of beef. AMI maintained that this prohibition violates Article XI of the General Agreement on Tariffs and Trade (GATT), nullifies and impairs tariff concessions on beef made by Korea under the GATT, and is otherwise

unjustifiable and unreasonable and burdens or restricts U.S. commerce.

On March 28, 1988, the USTR initiated an investigation of these practices (53 FR 16995). On May 4, 1988, the GATT Council of Representatives ("GATT Council") authorized establishment of a dispute settlement panel, under GATT Article XXIII:2, to examine the United States complaint regarding Korea's import restrictions on beef.

On May 24, 1989, the GATT dispute settlement panel issued a report concluding that Korea's import restrictions on beef are contrary to the provisions of GATT Article XI:1, and not justified for balance-of-payments purposes in light of the improvement of the Korean balance-of-payments situation. The panel recommended prompt establishment of a timetable for phasing out Korea's restrictions on beef. At meetings of the GATT Council on June 21 and July 19, 1989, Korea declined to agree to adoption of the panel report. Adoption will be reviewed again in October 1989.

Pursuant to 19 U.S.C. 2414, as amended by section 1301 of the Omnibus Trade and Competitiveness Act of 1988, the USTR is required to determine whether Korea's import restrictions deny "rights to which the United States is entitled" under the GATT and whether such practices are unjustifiable or unreasonable and burden or restrict U.S. commerce. This determination must be made no later than September 28, 1989, which is 18 months after the date of initiation of this investigation.

On the basis of the GATT panel report on this matter, the USTR has determined that rights to which the United States is entitled under a trade agreement (the GATT) are denied by Korea's restrictions on imports of beef. Section 301(a)(1) of the Trade Act provides that if the USTR makes such a determination, the USTR shall take action authorized under section 301(c) subject to the specific direction, if any, of the President. The USTR has determined that the appropriate action to take under section 301(c) is to suspend the application of GATT tariff concessions with respect to Korea, affecting products of Korea in an amount that is equivalent in value to the burden or restriction on United States commerce.

Section 305(a)(1) provides that any action to be taken under section 301 shall be implemented within 30 days—in this case, by October 28, 1989. Section 305(a)(2) further provides that such implementation may be delayed by not more than 180 days if the USTR determines that a delay is necessary or

desirable to obtain U.S. rights under a trade agreement. The USTR has decided that it is desirable to delay implementation of action under section 301 in this case beyond October 28, 1989, to allow additional time for proceedings in the GATT. However, the USTR has directed that a list of potential products on which to impose increased duties be published in the *Federal Register* by mid-November 1989 for public comment, if by that time substantial movement toward a resolution of this matter has not occurred.

A. Jane Bradley,

Chairman, Section 301 Committee.

[FR Doc. 89-23263 Filed 10-2-89; 8:45 am]

BILLING CODE 3190-01-M

DEPARTMENT OF TRANSPORTATION

Applications for Certificates of Public Convenience and Necessity and Foreign Air Carrier Permits Filed Under Subpart Q During the Week Ended September 22, 1989

The following applications for certificates of public convenience and necessity and foreign air carrier permits were filed under Subpart Q of the Department of Transportation's Procedural Regulations (See 14 CFR 302.1701 *et seq.*). The due date for answers, conforming application, or motion to modify scope are set forth below for each application. Following the answer period DOT may process the application by expedited procedures. Such procedures may consist of the adoption of a show-cause order, a tentative order, or in appropriate cases a final order without further proceedings.

Docket No. 46496

Date Filed: September 18, 1989

Due Date for Answers, Conforming Applications, or Motion to Modify Scope: October 16, 1989

Description: Application of American Airlines, Inc. pursuant to section 401 of the Act and subpart Q of the Regulations applies for a certificate of public convenience and necessity so as to authorize nonstop air service between Chicago, Illinois, and Glasgow, Scotland (via Abbotsinch Airport).

Docket No. 46500

Date Filed: September 20, 1989

Due Date for Answers, Conforming Applications, or Motion to Modify Scope: October 18, 1989

Description: Application of Cordoba Air Cargo S.A., pursuant to section 402 of the Act and subpart Q of the Regulations applies for a foreign air

carrier permit for authority to conduct up to four weekly round trips in nonscheduled foreign air transportation of property and mail between points in Argentina on the one hand and Miami, Florida, New York, New York, and Los Angeles, California on the other, via the intermediate traffic points of Santiago, Chile, Asuncion, Paraguay, Lima, Peru, Panama City, Panama, and Sao Paulo and Rio De Janeiro, Brasil.

Docket No. 46504

Due Date for Answers, Conforming Applications, or Motions to Modify Scope: October 19, 1989

Description: Application of Airline of The Marshall Islands, Inc., pursuant to section 402 of the Act and subpart Q of the Regulations, requests a foreign air carrier permit to engage in foreign transportation of passengers, property and mail between points in the Republic of the Marshall Islands including Majuro and Kwajalein, on the one hand, and points in the United States including Honolulu and Guam, on the other hand; and overseas and interstate air transportation as requested.

Docket No. 46508

Date Filed: September 22, 1989
Due Date for Answers, Conforming Applications, or Motion to Modify Scope: October 6, 1989

Description: Conforming Application of United Air Lines, Inc., pursuant to section 401 of the Act and subpart Q of the Regulations requests amendment of its Certificate of Public Convenience and Necessity for Route 57 to authorize service between Washington, DC on the one hand, and Montreal, P.Q., and Ottawa, Ontario, on the other hand.

Docket No. 46509

Due Date for Answers, Conforming Applications, or Motions to Modify Scope: October 20, 1989

Description: Application of Amerijet International, Inc., pursuant to section 401 of the Act and subpart Q of the Regulations applies for a certificate of public convenience and necessity authorizing it to provide foreign scheduled all-cargo service.

Phyllis T. Kaylor,

Chief, Documentary Services Division.

[FR Doc. 89-23232 Filed 10-2-89; 8:45 am]

BILLING CODE 4910-62-M

Federal Aviation Administration

Flight Standards District Office at Sacramento, CA; Relocation

Notice is hereby given that on or about October 15, 1989, the Flight

Standards District Office at Executive Airport, 6107 Freeport Blvd., Sacramento, California 95822 will be relocating to 6650 Belleau Wood Lane, Sacramento, California 95822. Services to the general public will continue to be provided by this office without interruption. This information will be reflected in the FAA Organization Statement the next time it is reissued.

(Sec. 313(a), 72 Stat. 752; 49 U.S.C. 1354.)

Issued in Hawthorne, CA, on September 20, 1989.

Carl B. Schellenberg,

Deputy Regional Administrator.

[FR Doc. 89-23271 Filed 10-2-89; 8:45 am]

BILLING CODE 4910-13-M

Federal Highway Administration

National Highway Traffic Safety Administration

[FHWA Docket No. 89-18]

RIN 2125-AC39

Uniform System for Handicapped Parking; Establishment of Advisory Committee Public Meeting

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

ACTION: Notice of establishment of advisory committee for regulatory negotiation; Charter; Notice of first meeting.

SUMMARY: This notice announces the establishment of an advisory committee for the purpose of regulatory negotiation. The committee will develop a report concerning the establishment of a uniform system for handicapped parking to enhance the safety of persons with disabilities. This report will include a recommended rulemaking proposal and will be submitted to the Administrators of FHWA and NHTSA. After the agencies issue a notice of proposed rulemaking (NPRM), the committee will review any comments submitted to the rulemaking docket and write a second report which will include a recommended final rule. The charter for the committee is set forth in this notice. This notice also announces the time and place of the first meeting of the advisory committee. This meeting is open to the public.

DATE: The first meeting of the advisory committee will be held at 9:00 a.m. on Wednesday, October 18, 1989, and will continue through Thursday, October 19, 1989.

ADDRESS: The first meeting of the advisory committee will be held at the Department of Transportation, Room 4200, 400 Seventh Street SW Washington, DC 20590.

FOR FURTHER INFORMATION CONTACT:

Agency contact: Mr. Vincent Nowakowski, FHWA, Office of Traffic Operations (202) 366-2146, Ms. Judith S. Kaleta, FHWA, Office of the Chief Counsel (202) 366-0764, or Mr. E. William Fox, NHTSA, Office of the Chief Counsel (202) 366-1834, 400 Seventh Street SW Washington, DC 20590. *Mediator:* Robert Roberatory, Deputy Chief Administrative Judge, Board of Contract Appeals, 400 Seventh Street SW Washington, DC 20590 (202) 366-4305.

SUPPLEMENTARY INFORMATION:

Background

The Congress passed Public Law 100-641, 102 Stat. 3335 (1988) which directs the Secretary of Transportation to establish a uniform system for handicapped parking. This authority has been delegated to FHWA and NHTSA. To implement this law, FHWA and NHTSA published a notice of intent to form an advisory committee for regulatory negotiation. 54 FR 24908 (1989). The notice stated that the committee would develop a report concerning the establishment of a uniform system for handicapped parking to enhance the safety of persons with disabilities. This report would include a recommended rulemaking proposal and would be submitted to the Administrators of FHWA and NHTSA. After the agencies issue a notice of proposed rulemaking (NPRM), the committee would review any comments submitted to the rulemaking docket, and write a second report which would include a recommended final rule.

We received nineteen comments on the notice of intent to form an advisory committee. Most of the commenters endorsed the use of regulatory negotiation for this rulemaking, and many requested appointment to the committee.

Establishment

Based on this response, and for the reasons stated in the notice of intent, FHWA and NHTSA have determined that establishment of an advisory committee for regulatory negotiation on this subject is necessary and in the public interest. Accordingly, FHWA and NHTSA have established an advisory committee for regulatory negotiation. The purpose of this committee is to provide a forum for the consideration

and development of a rulemaking to create a uniform system for handicapped parking. The charter, which explains the scope and objectives of the Committee, is set forth in appendix to this notice.

Mediator

In the notice of intent, we stated that a "convener/mediator/facilitator" will chair the negotiations, ask the parties to present additional material, and offer alternative suggestions toward the desired consensus.

Because the objectivity of the mediator is crucial, we opted for an administrative judge from the Board of Contract Appeals. He will be the chairperson of the committee, and will mediate all disputes and issues arising before the committee.

Membership and Interests to be Represented

The following organizations have been appointed as members of the advisory committee:

American Association of Motor Vehicle Administrators
 American Public Transit Association
 Arthritis Foundation
 Dignity for the Disabled, Inc.
 Disabled American Veterans
 Federal Highway Administration
 National Association of Governors' Highway Safety Representatives
 National Committee on Uniform Traffic Laws and Ordinances
 National Governors' Association
 National Highway Traffic Safety Administration
 National Sheriffs' Association
 New York State Office of the Advocate for the Disabled
 Paralyzed Veterans of America
 United States Architectural and Transportation Barriers and Compliance Board

In the notice of intent to form an advisory committee, we had tentatively identified the International Association of Chiefs of Police (IACP), Association of Persons with Severe Handicaps (APSH), and the American Automobile Association (AAA), as possible advisory committee members. Furthermore, several commenters suggested the appointment of other members. The Washington State Governor's Committee on Disability Issues and Employment (WSGCDE) suggested that the President's Committee on Employment of People with Disabilities, the National Council on Disability, the National Council on Independent Living (NCIL), and the National Rehabilitation Association, be appointed as members of the advisory committee. WSGCDE contacted each of the organizations it suggested for membership, and we sent

letters to IACP, APSH, AAA, and NCIL, advising of our intent to form this advisory committee. None of the organizations expressed any interest in appointment to the committee. Furthermore, the meetings of this committee will be open to the public. Any interested person or organization will, in the discretion of the chairperson of the committee, have the opportunity to address the committee. Therefore, we have not appointed any of the organizations suggested by WSGCDE nor IACP, APSH, or AAA, but we welcome their participation.

Persons with disabilities face problems when they travel throughout the United States, and their problems also extend outside of our borders. Many of our States have entered into reciprocity agreements with the provinces of Canada. For these reasons, we notified the Director of the Transportation of the Disable Program, Transport Canada, of our intent to form this advisory committee. He intends to participate in the meetings of the committee. Although we have invited Mexico to participate, Mexico has not expressed any interest at this time.

Major Issues

This advisory committee will consider the following issues:

1. The adoption of the International Symbol of Access (ISA) as the only recognized symbol for the identification of vehicles used for transporting individuals with handicaps that limit or impair the ability to walk.

2. The issuance of license plates displaying the ISA for vehicles which will be used to transport individuals with handicaps which limit or impair the ability to walk.

3. The issuance of removable windshield placards (displaying the ISA) to individuals with handicaps which limit or impair the ability to walk.

4. The fees charged for the licensing or registration of a vehicle used to transport individuals with handicaps.

5. The recognition of licenses and placards which display the ISA and are issued by other States and countries. We anticipate that this advisory committee may discuss matters that are ancillary to the issues set forth above.

Procedures

The Paralyzed Veterans of America (PVA) discussed several procedural aspects of the advisory committee.

First, PVA requested a series of negotiated rulemaking training sessions for the committee members. To provide the participants with an informal educational setting and augment and update their negotiation skills, we plan a

pre-negotiation training session. This session will be held on Tuesday, October 17, 1989, the day before the first day of negotiations, at the Department of Transportation, Room 4200, 400 7th Street, SW, Washington, DC. Chris Kirtz, the Director of the Regulatory Negotiation Project at the Environmental Protection Agency, will lead the session.

Second, PVA asked FHWA and NHTSA to accommodate the needs of persons with disabilities who will directly or indirectly participate in the negotiations. PVA asked that interpreters and assistive devices be made available for the hearing impaired, and that written materials and meeting transcripts be provided in braille and on tape for persons with visual impairments. With regard to persons with mobility impairments, PVA requested that the meetings be held in accessible locations, with accessible lavatories.

FHWA and NHTSA will take the appropriate steps to ensure that the advisory committee and its meetings are conducted in a way that enables all members, including those with disabilities, to participate. We request that those persons who will need special assistance to contact us at least one week prior to the first meeting. However, we do not intend to provide a braille transcript at this time. Given the limited funds available to the agencies, the cost of a braille transcript appears to outweigh any benefit that it would provide to parties interested in this rulemaking. (We had forwarded a copy of our notice of intent to form an advisory committee to the American Council for the Blind, and that organization did not submit any comments.) FHWA and NHTSA do not believe that it is appropriate to make any determination concerning a tape of each meeting. We believe that the method for keeping minutes should be discussed by the committee.

Third, with regard to membership on the committee, PVA suggested that DOT (the Office of the Secretary) be appointed as a member of the committee, and that FHWA and NHTSA merely advise the DOT member. To achieve the full benefits of regulatory negotiation, we believe that both agencies should be members of the committee. Without full participation as members, the committee would lack direct input from the agencies. We seek to work with all interested parties to define the issues and agree on acceptable solutions. Since the Secretary has delegated his authority to implement Public Law 100-641 to the

Administrators of FHWA and NHTSA, it is appropriate that FHWA and NHTSA are members.

Schedule

In light of the Congressional time frame and consistent with the importance that FHWA and NHTSA attach to this issue, we noted in the notice of intent that we intended to expedite the process. We had set a fifteen day comment period, and had hoped to establish the committee in July and to hold the first meeting in August. PVA was concerned that this period of time was too short. To ensure that all interested parties had the opportunity to express their concerns, we delayed the process and have reviewed the comments submitted after the closing date. Due to this delay, we were not able to hold our first meeting in August, as originally anticipated.

The following schedule is established for the regulatory negotiation process:

First meeting: October 18, 1989.

Completion of negotiations for NPRM: December 20, 1989.

Publication of the NPRM: January 20, 1990.

End of comment period: February 19, 1990.

Negotiations on final rule: February 26, 1990.

Conclusion of negotiations on final rule: March 30, 1990.

Publication of final rule: April 30, 1990.

Note: On October 17 1989, FHWA and NHTSA are sponsoring an orientation session for members of the advisory committee. The session will focus on successful approaches to negotiation. Chris Kirtz, Director of the Regulatory Negotiation Program for the Environmental Protection Agency will conduct the session.

The schedule is deliberately focused on the early stages of the committee's efforts, emphasizing our view of the importance of the committee's achieving consensus before the publication of the NPRM.

Notices of the meetings will be published in the *Federal Register*, if time permits. We note that publication may not be possible in cases when the committee decides to meet for a few days, break for a few days, and then resume negotiations.

Committee Dissolution

PVA notes that the notice of intent to form an advisory committee stated that FHWA and NHTSA would dissolve the committee if it "cannot reach agreement within 45 days after the final pre-NPRM meeting. 54 FR 24912 (1989). PVA agrees that a target date is useful, and PVA encourages FHWA and NHTSA to

incorporate issues upon which the committee has reached consensus into the NPRM, in the event that the committee is dissolved. FHWA and NHTSA intend to give careful consideration to all deliberations of the advisory committee and the agencies hope that they will be successful in obtaining a consensus report from this committee.

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

Appendix

Charter: Regulatory Negotiation Advisory Committee for Uniform System for Handicapped Parking Rulemaking

I. Purpose: This Charter establishes the Regulatory Negotiation Advisory Committee for the Federal Highway Administration's (FHWA's) and the National Highway Traffic Safety Administration's (NHTSA's) Uniform System for Handicapped Parking rulemaking and sets forth guidelines for its operation in accordance with the Federal Advisory Committee Act (FACA), 5 U.S.C. App. 2, Public Law 100-641, Federal regulation 49 CFR part 95 and Department of Transportation Order 1120.3A.

II. Sponsor and Office Providing Support Services: FHWA and NHTSA will be the sponsors. Support services will be provided by the Office of the Traffic Operations, FHWA.

III. The Committee shall develop a report to establish a system which:

(i) Adopts the International Symbol of Access (as adopted by Rehabilitation International in 1969 at its 11th World Congress on Rehabilitation of the Disabled) as the only recognized symbol for the identification of vehicles used for transporting individuals with handicaps which limit or impair the ability to walk;

(ii) Provides for the issuance of license plates displaying the International Symbol of Access for vehicles which will be used to transport individuals with handicaps which limit or impair the ability to walk, under criteria determined by the State;

(iii) Provides for the issuance of removable windshield placards (displaying the International Symbol of Access) to individuals with handicaps which limit or impair the ability to walk, under criteria determined by the State;

(iv) Provides that fees charged for the licensing or registration of a vehicle used to transport individuals with handicaps do not exceed fees charged for the licensing or registration of other similar vehicles operated in the State; and

(v) For purposes of easy access parking, recognizes licenses and placards displaying the International Symbol of Access which

have been issued by the other States and countries.

(b) This report shall include a recommended rulemaking proposal, form the basis for an FHWA and NHTSA Notice of Proposed Rulemaking (NPRM), and be included in the public docket for the rulemaking. The NPRM will be published in the *Federal Register* for public comment. The Committee will review the comments, and using the negotiation process, develop a report, including a recommended final rule.

(c) The Committee shall act solely in an advisory capacity to the agencies and shall not exercise any program management responsibility nor make decisions directly affecting the matters on which it provides advice.

IV. Duties: Consistent with the scope and objectives described in paragraph III, the Committee is authorized to:

(a) Review the current handicapped parking system of the States and identify the problems the handicapped encounter when traveling;

(b) Recommend approaches for the establishment of a uniform system for handicapped parking and indicate the most efficient means to pursue such approaches;

(c) Write a report which includes a recommended NPRM;

(d) Review comments submitted to rulemaking docket;

(e) Write a report which includes a recommended final rule; and

(f) Respond to specific assignments made by the sponsor.

V. Membership: (a) The Committee shall consist of approximately fifteen members appointed by the Secretary of Transportation after consultation with organizations that have an interest in the establishment of a uniform system for handicapped parking, including the State and local governments, associations representing handicapped persons, and law enforcement agencies.

(b) The membership will be fairly balanced in terms of the points of view represented.

VI. Chairperson: The Chairperson shall be appointed by agreement of the Administrators, FHWA and NHTSA. The Chairperson shall mediate all disputes and issues arising before the Committee. The Chairperson shall designate the Secretary for the Committee and the Secretary of each subcommittee established.

VII. Meetings: (a) The Committee and any subcommittee shall meet and terminate at the call of the Committee Chairperson. Agendas will be reviewed and approved by the Chairperson.

(b) All committee and subcommittee meetings shall be open to the public. A notice of each meeting shall be published in the *Federal Register* at least fifteen days in advance of the meeting. Shorter notice is permissible in case of emergency, but the reason for the emergency must be reported in the notice.

(c) Detailed minutes of each meeting shall be kept and their accuracy certified to by the Committee Chairperson. The minutes shall include the time and place of the meeting, a record of the persons present, a complete summary of matters discussed and

conclusions reached and copies of all reports received, issued or approved by the committee or subcommittee.

VIII. *Compensation for Non-Government Members:* Non-Federal government members serve without compensation and will not be reimbursed for expenses.

IX. *Estimated Annual Cost to the Government:* No cost to the government is anticipated. However, should costs be incurred, in no event shall those costs exceed \$2,000, which is the ceiling for this Committee. No government staff positions are being allocated to the Committee on a full-time basis.

X. *Public Interest:* The formation and use of the Committee is determined to be in the public interest in connection with the performance of duties imposed on the Department of Transportation by law.

XI. *Effective Date:* This charter is effective fifteen days after publication in the *Federal Register*, and terminates upon completion of the subject rulemaking or two years after this date, whichever occurs first, unless, prior to such time, it is extended in accordance with the FACA and other applicable requirements.

Issued on: September 29, 1989.

T. D. Larson,

Federal Highway Administrator.

Jeffrey R. Miller,

Acting Administrator, National Highway Traffic Safety Administration.

[FR Doc. 89-23491 Filed 10-2-89; 8:45 am]

BILLING CODE 4910-22-M

Environmental Impact Statement; Chittenden County, Vermont

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 a proposed highway project in Chittenden County, Vermont.

FOR FURTHER INFORMATION CONTACT:

George A. Jensen, Assistant Division Administrator, Federal Highway Administration, Federal Building, Montpelier, VT 05601, Telephone (802) 828-4423.

SUPPLEMENTARY INFORMATION: The FHWA, in cooperation with the Vermont Agency of Transportation, will prepare an EIS on a proposal to improve Interstate 89 (I-89) in Chittenden County, Vermont. The proposed improvement would involve the construction of an interchange between I-89 and US Route 2 (US 2) in Bolton. The proposed interchange would consist of exit and entrance ramps on I-89 and south bound lanes.

An interchange is proposed to provide for existing and projected traffic

demand. Alternatives under consideration include: (1) Taking no action; (2) improving US Route 2 between Jonesville and Waterbury; (3) constructing an interchange between I-89 and US 2 in Bolton.

No formal scoping meeting is planned at this time. Letters describing the proposed 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. The draft EIS will be available for review and comment prior to a public hearing. Public notice of the time and place of the hearing will be given.

Comments and suggestions are invited from all interested parties to ensure that the full range of issues related to this proposed action are addressed and that all significant issues are identified. Comments or questions concerning this proposed action and the EIS should be directed to the FHWA at the address provided above.

(Catalog of Federal Domestic Assistance Program Number 20.205, Highway Planning and Construction. The regulations implementing Executive Order 12372 regarding intergovernmental consultation on Federal programs and activities apply to this program.)

Issued on September 21, 1989.

Karle Snyder,

FHWA Division Administrator, Montpelier.

[FR Doc. 89-23218 Filed 10-2-89; 8:45 am]

BILLING CODE 4910-22-M

National Highway Traffic Safety Administration

Discretionary Grants To Support the Evaluation of the Effectiveness of Innovative Occupant Protection Countermeasures

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

ACTION: Announcement of a discretionary grant program to support the evaluation of the effectiveness of innovative occupant protection countermeasure strategies.

SUMMARY: The National Highway Traffic Safety Administration (NHTSA) announces the anticipated availability of a FY 1990 discretionary grant program to support the application of effectiveness evaluation methodologies and analytical techniques to quantifiably measure the impact of innovative occupant protection countermeasure strategies on the usage of occupant protection systems, including their influence on reducing the

death and injury consequences of motor vehicle crashes. This notice solicits applications from educational institutions and research organizations that are interested in participating in this grant program.

DATE: Applications must be received at the office designated below on or before November 15, 1989.

ADDRESS: Applications must be submitted to the National Highway Traffic Safety Administration, Office of Contracts and Procurement (NAD-30), ATTN: Rose Weston, 400 7th Street, SW Room 5301, Washington, DC 20590. All applications submitted must include a reference to NHTSA Grant Program No. DTNH22-90-Z-05008. Interested applicants are advised that no separate application package exists beyond the contents of this announcement.

FOR FURTHER INFORMATION CONTACT:

General administrative questions may be directed to Ms. Rose Watson, Office of Contracts and Procurement, at (202) 366-9557. Programmatic questions relating to this grant program should be directed to Dr. William E. Tarrants, NHTSA, Traffic Safety Programs, Evaluation Staff (NTS-02.1), 400 7th Street, SW., Room 5125-E, Washington, DC 20590 at (202) 366-2699.

SUPPLEMENTARY INFORMATION:

Background

One of the most effective countermeasures for reducing motor vehicle fatalities and crash injuries is automatic or manual occupant protection. The most recent 19-city survey (August, 1988) revealed that safety belt use by drivers had reached 46 percent, up from 43 percent the previous quarter. Program planners and managers involved in the implementation of State belt use laws and child passenger safety laws understand the importance of public attitudes about (1) the need for occupant protection, (2) the necessity of laws to achieve high usage rates, and (3) the tradeoff between the benefits obtained and interference with individual freedom of choice. As of December 1988, a total of 32 States plus the District of Columbia had enacted mandatory safety belt use laws.

NHTSA estimates that enactment of belt use laws saved nearly 4,000 lives in 1987. From 1983 through 1987 safety belts have saved nearly 11,000 lives. This accomplishment is primarily due to the efforts of State and local leadership in promoting occupant protection and implementation of safety belt use laws. If all States had belt use laws and usage levels were as high as those in many

foreign countries (for example, 85%), it is estimated that at least 10,000 lives could have been saved in 1987. The current national safety belt use goal is 70% by 1990 in those States with safety belt use laws.

Since 1981, NHTSA has conducted and promoted programs designed to increase safety belt use. Surveys during the early years indicated that the national safety belt use rate for drivers was below 11 percent and, prior to 1984, no State had enacted a mandatory safety belt usage law. An early program goal was to improve the public's knowledge and understanding of the benefits of occupant protection by promoting the active involvement of public interest organizations such as the American Red Cross, physician's professional organizations, nursing associations, civic groups and others. A program to involve various corporations, businesses, government agencies and other employers in promoting safety belt use by employees and their families was initiated by NHTSA, with emphasis on "The Profit of Safety Belts." With a vested interest in employee safety, both on and off-the-job, employers attended workshops, received instructional and promotional materials, and planned, organized and conducted worksite employee programs consisting of safety belt use policies, education, incentives, and strong management support. Employee safety belt usage rates exceeding 90 percent were achieved in many organizations.

Promoting the correct use of occupant protection systems is one of the highest priority highway safety program activities within NHTSA. Special emphasis is placed on working with the law enforcement units, as well as building community support for these efforts to raise the level of compliance with existing laws. Low use groups and those who are at greatest risk for crash involvement receive special attention. Public information and education programs concentrate on promoting the use of manual safety belts, including automatic restraint systems in motor fleets, and increasing the correct use of child safety seats. Community-based traffic safety programs concentrate on effective public information programs, increased law enforcement, face-to-face education, and laying the foundation for acceptance of belt use laws.

Objectives and Program Description

During FY 1990, State and local governments, State and local affiliates of national organizations, as well as community interest groups, will be conducting projects, in various locations throughout the United States, which

represent innovative countermeasure strategies designed to increase the usage of occupant protection systems. Such projects will be conducted utilizing various sources of funding.

The principal purpose of NHTSA's grant program is to support the application of evaluation research methodologies and analytical techniques to quantifiably assess the effectiveness of such projects, both in terms of their impact on the usage of occupant protection systems and their influence in reducing the death and injury consequences of motor vehicle crashes. Secondary objectives of this proposed grant program include the identification of projects involving innovative countermeasure strategies, as well as the dissemination of evaluation results and recommendations to concerned State and community leaders.

This grant program provides support for the planning, development, and conduct of the evaluation component of an innovative occupant protection countermeasure project being performed within a State, a county, a single community, or group of communities during FY 1990. The following evaluation topics relating to occupant protection countermeasures are examples of areas important to NHTSA:

The impact of innovative occupant protection law enforcement techniques, alone or in combination with Public Information and Education (PI&E) programs.

The impact of monetary fines of varying magnitude for violations of State mandatory safety belt use laws.

The effectiveness of primary versus secondary offense belt use laws.

Variations in belt usage as a function of age, education rural versus urban residency, profession or vocation, socio-economic status, etc.

Methods for increasing public awareness of safety belt use law enforcement.

Effectiveness of occupant protection usage programs intended for the young driver population.

Effectiveness of employer/corporate safety belt usage programs.

Techniques for sustaining interest and positive safety belt usage behavior by employees and their families.

Effectiveness of various models for planning, organizing and operating a successful community-based safety belt usage program.

Effectiveness of various occupant protection education and incentives programs.

Identification of ways to increase safety belt use by "high risk" drivers.

Identification of the characteristics of safety belt users and non-users for use in developing effective programs for the non-use target groups.

- Techniques to increase public understanding and acceptance of automatic occupant protection systems.

Applicants are encouraged to propose other innovative topics for evaluation that are believed to be of particular importance.

NHTSA Involvement

It is not anticipated that NHTSA will be substantially involved in activities undertaken as part of this grant program. Evaluation staff of the Office of Traffic Safety Programs, will make available one professional staff person, to be designated as the Contracting Officer's Technical Representative (COTR), with responsibility for providing:

1. Technical direction in finalizing the detailed evaluation work plan and evaluation design plan, and
2. Technical assistance and guidance to the recipient.

Period of Support

The grant program described in this notice will be supported through the award of approximately 5 to 6 grants, depending upon the merit of the applications received and the availability of funding. Each grant shall provide for an anticipated performance period of 12 months. The application for funding assistance should address what is proposed and can be accomplished during this period. No grant awarded as a result of this notice shall exceed \$50,000. This notice is published in advance of the availability of appropriations, and all awards shall be subject to the availability of funds in FY 1990.

Eligibility Requirements

In order to be eligible to participate in this grant program, an applicant must be an educational institution or research organization. For-profit research organizations may apply; however, no profit factor shall be allowed.

Application Procedure

Prior to the preparation of an application, interested applicants should contact the Governor's Representative for Highway Safety to ascertain those projects being conducted within the State in FY 1990 involving innovative occupant protection countermeasure strategies. From among those being conducted, the applicant should identify that project which appears to be most suitable for effectiveness evaluation,

and which offers the potential for contributing to increased occupant protection use, reducing death and injury consequences of motor vehicle crashes, and advancing the state-of-the-art technology in this field. Such coordination must also assure cooperation in the conduct of the evaluation.

Each applicant must submit one original and two copies of the application package to: National Highway Traffic Safety Administration, Office of Contracts and Procurement (NAD-30), ATTN: Rose Watson, 400 7th Street, Room 5301, Washington, DC 20590. All applications submitted must include a reference to NHTSA Grant Program No. DTNH22-90-Z-05008. Only complete applications received on or before November 15, 1989 shall be considered.

Application Contents

1. The application package must be submitted with OMB Standard Form 424 (Rev. 4-88, including 424A and 424B), Application for Federal Assistance, with the required information filled in and the certified assurances included. While the Form 424-A deals with budget information, and section B identifies Budget Categories, the available space does not permit a level of detail which is sufficient for a meaningful evaluation of the proposed costs. A supplemental sheet should be provided which presents a detailed breakdown of the proposed costs, as well as any costs which the applicant proposes to contribute in support of this effort.

2. Applications shall include a program narrative statement which addresses the following:

a. A detailed description of the innovative occupant protection countermeasure(s) project proposed for evaluation, including the factors and activities considered in the formulation and planned implementation of the project itself, as well as the rationale for selecting the project for evaluation.

b. A brief description of the proposed evaluation work plan and schedule for conducting the evaluation, including proposed personnel.

c. A brief description of the proposed evaluation design plan, including what will actually be measured and how the effectiveness evaluation goals will be accomplished.

d. The proposed program director and other key personnel identified for participation in the proposed evaluation effort, including a brief description of their qualifications and respective organizational responsibilities.

e. A brief description of previous organizational evaluation experience

involving similar or related efforts, including a description of the effort, the sponsoring agency, the evaluation methodology used, and the results of effectiveness evaluations conducted.

e. Applications shall include a letter(s) from the State Governor's Representative for Highway Safety and from the organization conducting the project to be evaluated, if other than the State Office of Highway Safety, which indicates that the applicant has appropriately coordinated the proposed evaluation component and that, if the applicant is awarded a grant, their cooperation will be provided during performance of the evaluation.

Evaluation Criteria and Review Process

Initially, all applications will be reviewed to confirm that the applicant is an eligible recipient and to assure that the application contains all of the information required by the Application Contents of this notice.

Each complete application from an eligible recipient will then be evaluated by an Evaluation Committee. The applications will be evaluated using the following criteria which are listed in descending order of importance:

1. The potential of the innovative countermeasure project proposed for evaluation to make a significant contribution to increasing occupant protection use, reducing death and injury consequences of motor vehicle crashes, and advancing the state-of-the-art technology in the occupant protection field.

2. The adequacy of organizational resources for accomplishing the proposed evaluation effort, including the qualifications and experience of the proposed personnel, the various disciplines represented, and the relative level of effort proposed for the professional, technical, and support staff.

3. The applicant's understanding of the purpose and objectives of the grant program as evidenced in the project proposed for evaluation, as well as the soundness of the proposed evaluation work plan and design, including the adequacy of proposed data collection methodology and the feasibility of statistical or other analytical methods proposed.

4. The adequacy of the organization's experience on similar or related evaluation efforts.

5. The adequacy, appropriateness, and realism of the applicant's plan for accomplishing the grant activities within the time period provided for grant support, and considering the schedule of the project proposed for evaluation.

Terms and Conditions of the Award

1. Prior to award, the recipient must comply with the certification requirements of 49 CFR part 29—Department of Transportation Government-wide Debarment and Suspension (Nonprocurement) and Government-wide Requirements for Drug-Free Workplace (Grants).

2. Reporting Requirements:

a. Evaluation Work Plan and Schedule—within 30 days after award, the recipient shall submit a detailed evaluation work plan and schedule to the NHTSA COTR which describes the major activities, with a breakdown of specific tasks, and a schedule which identifies the beginning and ending dates for each task, and the sequence of task performance. The work plan shall specify the research questions or issues to be studied in the evaluation. The work plan shall be subject to the technical direction, and approval, of the NHTSA COTR. In the event technical revisions to the work plan are necessary, the recipient shall submit a revised plan for approval. The schedule will be updated in monthly progress reports.

b. Evaluation Design Plan—within 45 days after grant award, the recipient shall submit a detailed evaluation design plan to the NHTSA COTR which, as a minimum, shall contain the following:

(1) a description of the evaluation research to be conducted, including the proposed methodology to be followed, and the rationale for its selection.

(2) an analytic framework and procedure for conducting an assessment and analysis of the data, including a specification of the statistical methodologies to be followed, and the rationale for their use.

(3) a data collection methodology or information acquisition procedure to be followed corresponding to the questions, issues and objectives specified in the evaluation work plan. The collection methodology or information acquisition procedure shall specify how the validity and accuracy of the data will be determined.

(4) draft data collection instruments along with instructions concerning their use.

The evaluation design plan shall be subject to the technical direction, and approval, of the NHTSA COTR. In the event technical revisions to the design plan are necessary, the recipient shall submit a revised plan for approval.

c. Monthly Progress Reports—The recipient shall submit monthly letter-type progress reports.

d. Final Report—the evaluation research results shall be documented in a Final Report prepared as a two-part document.

(1) Part One shall contain the formal technical report, including a discussion of the innovative occupant protection countermeasures used; the rationale for their selection; a description of the administrative procedures and tasks followed in conducting the project; the evaluation design plan, including the data collection and analysis procedures used; a discussion of the analyses conducted; the presentation of the evaluation results, including their interpretation; a discussion of the conclusions, including their rationale and interpretation; and recommendations, guidelines, and implementation procedures for use by other States and/or communities interested in adopting the countermeasure studied.

Part One of the Final Report shall also contain recommendations for future evaluation research, suggested occupant protection countermeasure strategy improvements, and any suggested organizational and/or operational changes which may enhance the implementation of the evaluated countermeasure.

(2) Part Two of the Final Report shall be a less technical document addressing the information needs of a general manager/administrator who may be interested in adopting the innovative occupant protection countermeasure. The Part Two document shall contain a description of the occupant protection countermeasure project studied, including its goals, strategies and methodology for use; a brief discussion of the findings, conclusions and recommendations; and guidelines for implementation of the innovative occupant protection countermeasure by the appropriate State or local community program official.

A minimum of 30 days prior to the end of the grant period, the recipient shall submit the final report, in draft form, to the NHTSA COTR for review and comments. The recipient shall incorporate the COTR's comments and suggestions, and resubmit the Final Report.

3. During the effective period of the grant(s) awarded as a result of this notice, the grant(s) shall be subject to the general administrative requirements of OMB Circular A-110 (or the "common rule," if effected prior to award), the cost principles of OMB Circular A-21, A-122, or FAR 31.2, as applicable to the recipient, and the requirements of 49 CFR part 29.

Issued On: September 28, 1989.

George L. Reagle,
Associate Administrator for Traffic Safety Programs.
[FR Doc. 89-23270 Filed 10-2-89; 8:45 am]
BILLING CODE 4910-59-M

DEPARTMENT OF THE TREASURY

Fiscal Services

Surety Companies Acceptable on Federal Bonds Liquidation; Southeastern Casualty and Indemnity Insurance Co., Inc., and Southeastern Reinsurance Co., Inc.

Southeastern Casualty and Indemnity Insurance Company, Inc., and Southeastern Reinsurance Company, Inc., both Florida corporations, formerly held Certificates of Authority as acceptable sureties on Federal bonds and were last listed as such at 53 FR 25075, July 1, 1988. The Companies' authorities were terminated by the Department of the Treasury effective May 12, 1989. Notices of these terminations were published in the *Federal Register* of May 18, 1989, on page 21521.

On September 1, 1989, upon a petition by the Insurance Commissioner of the State of Florida, the Florida Circuit Court of the Second Judicial Circuit, issued an Order of Liquidation with respect to Southeastern Casualty and Indemnity Insurance Company, Inc., and Southeastern Reinsurance Company, Inc. The Department of Insurance was appointed as the Liquidator. All persons having claims against the companies must file their claims by March 1, 1990, or be barred from sharing in the distribution of assets.

All claims must be filed in writing and shall set forth the amount of the claim, the facts upon which the claim is based, any priorities asserted, and any other pertinent facts to substantiate the claim. It is recommended that Federal Agency claimants asserting priority status under 31 U.S.C. 3713 who have not yet filed their claim should do so, in writing, to: Commercial Litigation Branch, Civil Division, Department of Justice, P.O. Box 875, Ben Franklin Station, Washington, DC 20044-0875. Attn: Ms. Sandra P. Spooner, Deputy Director.

The above office will be consolidating any and all claims against Southeastern Casualty and Indemnity Insurance Company, Inc., and Southeastern Reinsurance Company, Inc., on behalf of the United States Government. Any questions concerning filing of claims may be directed to Ms. Spooner at (202 or FTS 724-7194).

Questions concerning this notice may be directed to the Department of the Treasury, Financial Management Service, Finance Division, Surety Bond Branch, Washington, DC 20227 Telephone 202-287-3921.

Dated: September 25, 1989.
Mitchell A. Levine,
Assistant Commissioner, Comptroller Financial Management Service.
[FR Doc. 89-23211 Filed 10-2-89; 8:45 am]
BILLING CODE 4810-35-M

Sunshine Act Meetings

Federal Register

Vol. 54, No. 190

Tuesday, October 3, 1989

This section of the FEDERAL REGISTER contains notices of meetings published under the "Government in the Sunshine Act" (Pub. L. 94-409) 5 U.S.C. 552b(e)(3).

FEDERAL DEPOSIT INSURANCE CORPORATION

Pursuant to the provisions of the "Government in the Sunshine Act" (5 U.S.C. 552b), notice is hereby given that at 3:55 p.m. on Tuesday, September 26, 1989, the Board of Directors of the Federal Deposit Insurance Corporation met in open session to consider a proposal of the United States Treasury regarding the establishment of exit fees that must be paid by insured depository institutions that participate in "conversion transactions" (transfers or switches between the two deposit insurance funds).

In calling the meeting, the Board determined, on motion of Director C. C. Hope, Jr. (Appointive), seconded by Director Robert L. Clarke (Comptroller of the Currency), concurred in by Director M. Danny Wall (Director of the Office of Thrift Supervision), and Chairman L. William Seidman, that Corporation business required its consideration of the matter on less than seven days' notice to the public and that no earlier notice of the meeting was practicable.

The meeting was held in the Amphitheater of the Resolution Trust Corporation Building located at 801 17th Street, N.W. Washington, D.C.

Dated: September 28, 1989.

Federal Deposit Insurance Corporation.

Robert E. Feldman,

Deputy Executive Secretary.

[FR Doc. 89-23376 Filed 9-29-89; 11:23 am]

BILLING CODE 6714-01-M

FEDERAL DEPOSIT INSURANCE CORPORATION

Pursuant to the provisions of the "Government in the Sunshine Act" (5 U.S.C. 552b), notice is hereby given that at 8:53 a.m. on Wednesday, September 27, 1989, the Board of Directors of the Federal Deposit Insurance Corporation met in open session, by telephone conference call, to consider the requirements that a potential bidder must meet in order to qualify as an acceptable bidder for a failed thrift institution.

In calling the meeting, the Board determined, on motion of Director C. C. Hope, Jr. (Appointive), seconded by Director Robert L. Clarke (Comptroller of the Currency), concurred in by Chairman L. William Seidman and Director M. Danny Wall (Director of the Office of Thrift Supervision), that Corporation business required its consideration of the matters on less than seven days' notice to the public; and that no earlier notice of the meeting was practicable.

Dated: September 28, 1989.

Federal Deposit Insurance Corporation.

Robert E. Feldman,

Deputy Executive Secretary.

[FR Doc. 89-23377 Filed 9-29-89; 11:23 am]

BILLING CODE 6714-01-M

FEDERAL MINE SAFETY AND HEALTH REVIEW COMMISSION

September 28, 1989.

TIME AND DATE: 10:00 a.m., Thursday, October 5, 1989.

PLACE: Room 600, 1730 K Street, N.W. Washington, DC.

STATUS: Open.

MATTERS TO BE CONSIDERED: The Commission will consider and act upon the following:

1. Possible revisions to Commission Procedural Rules.

Any person intending to attend this meeting who requires special accessibility features and/or auxiliary aids, such as sign language interpreters; must inform the Commission in advance of those needs. Subject to 29 CFR § 2706.150(a)(3) and § 2706.160(d).

CONTACT PERSON FOR MORE

INFORMATION: Jean Ellen (202) 653-5629/ (202) 708-9300 for TDD Relay 800-877-8339 (Toll Free).

Jean H. Ellen,

Agenda Clerk.

[FR Doc. 89-23427 Filed 9-29-89; 1:36 pm]

BILLING CODE 6735-01-M

NATIONAL SCIENCE BOARD

DATE AND TIME: October 13, 1989, 8:30 a.m., Closed Session; 9:00 a.m., Open Session.

PLACE: National Science Foundation, 1800 G Street, NW, Room 540, Washington, DC 20550.

STATUS: Most of this meeting will be open to the public. Part of this meeting will be closed to the public.

MATTERS TO BE CONSIDERED AUGUST 18:

Closed Session (8:30 a.m. to 9:00 a.m.)

1. Minutes—August 1989 Meeting.
2. NSB and NSF Staff Nominees.
3. Future NSF Budgets.
4. Grants and Contracts—Action Items.

Open Session (9:00 a.m. to 12:00 noon)

5. Grants, Contracts, and Programs—Action Item.
6. Proposed 1990 Award Review Exemptions.
7. Chairman's Report.
8. Minutes—August 1989 Meeting.
9. Director's Report.
10. Reaffirmation of and Proposed Amendment to 1982 NSB Statement on Science in the International Setting.
11. Discussion of Major National Science Initiatives.
12. Other Business.

Thomas Ubois,

Executive Officer.

[FR Doc. 89-23474 Filed 9-29-89; 3:40 pm]

BILLING CODE 7555-01-M

NUCLEAR REGULATORY COMMISSION:

DATE: Weeks of October 2, 9, 16, and 23, 1989.

PLACE: Commissioners' Conference Room, 11555 Rockville Pike, Rockville, Maryland.

STATUS: Open and Closed.

MATTERS TO BE CONSIDERED:

Week of October 2

There are no meetings scheduled for the Week of October 2.

Week of October 9 (Tentative)

Thursday, October 12

3:30 p.m.

Affirmation/Discussion and Vote (Public Meeting) (if needed)

Week of October 16 (Tentative)

Thursday, October 19

10:00 a.m.

Briefing on Status of Comanche Peak (Public Meeting)

11:30 a.m.

Affirmation/Discussion and Vote (Public Meeting) (if needed)

Week of October 23 (Tentative)

Wednesday, October 25

10:00 a.m.

Briefing on Emerging Technical Issues (Public Meeting)

11:30 a.m.

Affirmation/Discussion and Vote (Public Meeting) (if needed)

Note.—Affirmation sessions are initially scheduled and announced to the public on a time-reserved basis. Supplementary notice is provided in accordance with the Sunshine Act as specific items are identified and added to the meeting agenda. If there is no specific subject listed for affirmation, this means that no item has as yet been identified as requiring any Commission vote on this date.

To verify the status of meetings call (Recording)—(301) 492-0292.

CONTACT PERSON FOR MORE INFORMATION: William Hill (301) 492-1661.

Dated: September 28, 1989.

William M. Hill, Jr.,

Office of the Secretary.

[FR Doc. 89-23449 Filed 9-29-89; 2:49 pm]

BILLING CODE 7590-01-M

Corrections

Federal Register

Vol. 54, No. 190

Tuesday, October 3, 1989

This section of the FEDERAL REGISTER contains editorial corrections of previously published Presidential, Rule, Proposed Rule, and Notice documents. These corrections are prepared by the Office of the Federal Register. Agency prepared corrections are issued as signed documents and appear in the appropriate document categories elsewhere in the issue.

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

[Docket No. 89-136]

Availability of Environmental Assessment and Finding of No Significant Impact Relative to Issuance of a Permit to Field Test Genetically Engineered Alfalfa Plants

Correction

In notice document 89-19242 beginning on page 33741 in the issue of Wednesday, August 16, 1989, make the following correction:

On page 33742, in the first column, in the 14th line, "introduction gener" should read "introduced gene"

BILLING CODE 1505-01-D

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 264

[Docket No. 90804-9204]

RIN 0648-9204

United States Standards for Grades of Frozen Fish Blocks

Correction

In proposed rule document 89-22208 beginning on page 38881 in the issue of Thursday, September 21, 1989, make the following corrections:

§ 264.104 [Corrected]

1. On page 38882, in the third column, in § 264.104 (b), in the third line, "§ 264.208" should read "§ 264.108"

2. On page 38883, in the third column, in § 264.104(e)(12), in the fifth line, "9.6s" should read "9.69"

BILLING CODE 1505-01-D

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. TQ89-3-23-001]

Eastern Shore Natural Gas Co., Proposed Changes in FERC Gas Tariff

Correction

In notice document 89-22002 appearing on page 38554 in the issue of Tuesday, September 19, 1989, make the following correction:

On page 38554, in the first column, the docket heading should read as set forth above.

BILLING CODE 1505-01-D

[Docket No. TQ90-1-33-001]

El Paso Natural Gas Co., Correction to Proposed Change in Rates

Correction

In notice document 89-22003 appearing on page 38554 in the issue of Tuesday, September 19, 1989, make the following correction:

On page 38554, in the second column, the docket heading should read as set forth above.

BILLING CODE 1505-01-D

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 61

[AD-FRL-3620-5]

National Emission Standards for Hazardous Air Pollutants; Benzene Emissions From Chemical Manufacturing Process Vents, Industrial Solvent Use, Benzene Waste Operations, Benzene Transfer Operations, and Gasoline Marketing System

Correction

In proposed rule document 89-21415 beginning on page 38083 in the issue of Thursday, September 14, 1989, make the following corrections:

1. On page 38083, in the first column, under **DATES**, in the second paragraph, in the fourth line, "October 4, 1989" should read "October 11, 1989"

2. On page 38090, in the first column, the heading *B. Benzene Category Operations* should read *B. Benzene Transfer Operations*.

§ 61.355 [Corrected]

3. On page 38133, in the first column, in § 61.355(e)(8), in table 1, in the heading in the third column to the table, "t" should read "t'"

4. On page 38134, in the third column, in § 61.355(p)(3)(v), in the equation, "100" should appear immediately to the right of the times sign.

BILLING CODE 1505-01-D

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Social Security Administration

20 CFR Parts 404 and 416

RIN 0960-AC07

Federal Old-Age, Survivors, and Disability Insurance; Supplemental Security Income for the Aged, Blind, and Disabled; Decisions by Administrative Law Judges in Cases Remanded by the Courts

Correction

In rule document 89-21447 beginning on page 37789 in the issue of Wednesday, September 13, 1989, make the following corrections:

§ 404.984 [Corrected]

1. On page 37792, in the third column, in § 404.984(a), in the 22nd line, remove the period between "either" and "make"

2. On page 37794, in the first column, the file line at the end of the document was omitted and should have appeared as follows:

[FR Doc. 89-21447 Filed 9-12-89; 8:45 am]

BILLING CODE 1505-01-D

DEPARTMENT OF THE INTERIOR**Bureau of Land Management**

[NV-930-09-4212-22]

Filing of Plats of Survey; Nevada*Correction*

In notice document 89-18776 appearing on page 33092 in the issue of Friday, August 11, 1989, make the following correction:

On page 33092, in the second column, under "**Mount Diablo Meridian Nevada**" the numerical designation for each township should be followed by an "N."

BILLING CODE 1505-01-D

**NUCLEAR REGULATORY
COMMISSION****10 CFR Part 2**

RIN 3150-AD27

**Procedures Applicable to Proceedings
for the Issuance of Licenses for the
Receipt of High-level Radioactive
Waste at a Geologic Respository***Correction*

The page number for proposed rule document 89-22604 appearing in the issue of Tuesday, September 26, 1989, was incorrectly cited on page V of the table of contents. The page number should read "39387"

BILLING CODE 1505-01-D

DEPARTMENT OF THE TREASURY**Internal Revenue Service****Tax on Certain Imported Substances;
Notice of Filing of Petition***Correction*

In notice document 89-21308 appearing on page 37757 in the issue of Tuesday, September 12, 1989, make the following correction:

In the third column, under "**SUPPLEMENTARY INFORMATION**" in the next to last paragraph, in the seventh line, "great" should read "graft"

BILLING CODE 1505-01-D

Tuesday
October 3, 1989

49 CFR

Part II

Part II

**Department of
Transportation**

Federal Highway Administration

**49 CFR Parts 383 and 391
Commercial Driver's License Standards;
Disqualifications; Final Rule**

DEPARTMENT OF TRANSPORTATION

Federal Highway Administration

49 CFR Parts 383 and 391

[FHWA Docket No. MC-88-14]

RIN 2125-AC19

Commercial Driver's License Standards; Disqualifications

AGENCY: Federal Highway Administration (FHWA), DOT.

ACTION: Final rule.

SUMMARY: The FHWA is amending 49 CFR part 383 to define the serious traffic violations for which commercial motor vehicle operators may be disqualified for periods of 60 and 120 days under § 383.51. Specifically, the FHWA is defining these serious traffic violations to include a conviction for "excessive speeding, which is any speed of 15 miles per hour or more above the posted speed limit; "reckless driving"; "improper or erratic traffic lane changes"; "following the vehicle ahead too closely" and, any other motor vehicle traffic control laws which arise in connection with a fatal traffic accident. The FHWA is also allowing States, under certain circumstances, to reduce a lifetime disqualification from driving a commercial motor vehicle (CMV) to ten years. This final rule also clarifies other issues pertaining to convictions and disqualifications of CMV drivers, and makes a conforming amendment to 49 CFR part 391 of the Federal Motor Carrier Safety Regulations.

EFFECTIVE DATE: November 2, 1989.

FOR FURTHER INFORMATION CONTACT: Ms. Jill L. Hochman, Chief, Standards Review Division, Office of Motor Carrier Standards, (202) 368-4001, or Mr. Paul Brennan, Office of the Chief Counsel, (202) 368-0834, Federal Highway Administration, 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 legal holidays.

SUPPLEMENTARY INFORMATION:

Background

On October 27 1986, the Commercial Motor Vehicle Safety Act of 1986, Title XII of Public Law 99-570 (the Act), was signed into law by the President. As a first step in implementing the requirements of the Act, a final rule and request for comments on "Commercial Driver Licensing Standards; Requirements and Penalties" was published in the Federal Register on June 1, 1987 (52 FR 20574), implementing the single license requirement,

notification requirements, Federal disqualifications, and other provisions of the Act required to be effective on July 1, 1987

The June 1, 1987 rule left several components under "serious traffic violations" undefined, and sought public comment on these areas. On January 31, 1989 the FHWA published a notice of proposed rulemaking (NPRM) (54 FR 5036) based on those comments, seeking to rectify the omissions and clarify other points of the June 1, 1987 rule. The FHWA received 60 responses to the NPRM; these are listed by category in Exhibit 1.

The final rule amends 49 CFR part 383, "Commercial Driver Licensing Standards; Requirements and Penalties, to clarify which violations will be defined as "serious traffic violations. It amends § 383.31 to clarify certain notification requirements, especially how such requirements would apply to casual, intermittent, or occasional drivers. Section 383.51, "Disqualification of Drivers, is modified to allow reduction of lifetime disqualifications under certain circumstances. Also, the final rule adds precision to the wording of other existing regulations pertaining to the disqualification of drivers in 49 CFR parts 383 and 391.

Each of these changes is discussed below in the context of the relevant public responses to the docket.

Exhibit 1—Respondents to the NPRM by Category

State agencies representing 14 States:	
Department of Motor Vehicles.....	11
State Police Departments.....	2
Other State Agencies.....	2
Total State Agencies.....	15
State Organizations (AAMVA).....	1
Trucking Industry and related parties:	
Associations.....	6
Carriers.....	2
Unions.....	1
Total trucking-related.....	9
Bus Industry and related parties:	
Associations.....	1
Carriers.....	1
Unions.....	4
Total Bus-related.....	6
Individuals.....	17
Insurance Industry.....	8
Trade associations.....	2
Consultant.....	1
Public Association (AAA).....	1
Total respondents.....	60

Definition of "Serious Traffic Violations"

Excessive Speeding

As demonstrated in Exhibit 2, the majority of respondents in most categories supported the definition of excessive speed proposed in the NPRM—15 miles per hour or more above the posted limit. In endorsing the FHWA's proposal, most respondents also favored a single standard which could be applied universally in all speed zones and under all conditions and situations. Several opposing views were, however, also presented for consideration.

EXHIBIT 2—RESPONDENTS' PROPOSED DEFINITIONS OF "EXCESSIVE SPEEDING"

	Number of respondents by category supporting		
	NPRM definition: 15 mph or more above posted speed limit	Definition more strict than NPRM	Definition less strict than NPRM
State Agencies.....	7	1	1
AAMVA.....	1		
Trucking Carriers and associations.....	5	1	2
Trucking Unions.....	1		
Bus Carriers and associations.....		1	1
Bus Unions.....			3
Trade Associations.....	2		
AAA.....		1	
Individual Drivers.....	3		2
Other Individuals.....	2		
Insurance Industry.....	1	6	
Totals.....	22	10	9

A motor carrier asserted that a "flat rate" concept of greater than 15 m.p.h. over the posted speed limit for excessive speed is not consistent with providing greater restriction for greater hazard. Claiming that areas that are posted with speed limits less than 55/65 m.p.h. are lower because excessive speed presents a greater danger, the respondent suggested that a standard based on percentage of increase over posted limits, specifically 20%, would provide a standard which is more representative of the risk factor at all speeds.

Another respondent from a bus transit company explained that many factors should influence the development of an appropriate definition for excessive speed. As an example, the respondent explained that a truck carrying hazardous materials loaded to 80,000 pounds, going 50 in a 35 m.p.h. zone should be considered to be traveling at an excessive speed. However, a bus or empty vehicle traveling at the same speed in the same speed zone may not be considered to be traveling at an excessive speed.

Other respondents recommended that maximum speed limits be included in the definition. The American Automobile Association (AAA) pointed out that in forty-one States which have a 65 m.p.h. maximum speed limit, the proposal would allow drivers to speed up to 80 m.p.h. before being charged with an excessive speeding violation. Thus, the AAA recommends a cap of 75 m.p.h. above which any speeding would be considered "excessive."

The majority of respondents reiterated the FHWA's belief that Congress intended the definition for "excessive speed" to be used to identify and penalize the most severe cases of speeding violations. Several respondents, however, maintain that any speed over the posted limit should be considered to be "excessive."

One commenter noted that no provision for appeal has been provided for those drivers with impeccable records who, quite inadvertently in many cases, are stopped for operating at 15 m.p.h. or more above the posted speed limit. The respondent suggested that the driver's record be taken into consideration before disqualifying him/her for two serious violations.

Although some of the alternatives offered by respondents may have merit, each one has related enforcement or administrative problems. For example, a standard which would change with posted limits would be confusing to drivers and to enforcement officials. The FHWA agrees with the overwhelming number of respondents who explained that anything other than a practical, straightforward definition would not be effective. To be practical, "excessive speed" needs to be defined in terms that are both easy to understand and practical to administer. Thus, the FHWA has elected to retain the proposed definition of "excessive speed" as any single conviction for any speed of 15 miles per hour or more, above the posted speed limit. This definition is not intended to supplant existing State cumulative point systems which continue to control the licensing privilege under existing administrative procedures. The concerns, therefore, expressed by commenters who believe that there would be no provisions for appeal or that conditions or special zones would no longer be considered will continue to be dealt with existing enforcement of State speeding convictions.

In retaining the proposed definition, the FHWA does not want to give the impression that other single speeding violations or that repeated violations of driving above the posted speed limit should be condoned because they may not be considered to be "excessive" according to the definition. On the contrary, the FHWA believes that all

speeding violations—either driving above the post limit or driving too fast for conditions—pose a potential hazard and should continue to be strictly enforced by the States. While a more stringent, encompassing definition which includes a cap of 75 m.p.h. or a standard based on percentage above posted limits may appear to give more recognition to the greater potential dangers associated with the higher speeds, the FHWA agrees with the majority of respondents that a single definition would be more enforceable than a more intricate definition which incorporates other factors. However, States are free to establish more stringent definitions to address local or particular concerns. The comments submitted by the Owner-Operators Independent Drivers Association of America, Inc. (OOIDA) reflect the concerns expressed by majority of the respondents who objected to a multi-part definition for "excessive speed." The OOIDA wrote: "The Association feels strongly that the CMVSA must be interpreted by the FHWA in a simple and straightforward manner such that drivers are aware of the specific offenses for which they may be disqualified, as well as the penalties to be imposed. OOIDA feels that a situational definition that includes other factors in the definition of "excessive speed" would needlessly confuse the issue among drivers, and create a very cumbersome administrative process. Also, the single license provision of the Act will greatly reinforce the states' authority to assess points for speeding, since drivers can no longer spread convictions over several licenses. The points will add up and the likelihood that a driver who habitually speeds will lose his/her license will be greatly increased. Thus, all CMV drivers will be deterred from speeding, even at levels below the 15 m.p.h. standard. Furthermore, States may apply other charges to address local concerns or special conditions. For example, States apply charges, such as "reckless driving" in cases of speeding at less than 15 m.p.h. above the posted speed limit where weather, traffic, hazardous cargo or other conditions combine to constitute a willful or wanton disregard for safety. Such actions are not prohibited by this rulemaking.

In sum, the FHWA believes that when considered in conjunction with the current State penalty systems, the definition that has been adopted will fully satisfy the Act's goal to promote compliance with the posted speed limits and encourage drivers to use good judgement under all kinds of driving conditions.

Reckless Driving

Regarding the definition of "reckless

driving, section 12019 of the Act states that: "reckless driving shall be as defined under State or local law. To promote uniformity and because a majority of the States are already using the Uniform Vehicle Code and Model Traffic Ordinance (UVCMTO) definition, the FHWA proposed to amend the definition of reckless driving to incorporate the language used in the UVCMTO, 1987 Edition, published by the National Committee on Uniform Traffic Laws and Ordinances. Such language states (in chapter 11, Rules of the Road, at section 11-901—Reckless Driving (a) that "any person who drives any vehicle in willful or wanton disregard for the safety of persons or property is guilty of reckless driving. The FHWA further proposed to amend the definition of "reckless driving" to clarify that it would include two additional traffic offenses, both of which are frequently associated with excessive speeding and/or reckless driving. These two additional offenses were:

1. Improper/erratic lane changes (Incorporating the concepts cited in the UVCMTO section 11-304 through section 11-306 and section 11-309); and
2. Following the vehicle ahead too closely (incorporating the concepts in the UVCMTO section 11-310).

The FHWA asked for comments on whether these two infractions should be listed separately as serious traffic violations instead of being included under "reckless driving. Of the 31 docket respondents who addressed this issue, of whom 12 represented State agencies, 23 (including 10 from State agencies) supported treating these two infractions as serious traffic violations either as part of "reckless driving" or as separate serious violations. However, most respondents stated that the inclusion of the two additional violations in the basic definition of "reckless driving" would overly complicate that definition and the manner in which existing State traffic codes are enforced and handled in the courts.

In opposition, several drivers, motor carriers, and union representatives asserted that the two additional violations should neither be included in the definition of "reckless driving" nor listed separately as serious violations. The Owner-Operators Independent Drivers Association of America contended that the two additional violations are relatively minor traffic infractions in the majority of cases in which they occur. They further claimed that since "following the vehicle ahead too closely" can be the equal fault of both vehicles, it would be unfair for a truck driver to be subject to a severe penalty for an infraction for which he/

she was only partly to blame. The International Brotherhood of Teamsters presented a similar argument for its recommendation against mentioning these additional violations in the rule.

Accident data available to FHWA show that these two violations are commonly attributed to commercial motor vehicle accidents in which human factors or driver error is cited as a causal factor. In a 1988 report entitled "Gearing Up for Safety: Motor Carrier Safety in a Competitive Environment, the Office of Technology Assessment (OTA) lists "following too closely" as a contributor in nearly 10 percent of the heavy truck accidents. The same report identifies "improper lane change" violations as major contributors in more than 13 percent of heavy truck accidents. The "Heavy Truck Safety Study" final report of the National Highway Traffic Safety Administration (NHTSA, 1987), explains that regardless of any improvements made to vehicle characteristics, to the roadways, or to other features of the operating environment to improve safety, the manner in which a vehicle is driven will always play a paramount role in the safe operation of the vehicle. The NHTSA report cites an analysis by the State of Ohio of crashes in which the truck driver was at fault. The analysis identifies "improper lane changes" and "following too closely" as the two most frequent driver errors contributing to the accident. On the basis of available accident data, and in light of the comments to the docket from State agencies which support including these violations because of their potential for causing serious accidents, the FHWA has concluded that "improper/erratic lane changes" and "following too closely" should be treated as serious violations for the purposes of the final rule.

The FHWA shares the concern of some of the respondents that enforcement officials may cite CMV drivers for these offenses when they are the equal fault of both drivers or the fault of noncommercial drivers. However, a CMV driver is not disqualified until he or she is convicted of the offense. The due process embodied in a conviction determination should prevent unfair or unfounded violations from becoming a conviction.

Finally, some of the respondents opposed including "improper/erratic lane changes" and "following too closely" as serious violations because of the resultant penalties. Under § 383.51, a CMV driver who is convicted a second time for a serious violation within a three-year period is disqualified for 60

days; the penalty for a third such violation in a three-year period is a 120 day disqualification. Given the potential importance of these penalties on a driver's employment and livelihood, the FHWA recognizes the possibility that more "improper/erratic lane changes" and "following too closely" traffic violations may be contested, resulting in lost time to drivers and an increased burden on the judicial system. The expected safety benefit, however, is considered countervailing, especially since these two types of violations are major contributors to accidents in which driver error is the causal factor. The penalties related to convictions for these violations are also considered by the FHWA to be appropriate.

In formulating the final definition for "reckless driving," the FHWA agrees with the numerous respondents who asserted that the two additional violations should be listed separately in order to minimize any administrative complications. Therefore, the definition of "reckless driving" in the final rule incorporates the UVCMT0 wording regarding "willful or wanton disregard for the safety of persons or property. The other two items, "improper or erratic lane changes" and "following the vehicle ahead too closely" are included, however, as serious traffic violations. States may apply their existing corresponding violations to deal with situations involving improper/erratic lane changes and following the vehicle ahead too closely.

Lifetime Disqualifications

The FHWA proposed to amend § 383.51(b)(3)(v), to allow States the option of providing an opportunity for sanctioned drivers to apply for a reduction of their lifetime penalty only after they serve a minimum disqualification period of ten years, and only after they successfully complete a requisite rehabilitation program as determined by their State's driver licensing agency. The lifetime disqualification would not be expunged from the driver's record for any reason even after successful rehabilitation and reinstatement, and a third conviction of an offense under § 383.51(b) would lead to permanent disqualification for life. A CMV driver convicted of any felony involving the manufacture, distribution, or dispensing of controlled substances (under § 383.51(b)(2)(v)) will continue to be ineligible to apply for any reduction whatsoever of the lifetime disqualification, hence, permanently disqualified for life.

Most respondents on this issue supported the FHWA's proposal, which is adopted in the final rule. Several

States and the American Association of Motor Vehicle Administrators (AAMVA), however, alerted the FHWA that other concerns related to the content and effectiveness of rehabilitation programs still need to be addressed. Since the States have until October 1, 1993, to begin enforcement of commercial driver qualifications, ample time remains for the States to develop, in concert, appropriate CMV driver rehabilitation programs. FHWA could then consider such State-developed programs in future rules. This approach is consistent with federalism considerations.

Section-by-Section Analysis

Items not discussed in detail in this section-by-section analysis are either highlighted as major issues above, adopted verbatim from the NPRM and discussed in its preamble, or of a nonsubstantive nature (for example, wording changes to conform with other items).

Section 383.1 Purpose and Scope

The wording changes in this section are for conformity with § 383.31, discussed below.

Section 383.5 Definitions

Disqualification. The FHWA has incorporated a definition for "disqualification" in the final rule in response to several requests that FHWA provide further clarification on how to apply the sanctions included in the Act and the implementing regulations. The FHWA agrees with the contention of the AAMVA's Model CDL Law Subcommittee that nothing in the Act or Federal rules prohibits the holder of a CDL, disqualified from driving a commercial motor vehicle, from driving a non-commercial motor vehicle, if he/she is otherwise legally eligible to do so. The FHWA further agrees with the Subcommittee that a CDL holder subject to a disqualification should not be allowed to operate a commercial motor vehicle under any circumstances during that period. The Act does not provide for any type of "limited" driving privilege for someone who is disqualified from operating a commercial motor vehicle.

In developing a definition for "disqualification," the FHWA recognized that procedures differ from State to State, and that the most effective way to impose the disqualification sanctions is to allow States to use their own current systems. States may impose the disqualification through a suspension, revocation, cancellation or any other means a State

determines to be appropriate, as long as the driver's privilege to operate a commercial motor vehicle is withdrawn in conformance with the Act. While the definition also provides for Federal disqualifications by the FHWA, the disqualification of drivers under the provisions of part 383 will be primarily the responsibility of the States through their existing driver's licensing mechanisms.

Employee. The FHWA noted in the NPRM that because the casual, intermittent or occasional type of driver has no "regular employer" per se, the regulations published on June 1, 1987 are unclear as to whom such casual, intermittent or occasional drivers should report their convictions and adverse actions against their driving privileges, as set forth in §§ 383.31 and 393.33. In response, the FHWA proposed to amend the definition of "Employee" to include all casual, intermittent or occasional type drivers, and to specify in § 383.31(b) that notification must be given to the "current" employer.

All the respondents to this issue agreed with FHWA's proposed definition, which has been incorporated in the final rule.

Section 383.31 Notification of Convictions for Driver Violations

The FHWA has made the following technical modifications to this section:

(1) Drivers must notify their licensing State and employer of "convictions" for violations of State or local motor vehicle traffic control laws (other than parking violations). Notification of the "violations" themselves is not required. This clarification, which is in keeping with due process, was endorsed by most commenters on this issue.

(2) The FHWA has replaced the term "State," as used in the June 1, 1987 rule, with the term "State or jurisdiction" in order to include convictions incurred in Canadian provinces and territories and other foreign jurisdictions which the FHWA recognizes, as testing drivers and issuing CDLs in accordance with or under standards similar to the standards of part 383. This change is consistent with the intent of the Act and incorporates concerns of AAMVA and several States that drivers licensed in the United States may fail to report their convictions by foreign jurisdictions to their employers and licensing States. In accordance with the commercial driver licensing reciprocity recently announced by the United States and Canada (at 54 FR 22392, May 23, 1989), the FHWA believes that foreign convictions must be reported in order to allow States to ascertain the driver's qualifications and fully implement the intent of the Act. (A

conforming change has also been made to § 383.33.)

(3) Section 383.31 requires that CDL holders report their convictions irrespective of the type of vehicle in which the violation occurs. This requirement, however, is only explicit in § 383.31(c)(5) which specifies that the notification to the State and employer must state whether the violation was in a commercial motor vehicle. To provide further clarification and eliminate any doubt on the applicability of the notification requirements, FHWA has included language in § 383.31(a) and § 383.31(b) to make it explicit that the notifications apply to "any type of motor vehicle."

The FHWA does not have the authority to impose disqualifications, or to require States to impose disqualifications, on CDL holders who commit criminal or other offenses under § 383.51 in noncommercial vehicles. However, the purpose of requiring drivers to report such convictions in noncommercial vehicles is to provide additional information to States which may wish to consider such convictions in their licensing actions. (Also see discussion of self-reporting below.)

(4) As discussed above under the definition of "employee," notification is to be made to the "current employer." Conforming changes have been made in §§ 383.1 and 383.33. If a driver is not currently employed, he/she must still notify the State of licensure. One respondent from a State motor vehicle department recommended that the rule further clarify that intermittent and occasional drivers need to also notify their permanent employers. Since it is the current employer who is in a position to take immediate action (including the permanent employer), and since the addition of further subtleties to this section will make its enforcement more difficult, the FHWA has not adopted that suggestion.

Several respondent States questioned the need for and efficacy of any self-reporting of convictions by drivers to their licensing States. These States assert that they cannot legally impose sanctions against a driver until they receive formal notification about the conviction. Similar objections were expressed prior to the publication of the June 1, 1987 final rule, "Commercial Driver Licensing Standards: Requirements and Penalties." As noted in that rule, one purpose of requiring driver notification to the State is to alert a State of violations which may ultimately warrant the suspension, revocation, or disqualification of the driver's CDL. At this time, States are not required to impose sanctions based on

the driver's informal notification. When the State-to-State reporting of convictions through the Commercial Driver's License Information System (CDLIS) is fully operational, the FHWA will consider elimination of this requirement.

Section 383.51 Disqualification of Drivers

Period of Disqualification

The FHWA has received several questions asking whether the period of time for which a driver may be disqualified is to begin on the date of the violation or the date of conviction. In the NPRM, the FHWA explained that, because the Act requires that drivers be disqualified when they are "found to have committed" certain offenses, the disqualification period should begin at the time when the driver is convicted of the disqualifying offense.

Several States and the AAMVA pointed out potential problems with the proposal that disqualification begin at the time of conviction. They asserted that, in many instances, the "conviction" is determined by a court or another State agency, and the motor vehicle agency responsible for taking action against the license is not notified of the conviction until sometime later. Others indicated that because of differences in the due process and appeals mechanisms among the various States, setting the disqualification starting point at the "time of conviction" is not manageable.

The FHWA is aware of the varying procedures used by the States in applying sanctions. The FHWA is also aware that under certain circumstances—i.e., when a driver is considered to be dangerous, or when the violation is severe enough—the courts are able to revoke the driver's driving privileges immediately upon conviction. On the other hand, the FHWA appreciates the administrative problems to which the AAMVA refers.

As a compromise between the practical reality adduced by the AAMVA and the expectations of the underlying legislation, the final rule omits the phrase "at the time of such conviction" from § 383.51 (b)(1) and (c)(1), and defers establishment of a time limit on when a State would begin the disqualification of drivers until the forthcoming rulemaking on State compliance under section 12009 of the Act. In the meantime, States should attach at least the same degree of urgency to CDL sanctions as they now do in similar instances. Without precluding States from using their

current penalty systems or from dealing with any due-process issues, the FHWA expects States to begin the disqualification process immediately upon conviction; and if circumstances warrant it, to provide an administrative mechanism whereby the CDL holder's driving privileges can also be taken away immediately upon conviction. In any event, whenever the disqualification period begins for a CDL sanction, States will still need to comply with sections 12009(a) (8) and (9) of the Act which specify that a State convicting a CMV operator of any traffic violation (other than a parking violation) must notify the State of license issuance within 10 days after such conviction; and that disqualifications must be reported to the CDLIS and to the State of license issuance within 10 days from the date of disqualification.

Leaving the Scene of an Accident

Because the driver of a large commercial motor vehicle may be involved in a minor accident of which he/she is genuinely unaware, the FHWA proposed to add "knowingly and willfully" to the disqualifying offense of "leaving the scene of an accident while operating a commercial motor vehicle.

Most respondents, including the States and the AAMVA, considered the addition of the "knowingly and willfully" qualifiers to be unnecessary, and to place a potentially unreasonable burden of proof on the States. Since the issues inherent in the words "knowingly and willfully" would undergo examination during the due process leading to a conviction, the FHWA has elected to eliminate "knowingly and willfully" from the proposed description of "leaving the scene of an accident. Section 383.51(b)(2)(iii) will therefore remain unchanged.

Lifetime Disqualification From Separate Incidents

In the NPRM, the FHWA proposed to clarify that the driver is disqualified for life if he or she is convicted for offenses which arise from two or more separate incidents.

All comments which addressed this issue agreed with this proposal, which is incorporated in § 383.51(b)(3)(iv) and applied by analogy to § 383.51(c)(2) (i) and (ii) dealing with serious traffic violations.

Section 383.73 State Procedure

All States currently have laws which deal with falsification of information on license documents. These laws, however, are not consistent. As part of the NPRM, the FHWA included a requirement that States must impose a

penalty on a CDL applicant who is discovered by the State to have falsified information required for the CDL. The FHWA explained in the NPRM that it believes that a minimum level for such penalties need to be established to ensure similar treatment of CMV operators across the country. Such penalties would also help deter an applicant from attempting to get a second license or a new CDL during the time he/she is disqualified.

All respondents who provided information on this issue endorsed the proposed 60 day penalty. Several respondents indicated, however, that they currently have and will continue to impose stringent penalties, a policy which the FHWA endorses.

Thus, the FHWA has amended § 383.73(g) to provide minimum penalties of at least 60 days for those persons who knowingly falsify or evade submitting required information when applying for any CDL licensing action under §§ 383.71 and 383.73. States may apply the sanction either through a license suspension, revocation, cancellation, or disqualification.

The deadline for imposing the penalty (formerly "30 days after discovering the falsification") has been eliminated because it does not allow for due process and State administrative procedures.

Regulatory Impact

The FHWA has determined that this action does not constitute a major rule under Executive Order 12291. The final rule is not expected to result in an annual effect on the economy of \$100 million or more, or lead to a major increase in costs or prices, or have significant adverse effects on the United States economy. Because of the public interest in the issue of commercial motor vehicle safety and the expected benefits of improved transportation safety, however, this action is considered significant under the regulatory policies and procedures of the DOT. For this reason and pursuant to Executive Order 12498, this rulemaking action has been included on the Regulatory Program for significant rulemaking actions.

The economic impacts of this rulemaking that will occur are primarily mandated by the statutory provisions themselves. For this reason, a full regulatory evaluation is not required. However, since an analysis of impacts, including economic factors, is necessarily involved in the preparation of related motor vehicle safety regulations, a regulatory evaluation has been prepared for this rulemaking action as well as other actions needed to implement the Commercial Motor

Vehicle Safety Act of 1986. This evaluation addresses the provisions contained in this action and has been placed in the public docket and is available for inspection in the Headquarters office of the FHWA, 400 Seventh Street SW Washington, DC 20590.

A significant part of the motor carrier industry and other employers covered by the Act are made up of small firms, from one-person, one-truck operations of some owner-operators, to the thousands of small fleet operators throughout the country. For this reason, the benefit and cost considerations described in the regulatory evaluation/regulatory flexibility analysis as applicable to employers and the motor carrier industry in general, are equally applicable to the small entity component of the industry. Small entities have been represented at public meetings held to discuss the Act and small entities have had the opportunity to submit comments to the public docket established in conjunction with FHWA's August 1, 1986, ANPRM as well as the several other rulemaking notices required by the Act. The FHWA is fully committed to doing all that it can to ensure that no undue burdens are placed on small entities as a result of this action.

For the foregoing reasons and under the criteria of the Regulatory Flexibility Act, the FHWA hereby certifies that this action will not have a significant economic impact on a substantial number of small entities.

Federalism Impact

The FHWA has reviewed these changes to the Commercial Driver Licensing Standards in light of the purposes of the Act and the President's Executive Order on Federalism (Executive Order 12612, October 26, 1987). In enacting the Commercial Motor Vehicle Safety Act of 1986, the Congress found that it is in the public interest to enhance commercial motor vehicle safety. Congress identified commercial motor vehicle safety as a matter of national importance and included requirements for a single license and driver disqualifications as part of the mandates in the Act.

In the Executive Order on Federalism, Executive Departments and agencies were directed to be guided by certain fundamental federalism principles in formulating and implementing policies that have federalism implications. These policies have been taken fully into account in the development of this rule. Thus rule would limit the policy making discretion of the States only in narrow ways, and does so only to achieve the

national purposes of the act. For example, States would continue to have sole discretion as to whether or not to license any CMV operator and what specific procedures, tests, fees or penalty applications are applicable. Thus, it is certified that the policies contained in this document have been assessed in light of the principles, criteria, and requirements of the Federalism Executive Order, and accord fully with the letter and spirit of the President's federalism initiative.

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

Paperwork Reduction Act

The collection of information required by the final rule published on June 1, 1987 to implement the single license and certain reporting and notification requirements has been approved by the Office of Management and Budget (OMB No. 2125-0542). No additional burdens are expected to result from this rulemaking.

List of Subjects in 49 CFR Part 383

Commercial driver's license standards requirements and penalties, Highways and roads, Motor carriers, Motor vehicle safety, Reporting and recordkeeping requirements.

(Catalog of Federal Domestic Assistance Program Number 20.217 motor carrier safety)

Issued on: September 22, 1989.

T.D. Larson,
Administrator.

In consideration of the foregoing, the FHWA hereby proposes to amend title 49, Code of Federal Regulations, subtitle B, chapter III, as set forth below:

PART 383—COMMERCIAL DRIVER'S LICENSE STANDARDS; REQUIREMENTS AND PENALTIES

1. The authority citation for 49 CFR part 383 continues to read as follows:

Authority: Title XII of Pub. L. 99-570, 100 Stat. 3207-170; 49 U.S.C. 3102; 49 U.S.C. App. 2505; and 49 CFR 1.48.

2. Section 383.1(b) (2) and (5) are revised as follows:

§ 383.1 Purpose and scope.

- (b)
(2) Requires a driver to notify the driver's current employer and the

driver's State of domicile of certain convictions;

(5) Establishes periods of disqualification and penalties for those persons convicted of certain criminal and other offenses and serious traffic violations, or subject to any suspensions, revocations, or cancellations of certain driving privileges;

3. Section 383.5 is amended by adding one definition entitled "Disqualification" and by revising four other definitions and placing them in alphabetical order as follows:

§ 383.5 Definitions.

Controlled substance has the meaning such term has under section 102(6), of the Controlled Substances Act (21 U.S.C. 802(6)) and includes all substances listed on schedules I through V of 21 CFR part 1308, as they may be revised from time to time. Schedule I substances are identified in appendix D of this subchapter and schedules II through V are identified in appendix E of this subchapter.

Disqualification means either:

- (a) The suspension, revocation, cancellation, or any other withdrawal by a State of a person's privileges to drive a commercial motor vehicle; or
(b) A determination by the FHWA, under the rules of practice for motor carrier safety contained in part 386 of this title, that a person is no longer qualified to operate a commercial motor vehicle under part 391; or
(c) The loss of qualification which automatically follows conviction of an offense listed in § 383.51.

Driver's license means a license issued by a State or other jurisdiction, to an individual which authorizes the individual to operate a motor vehicle on the highways.

Employee means any operator of a commercial motor vehicle, including full time, regularly employed drivers; casual, intermittent or occasional drivers; leased drivers and independent, owner-operator contractors (while in the course of operating a commercial motor vehicle) who are either directly employed by or under lease to an employer.

Serious traffic violation means conviction, when operating a commercial motor vehicle, of:

(a) Excessive speeding, involving any single offense for any speed of 15 miles per hour or more above the posted speed limit;

(b) Reckless driving, as defined by State or local law or regulation, including but not limited to offenses of driving a commercial motor vehicle in willful or wanton disregard for the safety of persons or property;

(c) Improper or erratic traffic lane changes;

(d) Following the vehicle ahead too closely; or

(e) A violation, arising in connection with a fatal accident, of State or local law relating to motor vehicle traffic control (other than a parking violation). (Serious traffic violations exclude vehicle weight and defect violations.)

4. Section 383.31 is amended by revising paragraphs (a), (b) and (c)(4) as follows:

§ 383.31 Notification of convictions for driver violations.

(a) Each person who operates a commercial motor vehicle, who has a commercial driver's license issued by a State or jurisdiction, and who is convicted of violating, in any type of motor vehicle, a State or local law relating to motor vehicle traffic control (other than a parking violation) in a State or jurisdiction other than the one which issued his/her license, shall notify an official designated by the State or jurisdiction which issued such license, of such conviction. The notification must be made within 30 days after the date that the person has been convicted.

(b) Each person who operates a commercial motor vehicle, who has a commercial driver's license issued by a State or jurisdiction, and who is convicted of violating, in any type of motor vehicle, a State or local law relating to motor vehicle traffic control (other than a parking violation), shall notify his/her current employer of such conviction. The notification must be made within 30 days after the date that the person has been convicted. If the driver is not currently employed, he/she must notify the State or jurisdiction which issued the license according to § 383.31(a).

(c)

(4) The specific criminal or other offense(s), serious traffic violation(s), and other violation(s) of State or local law relating to motor vehicle traffic control, for which the person was convicted and any suspension, revocation, or cancellation of certain

driving privileges which resulted from such conviction(s);

5. Section 383.33 is revised to read as follows:

§ 383.33 Notification of driver's license suspensions.

Each employee who has a driver's license suspended, revoked, or canceled by a State or jurisdiction, who loses the right to operate a commercial motor vehicle in a State or jurisdiction for any period, or who is disqualified from operating a commercial motor vehicle for any period, shall notify his/her current employer of such suspension, revocation, cancellation, lost privilege, or disqualification. The notification must be made before the end of the business day following the day the employee received notice of the suspension, revocation, cancellation, lost privilege, or disqualification.

6. The subpart heading for subpart D is revised to read as follows:

Subpart D—Driver Disqualifications and Penalties

7. Section 383.51 is amended by revising paragraphs (b)(1), (b)(3) (i) through (v), and (c) (1) and (2), to read as follows:

§ 383.51 Disqualification of drivers.

(b)

(1) *General rule.* A driver who is convicted of a disqualifying offense specified in paragraph (b)(2) of this section, is disqualified for the period of time specified in paragraph (b)(3) of this section, if the offense was committed while operating a commercial motor vehicle.

(3)

(i) *First offenders.* A driver who is convicted of an offense described in paragraphs (b)(2)(i) through (b)(2)(iv) of this section, is disqualified for a period of one year provided the vehicle was not transporting hazardous materials

required to be placarded under the Hazardous Materials Transportation Act (49 U.S.C. App. 1801-1813).

(ii) *First offenders transporting hazardous materials.* A driver who is convicted of an offense described in paragraphs (b)(2)(i) through (b)(2)(iv) of this section, is disqualified for a period of three years if the vehicle was transporting hazardous materials required to be placarded under the Hazardous Materials Transportation Act (49 U.S.C. App. 1801-1813).

(iii) *First offenders of controlled substance felonies.* A driver who is convicted of an offense described in paragraph (b)(2)(v) of this section, is disqualified for life.

(iv) *Subsequent Offenders.* A driver who is convicted of an offense described in paragraphs (b)(3)(i) through (b)(2)(iv) of this section, is disqualified for life if the driver had been convicted once before in a separate incident of any offense described in paragraphs (b)(2)(i) through (b)(2)(iv) of this section.

(v) Any driver disqualified for life under § 383.51(b)(3)(iv) of this paragraph, who has both voluntarily enrolled in and successfully completed, an appropriate rehabilitation program which meets the standards of his/her State's driver licensing agency, may apply to the licensing agency for reinstatement of his/her commercial driver's license. Such applicants shall not be eligible for reinstatement from the State unless and until such time as he/she has first served a minimum disqualification period of 10 years and has fully met the licensing State's standards for reinstatement of commercial motor vehicle driving privileges. Should a reinstated driver be subsequently convicted of another disqualifying offense, as specified in paragraphs (b)(2)(i) through (b)(2)(iv) of this section, he/she shall be permanently disqualified for life, and shall be ineligible to again apply for a reduction of the lifetime disqualification.

(c)

(1) *General rule.* A driver who is convicted of serious traffic violations is

disqualified for the period of time specified in paragraph (c)(2) of this section, if the offenses were committed while operating a commercial motor vehicle.

(2) *Duration of disqualification for serious traffic violations—(i) Second violation.* A driver who, during any 3-year period, is convicted of two serious traffic violations in separate incidents, is disqualified for a period of 60 days.

(ii) *Third violation.* A driver who, during any 3-year period, is convicted of three serious traffic violations in separate incidents, is disqualified for a period of 120 days.

8. Section 383.73(g) is revised to read as follows:

§ 383.73 State procedures.

(g) *Penalties for false information.* If a State determines, in its check of an applicant's license status and record prior to issuing a CDL, or at any time after the CDL is issued, that the applicant has falsified information contained in subpart J of this part or any of the certifications required in § 383.71(a), the State shall at a minimum suspend, cancel, or revoke the person's CDL or his/her pending application, or disqualify the person from operating a commercial motor vehicle for a period of at least 60 consecutive days.

PART 391—QUALIFICATIONS OF DRIVERS

9. Section 391.15(c)(2)(iv) is revised to read as follows:

§ 391.15 Disqualification of drivers.

(c)

(2)

(iv) Leaving the scene of an accident while operating a commercial motor vehicle; or

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Part III

Department of Justice

Office of Juvenile Justice and
Delinquency Prevention

Issuance of Program
Announcement, "Nonparticipating State
Initiative"; Notice

DEPARTMENT OF JUSTICE

Office of Juvenile Justice and
Delinquency PreventionIssuance of Program Announcement,
"Nonparticipating State Initiative"

AGENCY: Office of Juvenile Justice and
Delinquency Prevention.

ACTION: Notice of issuance of program
announcement.

SUMMARY: Notice is hereby given that the Office of Juvenile Justice and Delinquency Prevention (OJJDP), pursuant to the provisions of section 223(d) of the Juvenile Justice and Delinquency Prevention Act of 1974, as amended, 42 U.S.C. 5601 *et seq.*, as amended by the Juvenile Justice and Delinquency Prevention Amendments of 1988, subtitle F of title VII of Pub. L. 100-690, November 18, 1988 (hereinafter "Act") is issuing a program announcement and a solicitation for applications from states not participating in the Formula Grants Program established by Part B of the Act. Eligible applicants are limited to local public and private nonprofit agencies in nonparticipating States. Agencies in South Dakota and Wisconsin are currently eligible to receive funds. The amount available in South Dakota is up to \$225,000, in Wisconsin, up to \$838,000. If additional funds become available for other states, a notice will be placed in the **Federal Register** naming the state, the amount of funds available, and the deadline for submission of applications by agencies in that state.

I. Introduction and Background

A. Legislation

Pursuant to section 223(d) of the Act, the OJJDP Administrator must endeavor, under section 222(a) of the Act, to make the Formula Grants fund allotment of a State which chooses not to participate or loses its eligibility to participate in the Formula Grants Program available to local public and private nonprofit agencies within the nonparticipating State. Should a State choose not to participate or lose its eligibility to participate in OJJDP's Formula Grants Program, the OJJDP Administrator, pursuant to section 223(d) of the Act, must endeavor to make that nonparticipating State's formula grants fund allotment available to local public and private nonprofit agencies within the State pursuant to section 222(a) of the Act. The funds may be used only for the purpose(s) of achieving compliance with:

1. Section 223(a)(12)(A), which provides that juveniles shall not be placed in secure detention or correctional facilities if (1) they are charged with or have committed offenses that would not be criminal if committed by an adult, (2) they are charged with or have committed offenses which do not constitute violations of valid court orders, or (3) they are non-offenders such as dependent or neglected children;

2. Section 223(a)(13), which provides that juveniles alleged or found to be delinquent, status offenders, and non-offenders shall not be detained or confined in any institution in which they have regular contact with incarcerated adults convicted of crimes or awaiting trial on criminal charges; and

3. Section 223(a)(14), which provides that no juvenile shall be detained or confined in any jail or lockup for adults except criminal-type juvenile offenders awaiting an initial court appearance pursuant to an enforceable State law requiring such appearance within 24 hours after being taken into custody (excluding weekends and holidays) provided that such exceptions are limited to areas which:

- a. Are outside a Metropolitan Statistical Area,
- b. Have no existing acceptable alternative placements available, and
- c. Provide for the sight and sound separation of juveniles and incarcerated adults.

B. Definition of Terms

1. *Adult jail.* A locked facility administered, by State, county, or local law enforcement and public or private correctional agencies. The purpose of such facility is to detain adults charged with violating criminal law pending trial. Facilities used to hold convicted adult criminal offenders, usually sentenced for less than one year, are also considered adult jails.

2. *Adult lockup.* Similar to an adult jail except that an adult lockup is generally a municipal or police facility of a temporary nature which does not hold persons after they have been formally charged.

3. *Criminal-type offender.* A juvenile offender who has been adjudicated for conduct which would, under the law of the jurisdiction in which the offense was committed, be a crime if committed by an adult.

4. *Accused juvenile offender.* A juvenile on whom a petition has been filed in the juvenile court or other action has occurred alleging that such juvenile is a juvenile offender, (i.e., a criminal-type offender or a status offender), but

no final adjudication has been made by the juvenile court.

5. *Adjudicated juvenile offender.* A juvenile who the juvenile court has determined through an adjudicative procedure is a juvenile offender, (i.e., a criminal-type offender or a status offender).

6. *Facility.* A place, an institution, a building or part thereof, a set of buildings or an area, whether or not enclosing a building or set of buildings, that is used for the lawful custody and treatment of juveniles and that may be owned and/or operated by public and private agencies.

7. *Juvenile offender.* An individual within a juvenile court's jurisdiction for purposes of adjudication and treatment based on age and offense limitations as defined by State law (i.e., a criminal-type offender or a status offender).

8. *Lawful custody.* The exercise of care, supervision and control over a juvenile offender or non-offender pursuant to the provisions of the law, a judicial order or decree.

9. *Local private nonprofit agency.* A private nonprofit agency or organization that provides services within an identifiable unit or a combination of units of general local government, but which is not under public supervision or control. No part of the net earnings of such a private nonprofit agency or organization inures or may lawfully inure to the benefit of any private shareholder or individual. In addition such an agency or organization has been held by the IRS to be tax-exempt under the provisions of section 501(c)(3) of the 1954 Internal Revenue Code.

10. *Local public agency.* Any unit of local government, combination of such units, or any department, agency, or instrumentality of any such unit or combination of such units.

11. *Non-offender.* A juvenile who is subject to the jurisdiction of the juvenile court—usually under abuse, dependency, or neglect statutes—for reasons other than legally prohibited conduct of the juvenile.

12. *Nonparticipating State.* A State which chooses not to submit a plan, fails to submit a plan, or submits a plan which does not meet the requirements of section 223 of the Act and thus is not participating in the Formula Grants Program authorized by part B of the Act for a particular fiscal year; or a State found ineligible to receive funds because of failure to achieve or maintain substantial or full compliance with a mandate of the Act.

13. *Secure.* As used to define a detention or correction facility this term describes residential facilities which

include construction fixtures designed to physically restrict the movements and activities of persons in custody such as locked rooms and buildings, fences, or other physical structures. It does not include facilities where physical restriction of movement or activity is provided solely through facility staff.

14. *Status offender.* A juvenile offender who has been charged with or adjudicated for conduct which would not, under the law of the jurisdiction in which the offense was committed, be a crime if committed by an adult.

15. *Valid Court Order.* The term means a court order given by a juvenile court judge to a juvenile who has been brought before the court and made subject to a court order. The use of the word "valid" permits the incarceration of juveniles for violation of a valid court order only if they received their full due process rights as guaranteed by the Constitution of the United States. The requirements for taking this exception can be found in the Formula Grants Regulation, 28 CFR 31.303(f), published in the *Federal Register* of June 20, 1985.

16. *State Program Coordinator.* The agency/organization selected by OJJDP to implement Stage 1 and 2 of this Initiative.

C. Problem Addressed

Many communities within the boundaries of the nonparticipating States have not been able to implement the mandates of the Act because the State has elected not to participate in the Formula Grants Program, has become ineligible to continue participation in the program, or has elected to withdraw from participation. State or local policies, failure to coordinate, concentrate and redirect existing resources, and/or the limited number of alternative resources available to communities have resulted in an overreliance on the use of jails, lockups and other secure facilities for criminal-type offenders, status offenders and non-offenders.

This over-reliance on secure facilities may be due to a number of problems such as:

1. A lack of coordination and cooperation among juvenile justice system agencies including schools, law enforcement, prosecution, the judiciary, corrections, public and private service providers, and local public interest groups, which contributes to the inappropriate placement of juveniles in jails and lockups.

2. A lack of public awareness and policies regarding the issues of juveniles in jails and lockups and the secure confinement of status offenders and non-offenders.

3. The lack of a flexible network of services and programs that is responsive to the local jurisdiction's needs and capabilities and focused upon jurisdictions with the most difficult barriers to overcome.

4. The lack of alternative services which can be sustained over time with local resources, inclusive but not limited to:

a. Supervision of juveniles in secure facilities that conforms to the requirements set forth in the Formula Grants Regulation, 28 CFR part 31, published in the *Federal Register* of August 8, 1989.

b. Intensive supervision in a child's home as a placement alternative.

c. Emergency foster care, shelter care, group care and independent living arrangements.

d. Crisis intervention services and short-term residential crisis intervention programs that can be used for conflict mediation, emergency holding, and provision of emergency attention for youth with physical or emotional problems.

e. Objective intake criteria that are based upon a presumption of release, utilization of least restrictive alternatives, protection of the right to due process, and maintenance of a child's ties to the family and community.

f. Twenty-four (24) hour intake screening services.

II. Program Goals and Objectives

Pursuant to section 223(d) of the Act, the goal of this program is to assist nonparticipating states in developing a range of alternatives to secure confinement and revising associated policies and procedures and bring them into compliance with section 223(a)(12)(A), the deinstitutionalization of status offenders, section 223(a)(13), the separation of juveniles from adults in adult jails and lockups, and section 223(a)(14), the removal of juveniles from adult jails and lockups. To achieve this goal applicants must address the following objectives:

A. The removal of juveniles from adult jails and lockups through systemwide coordination, cooperation and concentration of existing and new resources to develop community juvenile service systems that provide viable alternatives to the use of adult jails and lockups.

B. The development of a statewide, flexible network of services and placement options for juvenile offenders and non-offenders that will provide such juveniles with supervision and control, give them protection from victimization and exploitation and hold them accountable for their offenses.

C. The development and implementation of objective intake criteria and operational policies and procedures that are consistent with nationally recognized standards and applicable to alleged juvenile offenders and non-offenders who are awaiting court appearance.

D. An enhanced capacity for parents, schools, police and other private and public youth serving agencies to resolve juveniles' problems without the use of jail and lockups. This includes, where appropriate, the coordination and interaction between public and private juvenile services.

E. An increased public awareness of the problems of juveniles in jails and lockups as well as the difficulties of status offenders and non-offenders in secure confinement, resulting in the development of public policies to address such problems.

III. Program Strategy

This program consists of two stages: (1) Assessment and Planning; and (2) Strategy Implementation. A single State Program Coordinator (SPC) will be selected through this program announcement to implement the program in each nonparticipating state. The SPC will develop a statewide strategy and provide funds and assistance to selected communities in developing and implementing comprehensive youth service systems focused on complying with the mandates of the JJDP Act.

An advisory committee that meets, to the degree appropriate, the provisions of section 223(a)(3) will be established for this program to provide comments and recommendations to the SPC regarding the program strategy and activities. At a minimum, a meeting of the advisory committee should be held at the beginning of stages 1 and 2 to brief them on the purpose and activities and determine their role in the program. Where appropriate, consideration should be given to appointing some of the persons who served effectively on the advisory board to each State's prior nonparticipating grantee, if any.

A. Stage 1, Assessment and Planning

The first stage of the program consists of an assessment of detention and incarceration legislation, policy, procedures and practices, and the development of a detailed, statewide, strategy to change these laws, policies, procedures, and/or practices to move the State toward compliance with subsections 223(a)(12)(A), 223(a)(13) and 223(a)(14). The strategy should provide for improving the supervision and

protection of status offenders and non-offenders in a non-secure setting as well as removing juveniles from adult jails and lockups. A major purpose of this stage is to establish a solid foundation of information and use it as the basis for developing a statewide strategy for implementing comprehensive community juvenile services systems.

1. The major activities of stage 1 consist of:

- a. Establishing the advisory committee;
- b. Developing the assessment plan;
- c. Collecting information and data on laws, policies, procedures, practices and programs;
- d. Preparing an assessment report; and

e. Developing an action plan.

2. The major products of stage 1 are:

a. An assessment plan that specifies each step of the first stage.

b. An assessment report that includes:

- (1) Problem statement;
- (2) Review of current legislation, policies, practices and programs pertaining to the detention and jailing of juveniles including alternative services;
- (3) Data on the number and types of jails, lockups, juvenile detention facilities, and correctional facilities in which juveniles are placed;
- (4) Data on the number and types of juveniles in juvenile detention facilities, correctional facilities and adult jails and lockups;

(5) An assessment of the needs of the juveniles involved in the State's juvenile justice system;

(6) Status of the State laws, policies, procedures and practices with regard to the deinstitutionalization of status offenders and non-offenders, the separation of juveniles from adults in adult jails and lockups and the removal of juveniles from jails and lock-ups;

(7) Identification of the needs that must be addressed to develop a statewide strategy for improving detention and incarceration practices and for bringing the State into compliance with the JJDP Act; and

(8) Specification of the State and local public and private resources available to support the implementation of the strategy.

c. A statewide strategy that specifies:

- (1) Who will be involved in implementing the strategy;
- (2) What the major activities will be and how they are related to the problems and needs identified during the assessment process;
- (3) Where in the State the activities will be targeted;
- (4) A schedule of strategy implementation;

(5) How the strategy will be implemented; and

(6) The project budget, including the detailed budget narrative.

B. Stage 2, Strategy Implementation

During stage 2 the strategy developed during stage 1 will be implemented. The SPC will contract with local public agencies and private nonprofit organizations within the State to support specific projects in local jurisdictions. These projects should emphasize the development and implementation of systemwide strategies for coordinating, concentrating and redirecting existing resources to improve services for the care and custody of juveniles and meet the mandates of the JJDP Act. Activities should promote a coordinated statewide effort. If projects were initiated under a previous non-participating State award, the SPC will need to review the projects funded under that award to determine what projects, if any, should be continued. The SPC will provide training and technical assistance to the projects to ensure their performance is consistent with, and enhances, the overall strategy.

1. The major activities of stage 2 consist of:

- a. Preparing an RFP for local projects;
- b. Reviewing applications, selecting finalists and making awards;
- c. Convening project staff and advisory committee members to review strategy;
- d. Providing training and technical assistance to projects supported under the initiative;
- e. Developing and implementing a statewide public education program; and
- f. Developing and implementing an assessment of the effectiveness of the overall program.

2. The major products of stage 2 are:

- a. A Request for Proposals to implement the program strategy developed under Stage 1;
- b. A plan for providing training and technical assistance to local projects and State agencies; and
- c. An assessment report on the effectiveness of the program in meeting its goals and objectives.

IV Dollar Amount and Duration

A. The project period for this program is three years from the date of award. The recipient in each of the nonparticipating States will be eligible for awards of up to the amount of that State's FY 1988 Formula Grant allocation for the initial one-year budget period unless the State has already received its FY 1988 Formula Grant allocation. Any State which has already received its FY 1988 Formula Grant

Award will be eligible for an award of up to the amount of that State's FY 1989 Formula Grant allocation for the initial one-year budget period. The second and third year awards, if made, will each be for an amount not to exceed that State's Formula Grant allocations for the succeeding two fiscal years, respectively. Both the second and third 12-month assistance awards will be subject to the availability of Federal funds; a demonstration of satisfactory completion of identified objectives; satisfactory progress toward compliance with the provisions of sections 223(a)(12)(A), 223(a)(13), and 223(a)(14); and whether the State has or has not announced an intention of becoming a participating State.

Funds will be made available through a cooperative agreement. Financial support for the SPC (planning and administration costs) may not exceed 20% of the total award for the project period. The SPC will contract the remainder of the first-year award to local public and private nonprofit agencies to enable them to implement Stage 2 of the initiative. SPC financial support for the second and third-year awards, if any, will be negotiated with each recipient but should not exceed 20% of the award. Financial assistance provided under this program requires no matching contribution with the exception of construction funds as provided in this announcement.

B. One application will be selected for each of the nonparticipating States pursuant to the selection criteria established in this announcement, and consistent with the OJJDP Competition and Peer Review Policy, 28 CFR part 34, subpart B, published August 2, 1985, at 50 FR 31366-31367. The agency or organization selected as the SPC will not be eligible to receive, beyond the three-year project period, funds allocated pursuant to section 222(a) for purposes related to section 223(d).

C. No more than one-fourth of the funds received by a public or private organization for Stage 2 may be used for construction or renovation purposes. Use of funds for construction is limited to innovative, community-based facilities for less than 20 persons and must be approved in advance by OJJDP. All construction funds must be matched dollar-for-dollar, in cash, by the local jurisdiction. The SPC and the local jurisdiction and/or the private organization will be held accountable for adherence to section 294 of the Act and the requirements for construction programs as contained in the effective edition of the OJP Financial and Administrative Guide for Grants,

M7100.1. The erection of new buildings or the renovation of secure facilities is not permitted with funds acquired through this program.

V Eligibility Criteria

Applications to serve as the SPC are invited from local public and private nonprofit agencies within the nonparticipating States that have knowledge and experience in developing and/or implementing programs and projects on a statewide basis at the local level.

To be eligible for consideration, the applicant must demonstrate in the application that it has experience in the following areas:

A. An understanding of the intent of the statutory mandates of the JJDP Act and the general approaches for implementing the mandates on the local level.

B. Knowledge of and experience with juvenile justice systems; local jails, lockups, and secure juvenile detention facilities; the specific problems, strategies, and program alternatives necessary to achieve the objectives of this program; and strategy development and implementation.

C. Capability to develop management and fiscal systems necessary for the proper administration of Federal funds.

D. Capability to fulfill the activities and responsibilities identified in the Program Strategy Section of this announcement.

E. Capability to work effectively with local and State elected public officials, key decision makers in the juvenile justice system and the boards of public and private youth service providers which exist within the State for the purposes of achieving the objectives of this program.

VI. Program Application Requirements

All applicants must submit a completed Application for Federal Assistance (Standard Form 424), including a program narrative, a detailed budget and a budget narrative. All applications must include the information outlined in this section of the solicitation (subsection VI).

In accordance with Executive Order 12549, 28 CFR 67.510, applicants must provide a certification that they have not been debarred (voluntarily or involuntarily) from the receipt of Federal funds. Form 4662/2, which will be supplied with the application information package, must be submitted with the application.

Applicants for this program must submit a copy of their application to the State Single Point of Contact (SPOC), if one has been established and if the

State has selected this program to be covered in its review process.

Applications must be submitted to the SPOC for review and comment at the same time they are submitted to OJP. Under the regulations, the State process has at least (30) days to comment on noncompeting continuation applications and at least sixty (60) days to comment on all other applications.

Applicants must provide a *Certification Regarding Drug-Free Workplace Requirements* which meets the requirements of the Drug Free Workplace Act of 1988 (Public Law 100-690, title V subtitle D). Form 4061/3, which will be supplied with the application information package, must be submitted with the application.

When submitting applications that contain more than one organization, the relationships among the parties must be set forth in the application. As a general rule, organizations that describe their working relationship as primarily cooperative or collaborative when developing products and delivering services will be considered co-applicants. In the event of a co-applicant submission, one co-applicant must be designated the payee and, as such, will receive and disburse project funds and be responsible for the supervision and coordination of the activities of the other co-applicant. Under this arrangement, each organization would agree to be jointly and severally responsible for all project funds and services. Each co-applicant must sign the SF-424 and indicate their acceptance of the conditions of joint and several responsibility with the other co-applicant.

Applications that include non-competitive contracts for the provision of specific services must include a sole source justification for any procurement in excess of \$25,000.

In addition to the requirements specified in the instructions for preparation of Standard Form 424, the following information must be included in the application:

A. Organizational Capability

Applicants must demonstrate that they are eligible to compete for this cooperative agreement on the basis of eligibility criteria established in this solicitation.

1. Organizational Experience

Applicants must concisely describe their organizational experience with respect to the eligibility criteria specified above. Applicants must demonstrate how their organizational experience and capabilities will enable

them to achieve the goals and objectives of this initiative.

2. Capability of Working with Other Organizations in the State

Applicants must demonstrate that they have discussed this program with local and State elected public officials or their staffs, key decision makers in the juvenile justice system such as juvenile court judges, associations of those involved in juvenile justice, the boards of public and private youth service providers, and other groups whose cooperation or participation is necessary to the success of the program. The applicant must certify that it is able to obtain the necessary cooperation or participation.

3. Financial Capability

In addition to the assurances provided in Part V Assurances (SF-424), applicants must also demonstrate that their organization has or can establish fiscal controls and accounting procedures which assure that Federal funds available under this announcement are disbursed and accounted for properly. Applicants who have not previously received federal funds will be asked to submit a copy of the Office of Justice Programs (OJP) Accounting System and Financial Capability Questionnaire (OJP Form 7120/1).

Copies of the form will be provided in the application kit and must be prepared and submitted along with the application. Other applicants may be requested to submit this form.

All questions are to be answered regardless of instructions (section C.I.B. note). The CPA certification is required only of those applicants who have not previously received Federal funding.

B. Program Goals

A succinct statement of your understanding of the goals and objectives of the program should be included. The application should also include a problem statement to include the following:

1. Discuss your understanding of: (a) The State's placement of juveniles in adult jails and lockups as well as status offenders and non-offenders in secure detention or correctional facilities and the issues surrounding the removal of such juveniles from the facilities, (b) State legislative, judicial and executive branch activities related to supervision and protection of status offenders and non-offenders and jail removal, and (c) programs, community services, organizations and planning approaches which can be used in an effort to

develop comprehensive community services and achieve the Act's mandates.

2. Discuss the anticipated major difficulties and problem areas in the management and implementation of Stage 1 activities, selection of jurisdictions for implementing Stage 2, management of Stage 2 activities, and coordination with OJJDP. This discussion of anticipated problems should also address potential or recommended approaches for their solution.

C. Program Strategy

Applicants should describe the proposed approach for achieving the goals and objectives of the program. A discussion of how each of the activities of both stages of the program will be accomplished and a description of the products to be prepared should be included.

D. Program Implementation Plan

Applicants should prepare a plan that outlines the major activities involved in implementing the program and describes how they will allocate available resources to implement the program and how the program will be managed. The plan must include an annotated organization chart that depicts the roles and responsibilities of the SPC and the public and private organizations that receive funds during Stage 2. The process for identifying, selecting, and awarding funds to these organizations must be described. The policies and procedures for managing the contracts and for monitoring and assessing the effectiveness of the overall program must be described.

E. Time-Task Plan

Applicants must develop a time-task plan for the 12-month project period, clearly identifying major milestones and products. This must include designation of organizational responsibility and a schedule for the completion of the activities and products identified in Section III, Program Strategy.

VII. Procedures and Criteria for Selection

All applications will be evaluated and rated based on the extent to which they meet the following weighted criteria. In general, all applications received will be reviewed in terms of their responsiveness to the program application requirements, organizational capability, the goals, objectives and program strategy described in this announcement, and thoroughness and innovation in responding to strategic issues in project implementation.

Applications will be evaluated by a peer review panel according to the OJJDP Competition and Peer Review Policy, 28 CFR part 34, subpart B, published August 2, 1985, at 50 FR 31366-31367. The selection criteria and their point values (weights) are as follows:

A. The statement of the problem to be addressed by the project is clear, concise and well justified. (5 Points)

B. The objectives of the proposed project are clearly defined. (10 Points)

C. The project design is sound and contains program elements directly linked to the achievement of project objectives. (15 Points)

D. Project Management (35 Points):

1. The project management structure is adequate to the successful conduct of the project. This criterion includes the adequacy and appropriateness of the activities and the project management structure, and the feasibility of the time task plan. (15 Points)

2. Highly qualified staff are identified to manage and implement the program including staff to be hired through contracts. This criterion includes the clarity and appropriateness of position descriptions, required qualifications and selection criteria relative to the specific functions set out in the Implementation Plan and the qualifications of existing staff demonstrated by their resumes. (20 Points)

E. Organizational capability is demonstrated at a level sufficient to successfully support the project. Applicants must evidence the following qualifications and experience: (35 Points)

1. The applicant demonstrates capability and diversified experiences in working with local jurisdictions to develop and implement plans and programs for youth and establishing services and policy changes at the local, regional and statewide level. (15 Points)

2. The applicant demonstrates an ability to establish effective relationships with the juvenile justice system and alternative service providers. (5 Points)

3. The applicant's key staff are experienced in providing diverse populations with technical expertise in substantive topics related to the development and implementation of plans. (5 Points)

4. The applicant demonstrates capability and expertise in maintaining and managing contracts where local agencies or jurisdictions will be implementing various projects, new policies, and different techniques. (10 Points)

F. The budget is complete, appropriate and cost-effective in relationship to the

proposed strategy and tasks to be accomplished. (5 Points)

Applications will be evaluated by a peer review panel. The results of peer review will be a relative aggregate ranking of applications in the form of "Summary of Ratings. These will be based on numerical values assigned by individual peer reviewers. Peer review recommendations, in conjunction with the results of internal review and any necessary supplementary reviews, will assist the Administrator in considering competing applications and in selection of the application for funding. The final award decision will be made by the OJJDP Administrator.

VIII. Submission Requirements

This program announcement is a request for proposals from local public and private nonprofit agencies in those States currently not participating in the JJDP program.

Applicants must submit the original signed application and three copies to OJJDP. The necessary forms for applications will be provided upon request.

Applications must be received by mail or hand delivered to the OJJDP by 5:00 p.m. EST on October 15, 1989. (Or six (6) weeks after the date of publication in the *Federal Register*) Those applications sent by mail should be addressed to: SRAD/OJJDP, United States Department of Justice, 633 Indiana Avenue, NW., Washington, DC 20531. Hand delivered applications must be taken to the SRAD, Room 768, 633 Indiana Avenue, NW., Washington, DC between the hours of 8:00 a.m. and 5:00 p.m. except Saturdays, Sundays or Federal holidays.

The OJJDP will notify applicants in writing of the receipt of their application. Subsequently, applicants will be notified by letter as to the decision made regarding whether or not their submission will be recommended for funding.

IX. Civil Rights Compliance

A. All recipients of OJJDP assistance, including any contractors, must comply with the nondiscrimination requirements of the Juvenile Justice and Delinquency Prevention Act of 1974, as amended; title VI of the Civil Rights Act of 1964; section 504 of the Rehabilitation Act of 1973 as amended; title IX of the Education Amendments of 1972; the Age Discrimination Act of 1975; and the Department of Justice Nondiscrimination Regulations (28 CFR part 42, subparts C, D, E, and G).

B. In the event a Federal or State court or Federal or State administrative agency makes a finding of

discrimination, after a due process hearing, on the grounds of race, color, religion, national origin or sex against a recipient of funds, the recipient will forward a copy of the finding to the Office of Civil Rights Compliance (OCRC) of the Office of Justice Programs.

C. Applicants shall maintain and submit to OJJDP upon request timely, complete and accurate data establishing the fact that no person or persons will be or have been denied or prohibited from participation in, benefits of, or denied or prohibited from obtaining employment in connection with any

program activity funded in whole or in part with funds made available under this program because of their race, national origin, sex, religion, handicap or age. In the case of any program under which a primary recipient of Federal funds extends financial assistance to any other recipient or contracts with any other person(s) or group(s), such other recipient, person(s) or group(s) shall also submit such compliance reports to the primary recipient as may be necessary to enable the primary recipient to assure its civil rights compliance obligations under a grant award.

X. Contact

For further information contact: Eric Peterson, Juvenile Justice Specialist, State Relations and Assistance Division, Office of Juvenile Justice and Delinquency Prevention, 633 Indiana Avenue, NW Washington, DC 20531, (202) 724-5924.

Dated: September 19, 1989.

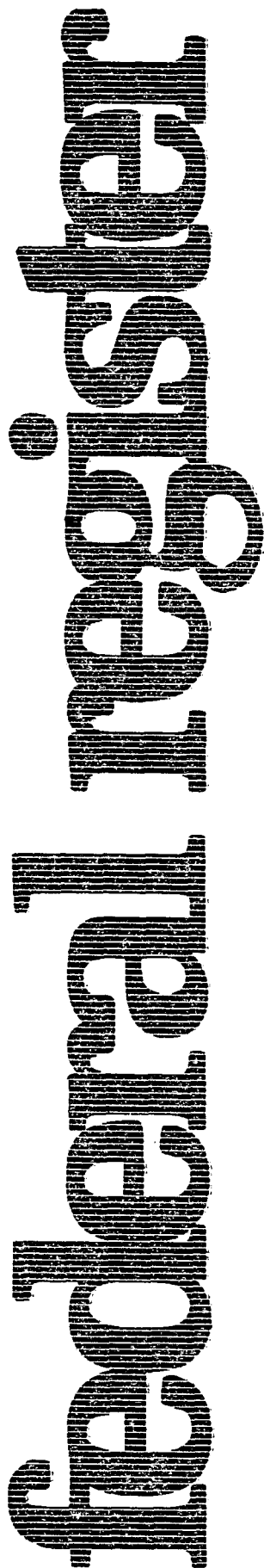
Terrence S. Donahue,

Acting Administrator, Office of Juvenile Justice and Delinquency Prevention.

[FR Doc. 89-23228 Filed 10-2-89; 8:45 am]

BILLING CODE 4410-19-M

Tuesday
October 3, 1989



Part IV

**Environmental
Protection Agency**

40 CFR Part 35
Financial Assistance for the National
Estuary Program; Interim Final Rule

ENVIRONMENTAL PROTECTION AGENCY**40 CFR Part 35**

[FRL-3553-6]

RIN 2040-AB54

Financial Assistance for the National Estuary Program**AGENCY:** Environmental Protection Agency (EPA).**ACTION:** Interim final rule.

SUMMARY: The Environmental Protection Agency (EPA) is promulgating an interim final rule on the award of financial assistance under the Clean Water Act (CWA) for the National Estuary Program (NEP). This rule codifies policies and procedures for financial assistance awarded by EPA to state, interstate, and local agencies and other eligible agencies, institutions, organizations, and individuals for pollution abatement and control programs under the NEP.

DATES: Effective Date: This interim final rule is effective on October 3, 1989. EPA will accept public comments on this rule until November 2, 1989. The docket for this rule and copies of the public comments submitted will be available for public inspection and copying at a reasonable fee at EPA Headquarters Library, Public Information Reference Unit, Room 2904, 401 M Street SW Washington, DC 20460. Telephone (202) 382-5926.

ADDRESSES: Comments may be mailed to Mr. Thomas Armitage, Office of Marine and Estuarine Protection (WH-556F), U.S. Environmental Protection Agency, 401 M Street SW Washington, DC 20460.

FOR FURTHER INFORMATION CONTACT: Mr. Thomas Armitage, (202) 475-7378.

SUPPLEMENTARY INFORMATION:**I. Background**

The Clean Water Act (CWA), as amended by the Water Quality Act of 1987 (WQA), established in section 320 the National Estuary Program (NEP) to promote long-term planning and management in nationally significant estuaries threatened by pollution, development, or overuse. Overall responsibility for the program is given to the U.S. Environmental Protection Agency (EPA). The CWA also authorizes up to \$12 million to be appropriated by Congress in each year through 1991 to support the NEP. For fiscal years 1989 and 1990, CWA section 205(1) directs the Administrator to reserve 0.5 percent of Title II funds appropriated for construction grants for

carrying out the NEP. EPA is today promulgating a regulation outlining the eligibility requirements for receiving funds under the NEP and specifying the general contents of an Annual Work Plan to be prepared by Management Conferences convened by the Administrator under the Act.

1. Description of the National Estuary Program

The NEP is managed by EPA's Office of Marine and Estuarine Protection (OMEP) to identify nationally significant estuaries threatened by pollution, development, or overuse, and to promote the preparation of comprehensive conservation and management plans to ensure the ecological integrity of these estuaries. The program seeks to protect and improve water and sediment quality, and to enhance living resources. To achieve these general goals, the NEP conducts activities to help to:

Establish working partnerships among Federal, State, and local governments

Transfer scientific and management experience and expertise to program participants

Increase public awareness of pollution problems and ensure public participation in consensus building

Promote basinwide planning to control pollution and manage living resources

Oversee development and implementation of pollution abatement and control programs.

The NEP builds on the experience of the Great Lakes and the Chesapeake Bay programs as well as six programs initiated in 1985 and 1986 in Narragansett Bay in Rhode Island, Buzzards Bay in Massachusetts, Long Island Sound in New York and Connecticut, Puget Sound in Washington, San Francisco Bay in California, and Albemarle/Pamlico Sounds in North Carolina. These efforts provide useful models and lessons for the NEP. One lesson is that the success of these programs in identifying and controlling pollution evolved from a phased process: identifying pollution problems, evaluating alternative solutions, and recommending and implementing cost-effective plans to alleviate the problems. Perhaps more importantly, these experiences indicate that collaborative problem solving is crucial to the success of an estuary program. The collaboration process involves all concerned parties in every phase of the program and secures commitments from these parties to carry out recommended actions.

Drawing on the lessons learned from these programs, the NEP focuses on the most significant problems, uses existing and readily available data, emphasizes applied research, provides funding for specifically targeted research, and employs time-tested and cost effective management strategies to meet its Congressionally mandated purposes. These techniques lead to early protection and corrective actions as well as efficient use of allocated resources.

(a) Water Quality Act of 1987

Prior to the enactment of the WQA, EPA made assistance awards for estuary activities based on its broad, general authority contained in section 104(b)(3) of the CWA. In the WQA, Congress provided a specific authorization for the NEP. Section 317(a) of the WQA declared that the increase in coastal population, demands for development, and other direct and indirect uses of the estuaries threaten these unique bodies of water. Section 317(b) of the WQA amended the CWA to add a new section 320. Under section 320(a), the Governor of any state may nominate an estuary located wholly or partly within the state and request that a Management Conference be convened to develop a comprehensive conservation and management plan (CCMP) for the estuary. Such nominations must document the national significance of the estuary, the need for the conference, and its likelihood of success. The nomination must also show that additional control of point and nonpoint sources of pollution is necessary to attain or maintain the water quality required to protect public water supplies; protect and propagate balanced, indigenous populations of shellfish, fish, and wildlife; and allow recreational activities in and on the water.

In response to a Governor's nomination or on his own initiative, the EPA Administrator is to determine whether the attainment or maintenance of a desired level of water quality in an estuary requires additional pollution abatement and control programs to supplement existing controls. The Administrator is authorized under CWA section 320(a)(2)(A) to select such estuaries and to convene Management Conferences to develop CCMPs for managing the estuaries. The conferees are charged with developing plans that balance the conflicting uses in the estuary while restoring or maintaining its natural character.

CWA section 320 also authorizes the appropriation of up to \$12 million per year through fiscal year 1991 to support

the NEP. These funds must be appropriated annually by Congress to support grants or cooperative agreements under section 320(g), monitoring the implementation of a CCMP by the Management Conference or the Administrator, and the administration of management conferences (not to exceed 10 percent of the annual appropriation). These funds assist in developing and conducting the initial three of four phases of an estuary program, as described below.

In addition, other sources of funds have been authorized or appropriated for estuary program activities. Section 205(1) of the CWA reserves funds to support section 320 activities. For convened Management Conferences, EPA currently uses portions of these funds to support Priority Action Demonstration Projects. These projects are designed to test, in part of an estuary, important environmental actions that have implications for the whole estuary. The CWA specifies this fund to be 1/3 of 1.0 percent of the section 207 funds appropriated under title II of the CWA in fiscal years 1987 and 1988, and 1/2 of 1.0 percent of the 207 funds in fiscal years 1989 and 1990.

Grants under section 320(g) using section 320(i) funds or section 205(1) funds can only be used for activities leading to the preparation of CCMPs. Section 320(g) grants cannot be used for implementation.

Funding for implementation activities may be available under CWA title II, title VI, and section 319 to the extent the activities meet the applicable requirements of these provisions.

(b) Matching Funds

Assistance awards under section 320(g) using either section 320(g) or section 205(1) appropriated funds for each estuary program must be matched, in proportion, by non-Federal funds. Consistent with CWA section 320(g)(3), EPA is requiring that 25 percent of the total estuary program cost be provided from non-Federal sources. The Annual Work Plan developed and approved by the Management Conference must make a demonstration showing that non-Federal sources provide at least 25 percent of the aggregate costs of research, surveys, studies, modeling, and other technical work necessary for the development of a CCMP for the estuary. Each assistance application must contain a copy of the Annual Work Plan that demonstrates the 25 percent match requirement is being met.

In many cases, recipients of individual assistance awards may not be required to provide matching funds for their projects because the aggregate

cost share is being provided by a state or a third party. Nevertheless, because such assistance awards are conditioned on compliance with the aggregate cost share requirement, the recipient remains responsible for matching funds if they are not provided as specified in the Annual Work Plan.

(c) Phases of an Estuary Program

Once an estuary has been selected for inclusion in the NEP the Administrator convenes a Management Conference to oversee its activities. The CWA defines seven purposes for the Management Conference:

1. Assess trends in water quality, natural resources, and uses of the estuary.
2. Collect, characterize, and assess data and identify the causes of environmental problems.
3. Evaluate relationships between pollutant loadings and environmental effects.

4. Develop a CCMP

5. Develop plans with states and other agencies to coordinate implementation of the CCMP

6. Monitor the effectiveness of actions taken pursuant to the CCMP

7. Review Federal financial assistance programs and development projects for consistency with the CCMP

To accomplish these purposes, the Management Conference first organizes the management framework for the estuary program—the Planning Initiative in Figure 1. Activities relating to the seven purposes are then divided among the three remaining phases; Characterization, CCMP Development, and CCMP Implementation.

During the Characterization Phase, the Management Conference objectively assesses the state of the estuary and evaluates existing management programs designed to protect the estuary. Characterization is the basis for identifying and selecting the problems to be addressed by the CCMP

In CCMP Development, the Management Conference establishes implementation goals and objectives through a collaborative process and determines desirable and allowable uses for the entire estuary and parts thereof. The goals may range from maintaining present conditions to restoring the estuary to a past condition to maintaining pristine quality. Cost-effective pollution control and resource management strategies, designed to meet each objective, are the core of the CCMP

After carefully evaluating the strategies, the conferees select for implementation those strategies that will produce the greatest environmental

benefit—in the most cost-effective and the most timely manner.

The final phase is Implementation of the CCMP. Strong public support and political commitments are required to accomplish the actions agreed upon in the CCMP. A key objective of the NEP is to help foster the necessary support and commitment for successful State/local implementation.

(d) Planning for Estuary Programs

As provided in § 35.9065, EPA is establishing a three-level process to assist individual estuary programs with planning and oversight of their activities and to manage the funds available to the NEP. The first level of planning is the Five-Year State/EPA Conference Agreement that is developed by each Management Conference shortly after it is convened. This Agreement sets out milestones to be achieved over the term of each program.

Based on this Agreement, OMEP sets budgetary targets for each Management Conference when the budget for the NEP is announced in each fiscal year. These budget targets establish the amount of Federal funds available to the Conference (the NEP contribution) and are used to support activities carried out by each Management Conference in a given year as specified in the Agreement. Given the possibility that required activities may change during the course of the Characterization and CCMP Development phases, Management Conferences may request that OMEP reconsider previously established targets prior to the budget cycle.

The second level of planning culminates in an Annual Work Plan which is developed by the Management Conference using the budgetary targets provided. These Annual Work Plans present progress to date, indicate major program directions necessary to meet previously established milestones, document projects to be undertaken in the upcoming year, and specify funds to be used to support the projects. They also document the way in which 25 percent program match requirements will be met.

At the most detailed level, the third level of planning is a series of individual assistance applications that are prepared by potential recipients and submitted to the Regional Administrator for review. These applications specify in detail the work to be conducted, who will do it, what will be accomplished and how, and the costs and schedule for completion to meet the overall goals for the work on a project-by-project basis. Assistance applications are essentially

the same as other grant applications for EPA funds, but the NEP has certain additional requirements, as addressed below.

(e) Annual Cycles

The first three phases of an estuary program (i.e., Planning Initiative, Characterization and Problem Definition, and CCMP Development) are completed within 5 years.

Implementation may require as much as 20 years before all goals set in the CCMP can be achieved.

Within the major phases of each estuary project, there are annual cycles for program review, assistance applications, and project activity. Although there is some flexibility in the annual cycle, OMEP encourages each Management Conference to adopt a cycle that allows for completing Annual Work Plans and assistance application review within the first quarter (by January 1) of each Federal fiscal year (1 October to 30 September). A typical annual cycle (Figure 2) calls for establishing program targets for total expenditure on each estuary program by October 15, submitting draft Management Conference Annual Work Plans by December 1, and submitting assistance applications by January 1.

However, the annual schedule depends on the date on which OMEP is informed of its annual budget. If Congress does not appropriate funds until after October 1, OMEP will not be able to inform conferences of program targets until at least 2 weeks after it has been informed of its budget. The schedule for such a year will be delayed.

(f) Development and Submission of Annual Work Plans and Assistance

Applications

As specified in § 35.9065(b), the Annual Work Plan for each estuary program must be approved by the Management Conference before individual assistance awards can be made by the Regional Administrator. Annual Work Plans should be prepared within 60 days of the receipt of targets for that year. The Management Conference must submit a draft Annual Work Plan to EPA Headquarters through EPA Regions for review and comment before final ratification by the Management Conference.

Individual assistance applications may be developed at the same time as the Annual Work Plan, but should not be submitted until after the Annual Work Plan is approved by the Management Conference. In FY 1989, and subsequent fiscal years, assistance award decisions will be made by the

Regional Administrator and thus applications should be sent to the appropriate EPA Regional grants office.

In addition to providing for assistance awards by the Regional Administrator to support individual estuary programs, the regulations (§ 35.9070) authorize the Assistant Administrator for Water at EPA Headquarters to approve National Program assistance agreements.

These headquarters awards are limited to projects the results of which have broad applicability to estuaries of national significance and shall be deemed to be consistent with Annual Work Plans and Five-Year State/EPA Conference Agreements approved by individual management conferences. Applications for such projects should be sent to OMEP for consideration.

Each Assistance Application submitted as part of an individual estuary program must be endorsed by the Management Conference before funds are awarded by the Regional Administrator. This requirement ensures that the Management Conference has control over how funds are spent on its estuary. This requirement also allows the Management Conference to direct the effort to be conducted on its behalf, ensuring that each project is consistent with annual goals and objectives of the Management Conference.

(g) Evaluation of Annual Work Plans

Section 35.9065 (b) and (c) of the regulation require the compilation of an Annual Work Plan. This requirement allows each Management Conference to review its current activities in light of its goals and past activities, and encourages direct focus on necessary activities for the upcoming year. The Annual Work Plan should be the result of extensive planning and review by each of the conference committees and should represent a consensus on directions to be taken.

The Management Conference's development of the Annual Work Plan should address the following questions:

Have successes and failures in the program in the previous year been taken into account in planning the activities of the upcoming year?

Is planned work for the upcoming year consistent with the seven purposes of the Management Conference specified in section 320(b) of the CWA?

Is planned work for the upcoming year directed toward meeting negotiated milestones contained in the Five-Year State/EPA Conference Agreement?

Will individual projects undertaken during the upcoming year obtain information necessary to further define problems or develop solutions?

Are the problems to be addressed during the upcoming year significant to the entire estuary?

Is there a demonstration of the 25 percent program cost share?

(h) Evaluation of Assistance Applications

Based on the information presented in each Assistance Application, the Regional Administrator approves or disapproves each application on the following criteria:

Is the work, schedule, and budget consistent with the Annual Work Plan?

Has the proposed work been adequately reviewed by the Management Conference, Conference committees, EPA, and if appropriate, other peer reviewers?

Do the benefits of the proposed effort exceed the costs of obtaining the products?

In the case of cooperative agreements, is there substantial Federal involvement in the project? (Cooperative agreements require some form of substantial Federal involvement.)

Is the organization that would perform the work qualified to do so?

Is the 25 percent non-Federal cost share requirement of CWA section 320(g)(3) being demonstrated?

II. Annual Work Plans

Each year a Management Conference sets realistic goals using the resources available. These goals are enunciated in the Annual Work Plan, designed as a blueprint for their achievement. Such a blueprint is a measuring stick against which to gauge the successes, delays, and failures of program activities and to identify the need, if any, to redirect program efforts. Accordingly, it must include a number of elements, each dealing with a different facet of the designed program. These elements are discussed below.

(a) Introduction

As provided in § 35.9065(c)(1), the Introduction to the Annual Work Plan must identify and discuss the major goals and milestones pursued in the past year and establish the goals and milestones to be achieved in the year to come. Goals are based on the five-year program goals established by the Management Conference. They are comprehensive and broad by design and will dictate the overall scope or primary emphasis of the program for the upcoming year.

An explanation of the key activities undertaken to accomplish these goals also should be included in the Introduction. This narrative should not

discuss the entirety of the projects or tasks performed, but rather should relate how attainment of goals was furthered. It should state whether the goals pursued were achieved, and if not, it should discuss any important information obtained from the endeavor.

Information acquired from pursuit of past goals may cause modification of existing goals or redistribution of program resources and efforts. It is expected that the Management Conference will take a flexible approach to drafting and implementing the Annual Work Plan. Goals and milestones will be established at the beginning of the year, but as activities make more definitive technical information available, these goals and milestones may be updated. This re-evaluation and re-orientation can be conducted informally during each year, but is formally documented in the upcoming year's Annual work Plan.

(b) Fund Sources

As provided in § 35.9065(c)(2), before the Annual Work Plan can be adopted by the Management Conference, the kinds and amounts of funds to be used in the upcoming year must be documented. These funds may come from a variety of sources and take a variety of forms. Mostly, the funds will come from Federal and State government sources, but will be augmented with funds from private or local government organizations.

Fund sources must be summarized in a table showing the source of funds to be used during the upcoming year (e.g., EPA, state matching funds, state in-kind services, or private donations), the amount of funds committed during the upcoming year, and the specific type of award or fund within each source during the upcoming year (e.g., Clean Water Act section 320, state appropriation, the type of state in-kind contribution, and other private sources of funds). The table must include, at a minimum, four types of sources:

- CWA section 320(g) funds
- CWA section 205(1) funds
- Matching funds (from non-Federal sources)
- Matching in-kind contributions (from non-Federal sources).

The table must also quantify the total amount of funds, by source, to be devoted to the NEP. Figure 3 is an example of the Fund Sources Table.

When a Management Conference uses in-kind contributions or services as part of its matching share, it must eventually provide an accounting of the sources of funds for those contributions. The CWA requires that matching funds come from non-Federal sources. Thus, details of appropriations, gifts, or non-Federal

grants that support these projects must be specifically identified in the Annual Work Plan.

(c) Projects

In addition to information on the amount of funding and its source(s), consistent with §§ 35.9065(c)(2) and 35.9065(c)(3), an acceptable Annual Work Plan contains information on how funds have been spent in the past year and how the Management Conference plans to spend funds in the upcoming year.

The discussion should be project-specific—a three- or four-sentence discussion of the activities of each project to be undertaken during the upcoming year in relation to the seven purposes of the Management Conference. The narrative description explains the relationship between the product for each project and the Management Conference purpose being served and outlines the activities being conducted as part of the project. For example, phrases such as "field collection of data to identify the cause of algal blooms" tell the reader the nature of the activity and likely products, and relate directly to the Management Conference purpose of identifying causes of environmental problems. The rest of the narrative can describe project status and any problems or results that have been reported. A table summarizing tasks will include the following items:

- Project or task name;
- Products delivered or to be produced;
- Schedule for (or date of) completion;
- Total projected (or actual) cost;
- Source of funds;
- Responsible organization.

A sample format is shown in Figure 4.

III. Assistance Agreement Applications

Before EPA will allocate Federal grant funds for any estuary program, the organization or agency requesting the funds must submit the appropriate completed application forms.

In accordance with § 35.9065, the application must have been approved by the Management Conference and be consistent with the Annual Work Plans. In addition, projects must comply with applicable administrative requirements contained in the 40 CFR parts 29, 30, 31, 32, 33, and 40 as well as other applicable Federal laws such as the Coastal Zone Management Act (CZMA). In implementing these requirements, OMEP policy specifies that projects must have a combined work/quality assurance project plan and Office of Research and Development (ORD) concurrence.

IV Effective Date

This regulation is effective immediately. The only purpose of this rule is to codify policies and procedures for financial assistance awarded by EPA under the NEP. Accordingly, this is a grants-related rule and the Administrative Procedure Act, 5 U.S.C. 553(a), does not require that it be published, in proposed form, prior to promulgation.

V Executive Order 12291

Under Executive Order 12291, EPA must judge whether a new regulation is "major" and therefore subject to the requirement of a Regulatory Impact Analysis. These amendments do not satisfy any of the criteria the Executive Order specifies for a major rulemaking. Therefore, this is not subject to a Regulatory Impact Analysis.

This regulation was submitted to the Office of Management and Budget (OMB) for review as required by Executive Order 12291. Any comments from OMB and EPA response to those comments are available for public inspection at the EPA Public Information Reference Unit, Room 2904, U.S. Environmental Protection Agency, 401 M Street SW Washington, DC 20460.

VI. Paperwork Reduction Act

The information collection requirements contained in this interim final rule have been submitted for approval to the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1980, 44 U.S.C. 3501 *et seq.* An Information Collection Request document has been prepared by EPA (ICR No. 1500) and a copy may be obtained from Harold Woodley, Information Policy Branch; EPA 401 M Street SW (PM-223); Washington, DC 20460 or by calling (202) 382-2738. This ICR covers the information collection requirements in both the Financial Assistance for the National Estuary Program Regulation and the Guidance on the Contents of the Governor's nomination.

Public reporting burden for this collection of information is estimated to average 1500 hours for each of the governor's nominations under the Guidance and 250 hours for each of the annual work plans under the Regulation.

Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to chief, Information Policy Branch, PM-223, U.S. Environmental Protection Agency, 401 M Street SW Washington, DC 20460; and to the Office of Information and Regulatory Affairs,

Office of Management and Budget,
Washington, DC 20503, marked
"attention: Desk Officer for EPA. The
final rule will respond to any OMB or
public comments on the information
collection requirements contained in this
interim final rule.

VII. Regulatory Flexibility Act

EPA did not develop a Regulatory
Flexibility Analysis for this regulation
because grant regulations are not
subject to the analytical requirements of
sections 603 and 604 of the Regulatory
Flexibility Act.

Dated: September 22, 1989.
William K. Reilly,
Administrator.

List of Subjects in 40 CFR Part 35

State and local assistance.

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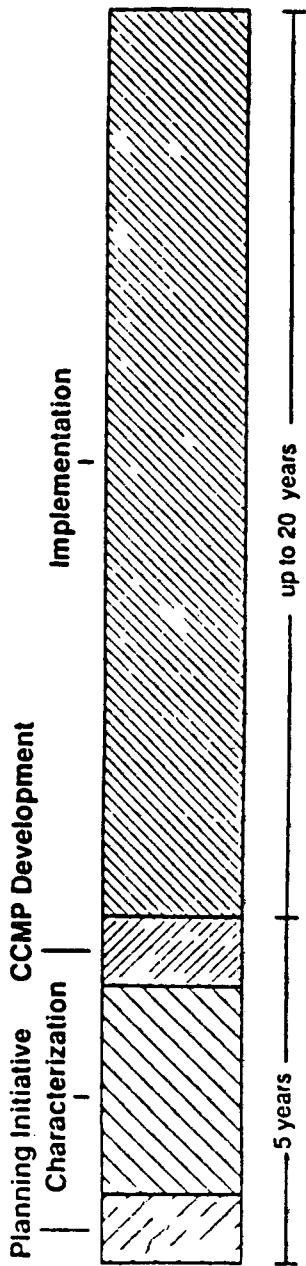


Figure 1 Phases of a Typical Estuary Project

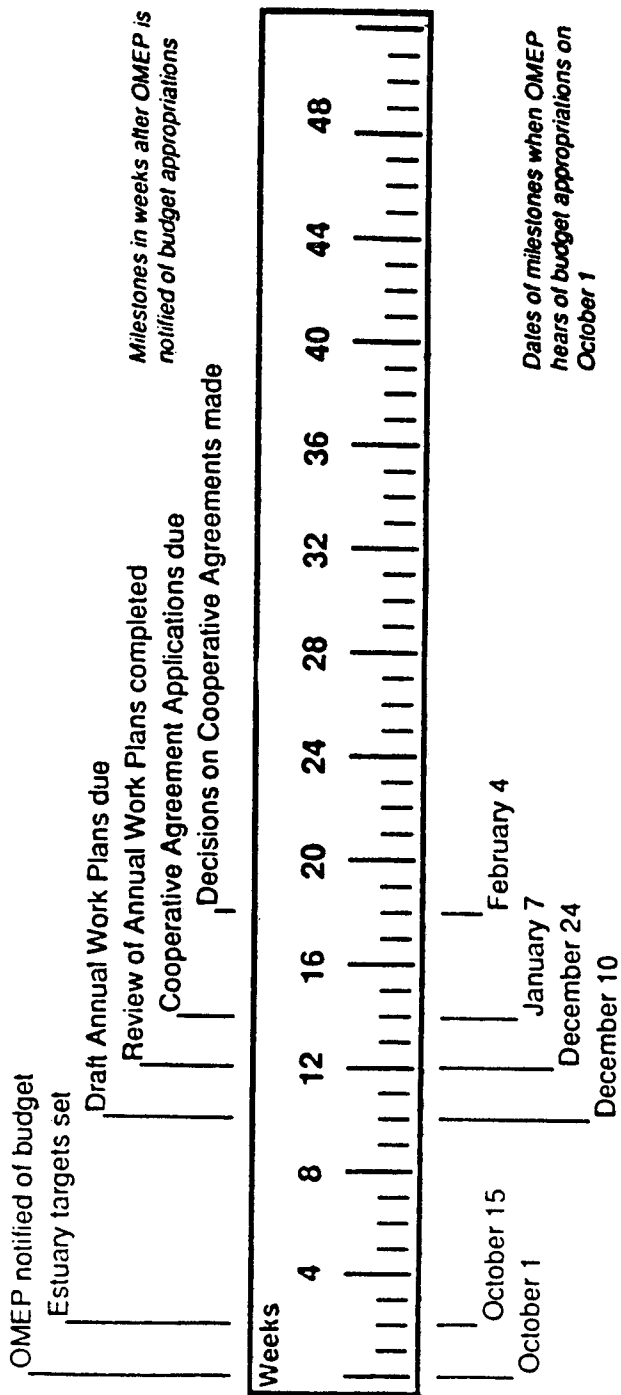


Figure 2 Cycle of Submission and Review of Annual Work Plans and Cooperative Assistance Application

Figure 3. Sample Table of Fund Sources
FUNDING TABLE, FISCAL YEAR 1989

Source of funds	Amount	Type of award
EPA.....	\$400,000	CWA Sect. 320.
State Matching Funds.	125,000	State Appropriation.
State Services in Kind.	62,000	Monitoring Program.

FUNDING TABLE, FISCAL YEAR 1989—
Continued

Source of funds	Amount	Type of award
Private Donations....	38,000	Contributions (Save the Bay Project).
Total funding....	625,000	

FUNDING TABLE, FISCAL YEAR 1989—
Continued

Source of funds	Amount	Type of award
EPA Share=\$400,000/\$625,000=64%		
Rec. Share=\$235,000/\$625,000=36%		

Figure 4. Sample Table of Project Status
PROJECT STATUS TABLE FISCAL YEAR 1989

Project name	Management conference purpose	Products delivered/ projected	Date of delivery	Cost	Source of funds	Responsible organization	Percent nonfederal share (percent)
Waste load allocation study.	1, 2.....	Study report.....	10/1/93	\$180,000	EPA.....	State Water Quality Management Office.	0
NPDES compliance report...	1, 2, and 3.....	Summary of compliance by each permitted facility.	6/30/89	10,000	State Appropriation 275.27(q).	State NPDES Program Office.	25
NPS study recommendations.	2, 3, and 4.....	Recommended NPS controls.	10/1/93	30,000 60,000	EPA State Appropriation 275.27(q).	State Water Resources Board.	100

Management conference purpose numbers refer to the seven purposes of a management conference set forth in section 320 of the Clean Water Act. This column provides an indication of the purposes(s) served by each project.

For the reasons set out in the preamble, title 40, chapter I, subchapter B, part 35 of the Code of Federal Regulations, is amended as follows:

PART 35—[AMENDED]

1. Part 35 is amended by adding an authority citation for subpart P to read as follows:

Authority: Sec. 320 of the Clean Water Act, as amended (33 U.S.C. 1330).

2. Subpart P is added to part 35 to read as follows:

Subpart P—Financial Assistance for the National Estuary Program

- Sec.
- 35.9000 Applicability.
- 35.9005 Purpose.
- 35.9010 Definitions.
- 35.9015 Summary of annual process.
- 35.9020 Planning targets.
- 35.9030 Work program.
- 35.9035 Budget period.
- 35.9040 Application for assistance.
- 35.9045 EPA action on application.
- 35.9050 Assistance amount.
- 35.9055 Evaluation of recipient performance.
- 35.9060 Maximum Federal share.
- 35.9065 Limitations.
- 35.9070 National program assistance agreements.

Subpart P—Financial Assistance for the National Estuary Program

§ 35.9000 Applicability.

This subpart codifies policies and

procedures for financial assistance awarded by the EPA to state, interstate, and regional water pollution control agencies and entities and other eligible agencies, institutions, organizations, and individuals for pollution abatement and control programs under the National Estuary Program (NEP). These provisions supplement the EPA general assistance regulations in 40 CFR parts 30 and 31.

§ 35.9005 Purpose.

Section 320(g) of the Clean Water Act (CWA) authorizes assistance to eligible states, agencies, entities, institutions, organizations, and individuals for developing a comprehensive conservation and management plan (CCMP) for an estuary.

§ 35.9010 Definitions.

Aggregate Costs. The total cost of all research, surveys, studies, modeling, and other technical work completed by a Management Conference during a fiscal year to develop a Comprehensive Conservation and Management Plan for the estuary.

Annual Work Plan. The plan, developed by the Management Conference each year, which documents projects to be undertaken during the upcoming year. The Annual Work Plan is developed within budgetary targets provided by EPA.

Five-Year State/EPA Conference Agreement. Agreement negotiated among the States represented in a

Management Conference and the EPA shortly after the Management Conference is convened. The agreement identifies milestones to be achieved during the term of the Management Conference.

Management Conference. A Management Conference convened by the Administrator under Section 320 of the CWA for an estuary in the NEP

National Program Assistance Agreements. Assistance Agreements approved by the EPA Assistant Administrator for Water for work undertaken to accomplish broad NEP goals and objectives.

Work Program. The Scope of Work of an assistance application, which identifies how and when the applicant will use funds to produce specific outputs.

§ 35.9015 Summary of annual process.

(a) EPA considers various factors to allocate among the Management Conferences the funds requested in the President's budget for the NEP. Each year, the Director of the Office of Marine and Estuarine Protection issues budgetary targets for the NEP for each Management Conference. These targets are based upon negotiated Five-Year State/EPA Conference Agreements.

(b) Using the budgetary targets provided by EPA, each Management Conference develops Annual Work Plans describing the work to be completed during the year and identifies individual projects to be funded for the

completion of such work. Each applicant having a scope of work approved by the Management Conference completes a standard EPA application, including a proposed work program. After the applicant submits an application, the Regional Administrator reviews it and, if it meets applicable requirements, approves the application and agrees to make an award when funds are available. The Regional Administrator awards assistance from funds appropriated by Congress for that purpose.

(c) The recipient conducts activities according to the approved application and assistance award. The Regional Administrator evaluates recipient performance to ensure compliance with all conditions of the assistance award.

(d) The Regional Administrator may use funds not awarded to an applicant to supplement awards to other recipients who submit a score of work approved by the management conference for NEP funds.

(e) The EPA Assistant Administrator for Water may approve National Program awards as provided in § 35.9070.

§ 35.9020 Planning targets.

The EPA Assistant Administrator for Water develops planning targets each year to help each Management Conference develop an Annual Work Plan. These targets are broad budgetary goals for total expenditures by each estuary program and are directly related to the activities that are to be carried out by each Management Conference in that year as specified in the Five-Year State/EPA Conference Agreement. The planning targets also are based on the Director's evaluation of the ability of each Management Conference to use appropriated funds effectively.

§ 35.9030 Work program.

The work program is part of the application for financial assistance and becomes part of the award document. It is part of the basis for an award decision and the basis for management and evaluation of performance under an assistance award. The work program must specify the level of effort and amount and source of funding estimated to be needed for each identified activity, the outputs committed for each activity, and the schedule for delivery of outputs.

§ 35.9035 Budget period.

An applicant may choose its budget period in consultation with and subject to the approval of the Regional Administrator.

§ 35.9040 Application for assistance.

Each applicant should submit a complete application at least 60 days before the beginning of the budget period. In addition to meeting applicable requirements contained in 40 CFR part 30 or 31, a complete application must contain a discussion of performance to date under an existing award, the proposed work program, and a list of all applicable EPA-approved State strategies and program plans, with a statement certifying that the proposed work program is consistent with these elements. The annual workplan developed and approved by the management conference each fiscal year must demonstrate that non-Federal sources provide at least 25 percent of the aggregate costs of research, surveys, studies, modeling, and other technical work necessary for the development of a CCMP for the estuary. Each application must contain a copy of the Annual Work Plan as specified in § 35.9065(c) (2) and (3) for the current Federal fiscal year. The funding table in the workplan must demonstrate that the 25 percent match requirements is being met, and the workplan table of project status must show the sources of funds supporting each project.

§ 35.9045 EPA action on application.

The Regional Administrator will review each completed application and should approve, conditionally approve, or disapprove the application within 60 days of receipt. When funds are available, the Regional Administrator will award assistance based on an approved or conditionally approved application. For a continuation award made after the beginning of the approved budget period, EPA will reimburse the applicant for allowable costs incurred from the beginning of the budget period, provided that such costs are contained in the approved application and that the application was submitted before the expiration of the prior budget period.

(a) *Approval.* The Regional Administrator will approve the application only if it satisfies the requirements of CWA section 320; the terms, conditions, and limitations of this subpart; and the applicable provisions of 40 CFR parts 30, 31, and other EPA assistance regulations. The Regional Administrator must also determine that the proposed outputs are consistent with EPA guidance or otherwise demonstrated to be necessary and appropriate; and that achievement of the proposed outputs is feasible, considering the applicant's past performance, program authority, organization, resources, and procedures.

(b) *Conditional approval.* The Regional Administrator may conditionally approve the application after consulting with the applicant if only minor changes are required. The award will include the conditions the applicant must meet to secure final approval and the date by which those conditions must be met.

(c) *Disapproval.* If the application cannot be approved or conditionally approved, the Regional Administrator will negotiate with the applicant to change the output commitments, reduce the assistance amount, or make any other changes necessary for approval. If negotiation fails, the Regional Administrator will disapprove the application in writing.

§ 35.9050 Assistance amount.

(a) *Determining the assistance amount.* In determining the amount of assistance to an applicant, the Regional Administrator will consider the Management Conference planning target, the extent to which the applicant's Work Program is consistent with EPA guidance, and the anticipated cost of the applicant's program relative to the proposed outputs.

(b) Reduction of assistance amount. If the Regional Administrator determines that the proposed outputs do not justify the level of funding requested, he will reduce the assistance amount. If the evaluation indicates that the proposed outputs are not consistent with the priorities contained in EPA guidance, the Regional Administrator may reduce the assistance amount.

§ 35.9055 Evaluation of recipient performance.

The Regional Administrator will oversee each recipient's performance under an assistance agreement. In consultation with the applicant, the Regional Administrator will develop a process for evaluating the recipient's performance. The Regional Administrator will include the schedule for evaluation in the assistance agreement and will evaluate recipient performance and progress toward completing the outputs in the approved work program according to the schedule. The Regional Administrator will provide the evaluation findings to the recipient and will include these findings in the official assistance file. If the evaluation reveals that the recipient is not achieving one or more of the conditions of the assistance agreement, the Regional Administrator will attempt to resolve the situation through negotiation. If agreement is not reached, the Regional Administrator may impose

sanctions under the applicable provisions of 40 CFR part 30 or 31.

§ 35.9060 Maximum federal share.

The Regional Administrator may provide up to 100 percent of the approved work program costs for a particular application provided that non-Federal sources provide at least 25 percent of the aggregate costs of research, surveys, studies, modeling, and other technical work necessary for the development of a comprehensive conservation and management plan for the estuary as specified in the estuary Annual Work Plan for each fiscal year.

§ 35.9065 Limitations.

(a) *Management conferences.* The Regional Administrator will not award funds pursuant to CWA section 320(g) to any applicant unless and until the scope of work and overall budget have been approved by the Management Conference of the estuary for which the work is proposed.

(b) *Consistency with work plans.* The Regional Administrator will not award funds pursuant to section CWA 320(g) to any applicant whose application is not consistent with work plan elements in an approved Annual Work Plan and an

approved Five-Year State/EPA Conference Agreement by the Management Conference of the estuary for which the work is proposed.

(c) *Elements of annual work plans.* Annual Work Plans to be prepared by estuary Management Conferences must be reviewed by the Office of Marine and Estuarine Protection before final ratification by the Management Conference and must include the following elements:

(1) *Introduction*—A discussion of achievements in the estuary, a summary of activities undertaken in the past year to further each of the seven purposes of a Management Conference specified in section 320(b) of the CWA, the major emphases for activity in the upcoming year, and a schedule of milestones to be reached during the year.

(2) *Funding sources*—A table of fund sources for activities in the new year, including a description of the sources and types (e.g., in-kind contributions to be performed by the applicant) of funds comprising the contribution by applicants or third parties, and the source and type of any other non-Federal funds or contributions.

(3) *Projects*—A description of each project to be undertaken, a summary

table of project status listing all activities, the responsible organization or individual, the products expected from each project, approximate schedules, budgets, and the source and type of the non-Federal 25 percent minimum cost share of the aggregate costs of research, surveys, studies, modeling, and other technical work necessary for the development of a comprehensive conservation and management plan for an estuary.

§ 35.9070 National program assistance agreements.

The Assistant Administrator for Water may approve the award of NEP funds for work that has broad applicability to estuaries of national significance. These awards shall be deemed to be consistent with Annual Work Plans and Five-Year State/EPA Conference Agreements approved by individual management conferences. The amount of a national program award shall not exceed 75 percent of the approved work program costs provided the non-Federal share of such costs is provided from non-Federal sources.

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Tuesday
October 3, 1989

**FRIDAY
OCTOBER 6, 1989
PART I
DEPARTMENT OF
HEALTH AND HUMAN
SERVICES
FOOD AND DRUG
ADMINISTRATION**

Part V

**Department of
Health and Human
Services**

Food and Drug Administration

21 CFR Parts 347 and 348

**Skin Protectant and External Analgesic
Drug Products for Over-the-Counter
Human Use; Proposed Rulemaking for
Poison Ivy, Poison Oak, Poison Sumac,
and Insect Bites Drug Products**

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 347

[Docket No. 78N-021P]

RIN 0905-AA06

Skin Protectant Drug Products for Over-the-Counter Human Use; Proposed Rulemaking for Poison Ivy, Poison Oak, Poison Sumac, and Insect Bites Drug Products

AGENCY: Food and Drug Administration.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Food and Drug Administration (FDA) is issuing a notice of proposed rulemaking amending the tentative final monograph (proposed rule) for over-the-counter (OTC) skin protectant drug products. The proposed rulemaking would establish conditions under which OTC skin protectant drug products for the treatment and/or prevention of poison ivy, poison oak, and poison sumac as well as for the treatment and/or neutralization of insect bites are generally recognized as safe and effective and not misbranded. FDA is issuing this notice of proposed rulemaking after considering the statements on OTC drug products for poison ivy, poison oak, and poison sumac, and for use as insect bite neutralizers of the Advisory Review Panel on OTC Miscellaneous External Drug Products, public comments on an advance notice of proposed rulemaking that was based on those statements, and public comments on the notice of proposed rulemaking for OTC skin protectant drug products. (See the *Federal Register* of February 15, 1983; 48 FR 6820.) The agency's proposals concerning the use of other OTC drug products for treating the symptoms of poison ivy, poison oak, poison sumac, and insect bites are being published elsewhere in this issue of the *Federal Register*. These proposals are part of the ongoing review of OTC drug products conducted by FDA.

DATES: Written comments, objections, or requests for oral hearing on the proposed rulemaking before the Commissioner of Food and Drugs by January 31, 1990. The agency is allowing a period of 120 days for comments and objections instead of the normal 60 days for the following reasons: (1) The concurrent publication of two rulemakings regarding OTC drug products for poison ivy, poison oak, poison sumac, and insect bites and (2) this document contains the first

published evaluation of several submissions of data on OTC drug products for the treatment and/or prevention of these conditions that were made to, but not reviewed by, the Advisory Review Panel on OTC Miscellaneous External Drug Products (Miscellaneous External Panel). New data by October 3, 1990. Comments on the new data by December 3, 1990. Written comments on the agency's economic impact determination by January 31, 1990.

ADDRESS: Written comments, objections, new data, or requests for oral hearing to the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857

FOR FURTHER INFORMATION CONTACT: William E. Gilbertson, Center for Drug Evaluation and Research (HFD-210), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857 301-295-8000.

SUPPLEMENTARY INFORMATION: In the *Federal Register* of September 7 1982, FDA published, under § 330.10(a)(6) (21 CFR 330.10(a)(6)), advance notices of proposed rulemaking and reopened the administrative records for OTC external analgesic drug products (47 FR 39412) and skin protectant drug products (47 FR 39436). The notices were published to allow for consideration of statements on OTC drug products for the prevention of poison ivy, poison oak, poison sumac, and for use as insect bite neutralizers. The statements were prepared by the Miscellaneous External Panel, which was the advisory review panel responsible for evaluating data on the active ingredients used for these conditions. Interested persons were invited to submit comments by December 6, 1982. Reply comments in response to comments filed in the initial comment period could be submitted by January 5, 1983.

In the *Federal Register* of December 28, 1982 (47 FR 57738), in response to a request for an extension of time, the comment period and reply comment period for OTC skin protectant drug products were extended to February 4, 1983, and to March 7 1983, respectively.

In accordance with § 330.10(a)(10), the data and information considered by the Panel were put on public display in the Dockets Management Branch (address above), after deletion of a small amount of trade secret information.

One trade association and five drug manufacturers submitted comments concerning the use of skin protectant drug products for poison ivy, poison oak, poison sumac, and insect bites (poison ivy-oak-sumac and insect bites). Some

of these comments were submitted to both the external analgesic and skin protectant rulemakings. In those cases where the same comments were submitted to both rulemakings, the comments will be addressed only in the appropriate amendment to either the proposed rule for OTC skin protectant drug products or for OTC external analgesic drug products published elsewhere in this issue of the *Federal Register*. Copies of the comments received are on public display in the Dockets Management Branch.

The Panel provided general statements on OTC drug products for the prevention of poison ivy, poison oak, poison sumac, and for use as insect bite neutralizers. However, the Panel did not review all of the submitted individual ingredients nor develop labeling for drug products for these indications. Also, the Panel reviewed only ingredients with labeling claims for prevention of poison ivy, poison oak, or poison sumac, or for treatment of insect bites by neutralization or inactivation of insect venom. However, many submissions to the Panel were for drug products used to treat the symptoms (i.e., itching, minor irritations) of poison ivy-oak-sumac and insect bites by the mechanism of providing a physical or mechanical barrier to protect the exposed skin surfaces from harmful or annoying stimuli. Additionally, a number of skin protectant drug products labeled for the treatment and/or prevention of poison ivy, poison oak, poison sumac and for the treatment and/or neutralization of insect bites were not submitted to the Miscellaneous External Panel. Therefore, the agency is expanding the scope of this segment of the skin protectant rulemaking to include all OTC skin protectant drug products labeled for any of these uses.

In this document, the agency is addressing comments concerning drug products for the treatment and/or prevention of poison ivy, poison oak, and poison sumac and for the treatment and/or neutralization of insect bites when the mechanism of action for these uses involves the ingredient's ability to neutralize or inactivate insect venom or the ingredient's ability to provide a mechanical barrier to protect exposed skin surfaces from harmful or annoying stimuli. In the external analgesic rulemaking (published elsewhere in this issue of the *Federal Register*), the agency is addressing claims for the treatment of symptoms of poison ivy-oak-sumac and insect bites when the mechanism of action for these claims involves the depression or stimulation of cutaneous sensory receptors.

In the *Federal Register* of February 15, 1983 (48 FR 6820), the agency published a tentative final monograph (proposed rule) for OTC skin protectant drug products. The agency issued this notice after considering the report and recommendations of the Advisory Review Panel on OTC Topical Analgesic, Antirheumatic, Otic, Burn, and Sunburn Prevention and Treatment Drug Products (Topical Analgesic Panel) and public comments on an advance notice of proposed rulemaking that was based on those recommendations.

Interested persons were invited to submit comments by April 18, 1983, new data by February 15, 1984, and comments on new data by April 16, 1984. In response to that notice, one manufacturer's association and five drug manufacturers submitted comments concerning the use of skin protectant ingredients for the treatment and/or prevention of poison ivy, poison oak, and poison sumac as well as for the treatment and/or neutralization of insect bites. The agency is also addressing these comments in this notice of proposed rulemaking. Copies of the comments received are on public display in the Dockets Management Branch (address above).

In this notice of proposed rulemaking, FDA responds to public comment and further discusses its position on OTC skin protectant drug products for the treatment and/or prevention of poison ivy, poison oak, and poison sumac as well as for the treatment and/or neutralization of insect bites. Final agency action on this matter will occur with the publication at a future date of a final rule relating to OTC skin protectant drug products for these conditions.

The OTC drug procedural regulations (21 CFR 330.10) now provide that any testing necessary to resolve the safety or effectiveness issues that formerly resulted in a Category III classification, and submission to FDA of the results of that testing or any other data, must be done during the OTC drug rulemaking process before the establishment of a final monograph. Accordingly, FDA will no longer use the terms "Category I" (generally recognized as safe and effective and not misbranded), "Category II" (not generally recognized as safe and effective or misbranded), and "Category III" (available data are insufficient to classify as safe and effective, and further testing is required) at the final monograph stage, but will use instead the terms "monograph conditions" (old Category I) and "nonmonograph conditions" (old Categories II and III). This document

retains the concepts of Categories I, II, and III at the tentative final monograph stage.

The agency advises that the conditions under which the drug products that are subject to this monograph would be generally recognized as safe and effective and not misbranded (monograph conditions) will be effective 12 months after the date of publication of the final monograph in the *Federal Register*. On or after that date, no OTC drug product that is subject to the monograph and that contains a nonmonograph condition, i.e., a condition that would cause the drug to be not generally recognized as safe and effective or to be misbranded, may be initially introduced or initially delivered for introduction into interstate commerce unless it is the subject of an approved application. Further, any OTC drug product subject to this monograph that is repackaged or relabeled after the effective date of the monograph must be in compliance with the monograph regardless of the date the product was initially introduced or initially delivered for introduction into interstate commerce. Manufacturers are encouraged to comply voluntarily with the monograph at the earliest possible date.

If the agency determines that any labeling for a condition included in the final monograph should be implemented sooner than the 12-month effective date, a shorter deadline may be established. Similarly, if a safety problem is identified for a particular nonmonograph condition, a shorter deadline may be set for removal of that condition from OTC drug products.

All "OTC Volumes" cited throughout this document refer to the submissions made by interested persons pursuant to the call-for-data notices published in the *Federal Register* on November 16, 1973 (38 FR 31697) and August 27, 1975 (40 FR 38179) or to additional information that has come to the agency's attention since publication of the advance notices of proposed rulemaking. The volumes are on public display in the Dockets Management Branch (address above).

I. The Agency's Tentative Conclusions on the Comments

The agency has reviewed the comments submitted to this rulemaking. As noted above, most of the comments were also submitted to the external analgesic rulemaking. The agency has addressed the general comments in the proposed rulemaking to amend the tentative final monograph for OTC external analgesic drug products, published elsewhere in this issue of the

Federal Register. These comments are incorporated into this rulemaking.

1. One comment requested that colloidal oatmeal be included in the skin protectant monograph as a safe and effective ingredient for the claim: "For prompt temporary relief of itchy, sore, sensitive skin due to: poison ivy/oak." The comment based its request on the Miscellaneous External Panel's review of colloidal oatmeal as an antipruritic at that Panel's 23d meeting on January 29 and 30, 1978. The comment noted that the Panel found colloidal oatmeal at all concentrations to be safe and effective as a bath additive, cleansing bar, and soak for the symptomatic relief and treatment of dry skin and the resultant itching (Ref. 1).

The comment contended that colloidal oatmeal falls within the Topical Analgesic Panel's definition of a skin protectant. The comment argued that, due to its physical and chemical properties, colloidal oatmeal isolates exposed skin or mucous membrane surface from harmful or annoying stimuli. (See proposed § 347.3 at 43 FR 34628 at 34648; August 4, 1978.) Moreover, the comment added that colloidal oatmeal meets the Panel's criteria described at 43 FR 34630 in that it protects by mechanical or other physical means, is inert, insoluble, finely subdivided, and adsorbs some moisture. The comment stated that colloidal oatmeal that is dispersed in water and applied to the skin deposits particles on the skin and leaves behind an occlusive film barrier that is helpful in protecting skin against irritation and in soothing irritated or pruritic skin conditions. The comment added that colloidal oatmeal when added to water controls the osmotic pressure of water with respect to the skin and permits adequate water to enter into the stratum corneum. The comment stated that the oatmeal leaves behind a thin occlusive film on the skin and this serves to hold in the adsorbed moisture. The result of this coating is that the skin is protected against irritation; hence, the ingredient has an antipruritic and generally soothing effect. The comment noted that the Topical Analgesic Panel stated at 43 FR 34630 that "the fluids from seeping rashes or toxic dermatoses (poison ivy, poison sumac, *) are absorbed or adsorbed by many of these drugs. Often itching is ameliorated. Based on the above, the comment contended that the following claim for colloidal oatmeal is justified: "For prompt temporary relief of itchy, sore, sensitive skin due to: poison ivy and oak."

The Topical Analgesic Panel stated at 43 FR 34630 that well-controlled clinical

studies have not been conducted for most of the skin protectant ingredients. The Panel recommended that the requirement for well-controlled studies be waived, on the grounds that clinical studies are not necessary to support the use of mechanical barriers such as these ingredients to protect the skin from further injury. The agency agrees with this recommendation regarding skin protectant (physical barrier type) ingredients.

In addition, the agency agrees that colloidal oatmeal qualifies as a skin protectant because of its barrier-like properties. Montebovi (Ref. 2) identified and evaluated a number of hydrophilic colloids including colloidal oatmeal using the "Gold Number" as a means of determining the protective ability of hydrophilic solutions. The "Gold Number" is an *in vitro* physical chemical determination intended to measure the protective ability of hydrophilic colloids. Montebovi also measured and evaluated the viscosity of hydrophilic colloids with particular reference to colloidal oatmeal and stated that:

The colloidal adsorbents are used in dermatology primarily for their protective demulcent effects. On the basis of the physical properties of the agents commonly used for this purpose, the role of colloidal oatmeal appears to be well founded. Chemically it is made up of gums, protein, and oil in a ratio which is consistent with the desirable characteristics of the purified agents. Its high protective colloidal activity is demonstrated by the low Gold Number. The viscosity and surface tension establish a good spreading and clinging property which would be necessary for sustained protective action.

Furthermore, the agency has reviewed the data submitted by the comment (Ref. 3) in view of the Panel's recommendations and concludes there is sufficient information to demonstrate that colloidal oatmeal is safe and effective when used in a bath to relieve minor skin irritation and itching due to poison ivy, poison oak, and poison sumac. The comment cited the Merck Manual (Ref. 4) which recommends that, in extensive pruritis, the patient should soak for 10 to 20 minutes twice a day in a colloidal oatmeal bath. Also, the American Medical Association Drug Evaluations (Ref. 5) states that pruritis accompanying acute dermatitis or extensive exanthematous lesions is often alleviated by immersion of the part or the entire body in water and that colloidal substances can be added to such baths for their soothing and antipruritic activities. It recommends the use of colloidal oatmeal added to a tub half-filled with water.

Other references submitted by the comment also describe the use of colloidal oatmeal in therapeutic baths to relieve minor skin irritation. Epstein (Ref. 6) recommended tepid colloidal oatmeal baths (250 grams in a tub of water twice daily) to ease discomfort in cases of generalized dermatitis. Lewis and Wheeler (Ref. 7) recommended the use of baths (e.g., colloidal oatmeal ½ to 1 cupful to a tub of water) when dermatosis is extensive and stated that such baths are used for their soothing or antipruritic properties and are often the most efficient method for applying medication to exudative surfaces. Whyte (Ref. 8) stated that, in acute (exudative) dermatitis and subacute dermatitis (less exudative), colloidal oatmeal in warm water should be used to soothe and coat the inflamed skin with a bland colloid. Whyte added that a paroxysm of itching is often best treated by a comfortable warm colloid bath once or more daily. O'Brasky (Ref. 9) described one patient with "an erythematous, vesicular and edematous eruption, typical of a contact dermatitis (ivy). The investigator stated that the patient responded well to treatment with colloidal oatmeal baths (no other medication was used), and was discharged 10 days after treatment began. O'Brasky treated 111 patients with dry skin manifestations (including one patient with multiple insect bites) and noted that the colloidal oatmeal baths had antipruritic properties because patients complained of recurrent itching when the baths were omitted.

The agency agrees with the comment that the evidence is supportive of the general recognition of colloidal oatmeal as a safe and effective skin protectant. Based on the available information, the agency believes that colloidal oatmeal could be classified as a Category I skin protectant when labeled with the following claim: "Provides temporary skin protection and relieves minor irritation and itching due to poison ivy, poison oak, poison sumac, and insect bites.

However, in order for colloidal oatmeal to be generally recognized as safe and effective as a skin protectant, the agency must have sufficient data on the composition and concentration of the different constituents and the quantity (range) of each that is contained in marketed products. For an ingredient or mixture to be included in an OTC drug final monograph, it is necessary to have publicly available chemical information that can be used by all manufacturers to determine that the ingredient is appropriate for use in their products.

The comment submitted a report by MonteBovi (Ref. 2) that describes colloidal oatmeal as a specifically milled constant fraction of the colloid-producing portion of the oat grain, having a chemical analysis of 46 percent carbohydrate, 9.0 percent oil, 24.0 percent protein, 8.0 percent moisture, and 0.03 percent crude fiber. However, the agency does not find this information to be an adequate public standard for colloidal oatmeal.

The agency believes that it would be appropriate for interested parties to develop with the United States Pharmacopeial Convention appropriate standards for the quality and purity of colloidal oatmeal. In this tentative final monograph, colloidal oatmeal is proposed in Category I. However, should interested parties fail to provide necessary information so that an appropriate standard may be established, colloidal oatmeal will not be included in a final monograph.

The comment submitted the following directions for the use of colloidal oatmeal in a bath: Turn the warm bath water on to full force, then slowly sprinkle one cupful of colloidal oatmeal into the bathtub under the faucet. Before entering the tub, stir any colloidal oatmeal that may have settled to the bottom of the tub. Bathe for 15 to 20 minutes. For infants, use 2 tablespoonfuls per bath. Use once or twice daily, or as directed by your physician.

The agency is proposing these directions for colloidal oatmeal with minor revisions. Because it is desirable to leave a thin layer of the colloidal oatmeal on the skin after bathing, the agency is adding directions to pat the skin dry, rather than to rub it dry, after the bath. In addition, the submitted labeling recommends a dosage for infants, but it does not specify a particular age range, how much water to which the 2 tablespoonfuls of colloidal oatmeal should be added, or how it should be added to ensure dispersion of the colloidal oatmeal to make a colloidal suspension. In general, infants would be bathed in something smaller than an adult-sized tub and the amount of water would be less. Therefore, the agency has not included specific directions for children under 2 years of age at this time and requests specific comment on appropriate directions for this age group as well as a possible lower age limit for use of this ingredient.

Based on the submitted labeling, the following directions are being proposed for colloidal oatmeal for use as a skin protectant: Adults and children 2 years of age and over: For use as a soak in a

tub. Turn tub warm water faucet on to full force, then slowly sprinkle 1 cupful of colloidal oatmeal directly under the faucet into the tub. Before entering the tub, stir any colloidal oatmeal that may have settled to the bottom of the tub. Soak the affected area for 15 to 20 minutes as needed. Do not rub area dry, but instead pat dry so that a thin layer of the colloidal oatmeal will be left on the skin. Soak once or twice daily, or as directed by your doctor. Children under 2 years of age: consult a doctor.

In addition, several references mentioned that patients should be careful when using colloidal oatmeal in a bath to avoid slipping in the tub (Ref. 3). Current labeling for the submitted product states: "Take special care to avoid slipping" (Ref. 10). The agency believes it is appropriate to propose that a statement like this be required as a warning for skin protectant drug products containing colloidal oatmeal. The agency is expanding the statement to read "Take special care to avoid slipping when getting into and out of the tub" to make it more specific for consumers.

References

- (1) Summary of Minutes of the Twenty-Third Meeting of the Advisory Review Panel on OTC Miscellaneous External Drug Products, January 29 and 30, 1978, OTC Volume 16DPA1, Docket No. 78N-0021, Dockets Management Branch.
- (2) MonteBovi, A. J., "The Colloidal Demulcents. I. Physical and Chemical Properties," *American Journal of Pharmacy*, 126:4-7 1954.
- (3) OTC Volumes 160069 and 160070.
- (4) "The Merck Manual, 12th Ed., Merck Sharpe & Dohme Research Laboratories, West Point, PA, p. 1431, 1972.
- (5) "Drug Evaluations, 6th Ed., American Medical Association, Chicago, p. 1030, 1986.
- (6) Epstein, W. L., "Contact Dermatitis, in OTC Volume 160070.
- (7) Lewis, G. M., and C. E. Wheeler, Jr., "Practical Dermatology, in OTC Volume 160070.
- (8) Whyte, H. J., "Atopic Dermatitis, in OTC Volume 160070.
- (9) O'Brasky, L., "Management of Extensive Dry Skin Conditions, *Connecticut Medicine*, 23:20, 1959.
- (10) Labeling for Colloidal Oatmeal Product in OTC Volume 06P1STFM, Docket No. 78N-021P Dockets Management Branch.

2. Two comments requested that corn starch be classified as a Category I skin protectant for the treatment of poison ivy, poison oak, and poison sumac. One comment, noting that the agency had tentatively deleted corn starch from the skin protectant tentative final monograph until diaper rash drug products are reviewed, stated that although corn starch is widely used in diaper rash products, it is also an

ingredient in skin protectant products for use by the general population. The second comment agreed with the agency's proposal that the maximum Category I concentration of corn starch be raised from 85 to 97 percent (48 FR 6820 at 6826). However, the comment disagreed with the agency's statement in the tentative final monograph that "at the present time none of the proposed Category I indications are applicable to corn starch, (48 FR 6820 at 6828). Accordingly, both comments requested that corn starch be included in the skin protectant monograph as a general skin protectant labeled with the following indication proposed in § 347.50(b)(3) of the tentative final monograph: "Dries the oozing and weeping of poison ivy, poison oak, and poison sumac.

The Topical Analgesic Panel classified 10 to 85 percent corn starch as a Category I skin protectant in its report (43 FR 34628 at 34636). One of the skin protectant indications recommended by the Panel for corn starch in § 347.50(b) reads "For symptoms of oozing or weeping" (optional, any or all of the following) "due to contact dermatitis, poison oak, or poison ivy" (43 FR 34648). In its discussion of corn starch, the Panel mentioned that absorption by corn starch probably surpasses that of any powder described in the official compendia. It protects the skin by absorbing moisture, perspiration, and noxious secretions, and it soothes dermal irritation and itching (43 FR 34636). However, the Panel did not cite any studies or literature references on the use of corn starch for the treatment of poison ivy, poison oak, poison sumac, or other types of contact dermatitis.

In the tentative final monograph for OTC skin protectant drug products (48 FR 6820 at 6828), the agency stated that "at the present time, none of the proposed Category I indications are applicable to corn starch. Most of the uses of corn starch discussed by the Topical Analgesic Panel are cosmetic uses. The primary OTC drug use of corn starch appears to be in diaper rash drug products. Therefore, the agency did not include corn starch in the tentative final monograph, but deferred evaluation of corn starch until its use in diaper rash drug products was reviewed. That evaluation will be published in a future issue of the **Federal Register**.

In the present document, the agency is classifying topical starch in Category III for the treatment of poison ivy, poison oak, and poison sumac.

Note: Although "corn starch" has been used as the name for this ingredient, "topical starch" is the official title used in the United States Pharmacopeia XXI (Ref. 1).

The comments did not submit any data on the use of topical starch for use as a treatment for poison ivy, poison oak, and poison sumac. In addition, the submissions to the Panel do not contain any data on the use of topical starch as a poison ivy treatment. Several articles in one submission state that starch is used to cover and protect the skin, mucous membranes, ulcers, and wounds, but also state that water-absorbent powders should not be used on extensive profusely secreting raw surfaces, as they tend to cake and form adherent crusts, and that starch becomes doughy (Refs. 2 through 5). Further, although two submissions to the Panel contain information on products containing topical starch and include poison ivy labeling claims (e.g., helps dry weeping of poison ivy, poison oak, and poison sumac), the therapeutic properties of the products were attributed to other ingredients in the product, and topical starch was only included as an inactive ingredient (Ref. 6). Other submissions of products containing topical starch did not contain any poison ivy treatment labeling claims (Ref. 7). Additionally, the agency is unaware of any products that bear poison ivy treatment labeling claims that contain topical starch as an active ingredient.

The initial symptoms following exposure to poison ivy include erythema or rash. The development of raised lesions follows, and finally vesicles and bullae form, caused by fluid accumulation in the epidermis. The initial lesions usually are marked by mild to intense itching and burning. The affected area, often hot and swollen, oozes and eventually dries and crusts. Most cases of poison ivy are self-limiting and disappear in 14 to 20 days (Ref. 8). Topical starch is safe when applied topically, but should not be used on broken skin because crusting and skin granulomas have been known to occur when starch is applied to broken skin (Refs. 9 and 10). Thus, because of the weeping and oozing vesicles associated with poison ivy and related contact dermatitis, the agency believes that topical starch may not be appropriate to treat the symptoms of poison ivy, poison oak, and poison sumac. Further, because of a lack of data on effectiveness and a suitable concentration of topical starch for this use, and because the agency is unaware of any marketed products that contain topical starch as an active ingredient for the treatment of poison ivy, as discussed above, the agency proposes that topical starch be classified in Category III as a skin protectant drug

product for the treatment of poison ivy, poison oak, and poison sumac. Other skin protectant uses of topical starch will be addressed in the diaper rash amendment to the tentative final monograph for OTC skin protectant drug products and in the final monograph for OTC skin protectant drug products.

References

- (1) "The United States Pharmacopeia, XXI—The National Formulary XVI, United States Pharmacopeial Convention, Inc., Rockville, MD, p. 984, 1985.
- (2) Welsh, A.L., "Powders, in "The Dermatologist's Handbook, Charles C. Thomas, Springfield, IL, pp. 12-14, 1957
- (3) Martin, E.W., "Techniques of Medication. A Manual on the Administration of Drug Products, J.B. Lippincott Co., Philadelphia, pp. 56-57 1969.
- (4) Balsam, M.S., and E. Sagarin, editors, "Cosmetics: Science and Technology, Vol. 1, 2d Ed., Wiley-Interscience, New York, pp. 136-138 and 152-154, 1972.
- (5) Swinyard, E.A., "Locally Acting Drugs, in "The Pharmacological Basis of Therapeutics, 4th Ed., edited by L. S. Goodman and A. Gilman, The Macmillan Co., New York, p. 989, 1970.
- (6) OTC Volumes 160040 and 160077
- (7) OTC Volumes 060137 and 160242.
- (8) Wormser, H., "Poison Ivy and Poison Oak Products, in "Handbook of Nonprescription Drugs, 8th Ed., American Pharmaceutical Association, Washington, pp. 633-642, 1986.
- (9) Kelly, R., and P.E. Campbell, "Granuloma Glutaeale Infantum with Starch Granules in the Lesion, *The Medical Journal of Australia*, 2:438-439, 1973.
- (10) Leonard, D.D., "Starch Granulomas, *Archives of Dermatology*, 107:101-103, 1973.

3. One comment requested that sodium bicarbonate (baking soda) be classified as a Category I skin protectant for drying the oozing and weeping of poison ivy, poison oak, and poison sumac, and for protecting and relieving the irritation associated with various skin problems, such as poison ivy and minor insect bites and stings. Referring to the tentative final monograph for OTC skin protectant drug products (48 FR 6820 at 6830), which discussed FDA's decision to transfer sodium bicarbonate from the rulemaking for OTC skin protectant drug products to the rulemaking for OTC external analgesic drug products, the comment stated that baking soda should be considered in both rulemakings. The comment expressed concern that sodium bicarbonate had been placed in Category II as an insect bite neutralizer by the Miscellaneous External Panel in its statement on OTC insect bite neutralizer drug products, published in the *Federal Register* of September 7 1982 (47 FR 39448). The comment contended that the ingredient was incorrectly categorized. The comment

asked that the data on sodium bicarbonate previously submitted to the Miscellaneous External Panel (Ref. 1) and to the rulemakings for OTC skin protectant and external analgesic drug products (Refs. 2 through 5) be reconsidered as demonstrating that sodium bicarbonate has been used and marketed for many dermatological conditions, including for the relief, protection, and for drying the oozing and weeping of poison ivy, poison oak, and poison sumac, and for the relief of itching of poison ivy-oak-sumac and insect bites. The comment added that a survey (Ref. 1) indicates that many dermatologists and other physicians routinely prescribe sodium bicarbonate for a wide variety of external drug uses, including, but not limited to, relief of minor insect stings and bites.

The comment noted that, although sodium bicarbonate has not been the subject of double-blind clinical trials (a concept of relatively recent development, circa 1952), it has been used for a long time for its effectiveness in the treatment of a variety of skin conditions (Ref. 6). The comment included a "dermatological summary of baking soda" (sodium bicarbonate) (Ref. 6) which contained references in the medical literature on the topical use of sodium bicarbonate (e.g., as a powder and in a bath) in a number of dermatological conditions.

The Topical Analgesic Panel classified sodium bicarbonate as safe and effective for use as a skin protectant (43 FR 34628 at 34640). That Panel concluded that sodium bicarbonate is safe for use as a skin protectant with no age or concentration limits. That Panel stated that sodium bicarbonate has a long history of market acceptability, soothes irritated skin, and as a topical protectant is effective in the symptomatic relief of minor irritations, insect bites, and stings (43 FR 34640). That Panel stated that sodium bicarbonate is effective as a skin protectant due to its absorbent properties, but did not include the ingredient in its table which categorized the purposes (i.e., for dryness, wetness, or lubricity) for which Category I skin protectants are used (43 FR 34632).

In the tentative final monograph for OTC skin protectant drug products (48 FR 6820 at 6830), the agency stated that the Panel pointed out that sodium bicarbonate is an effective antipruritic in relieving itching due to nonpoisonous insect stings and bites, or due to sunburn, and that it is also used to relieve the pain of minor acid burns. Because the indication "for the temporary relief of pain and itching due to minor burns, sunburn, insect

bites, and minor skin irritations" was being addressed in the external analgesic rulemaking (December 4, 1979; 44 FR 69768), the agency transferred sodium bicarbonate to that rulemaking proceeding.

Now that all of the information submitted on the uses of sodium bicarbonate has been reviewed, the agency has determined that sodium bicarbonate should be addressed in the skin protectant rulemaking, not in the external analgesic rulemaking. For reasons discussed below, the agency believes that claims related to the "relief of itching of poison ivy and insect bite for sodium bicarbonate should be considered under the skin protectant rulemaking.

The agency has reviewed the data referred to by the comment (Refs. 1 through 6), which include information on (1) the historical use of sodium bicarbonate as a paste for treatment of skin irritation, including insect bites and poison ivy, (2) eye, skin, and oral toxicity data, which indicate that sodium bicarbonate is relatively nontoxic, (3) a survey of dermatologists and general practitioners in which it was concluded that one out of three responding dermatologists and one out of two responding general practitioners have used or recommended use of sodium bicarbonate for relief of insect bites, minor burns, and pruritis, and (4) efficacy data consisting of references indicating that sodium bicarbonate used as a paste, wet dressing, or in a tub bath provides relief of skin irritation and minor skin conditions such as mild itching, erythema, and insect bites, and because of its emollient effect relieves skin irritation.

The data show that alkaline baths (sodium bicarbonate) are useful in chronic, scaly dermatoses and urticaria, and help to soften the skin. However, for insect bites and stings, first aid measures are not entirely effective because the bite wound extends beneath the skin, although a paste made of baking soda and cold cream provides some relief. The comment claimed that sodium bicarbonate reduces pain by neutralizing the formic acid injected by the insect.

The agency agrees with the Topical Analgesic Panel that sodium bicarbonate can be generally recognized as a safe and effective skin protectant (43 FR 34628 at 34640). Additionally, the agency agrees with the Panel's statement in its report on skin protectant drug products that sodium bicarbonate has antipruritic activity (43 FR 34640). Moreover, other information discussed above indicates that sodium bicarbonate

provides relief of itching (Refs. 1 through 6). The Panel's discussion of sodium bicarbonate's antipruritic activity concerned the ingredient's use as a skin protectant, not as an external analgesic. The relief of itching attributed to skin protectants was based on the pharmacologic action of these drugs in providing a physical or mechanical barrier to protect exposed skin surfaces from harmful or annoying stimuli (43 FR 34630). The pharmacological action of external analgesics is to depress or stimulate the cutaneous sensory receptors as a means of relieving the symptoms of pain and itching (44 FR 69768 at 69772). Thus, sodium bicarbonate's mechanism of action in relieving itching is based on its use as a mechanical barrier (i.e., skin protectant), rather than on physiological or physiochemical factors (i.e., external analgesic). Therefore, the "relief of itching" claim for sodium bicarbonate is addressed in this rulemaking.

Based on the available information, the agency believes that sodium bicarbonate can be classified as a Category I skin protectant when labeled with the following claim: "Provides temporary skin protection and relieves minor irritation and itching due to poison ivy, poison oak, poison sumac, and insect bites. However, the submitted data do not provide any information on sodium bicarbonate's drying effect in conditions such as poison ivy, poison oak, and poison sumac; therefore, the indication "Dries the oozing and weeping of poison ivy, poison oak, and poison sumac" is not being proposed for sodium bicarbonate. Nor is there evidence to support the use of sodium bicarbonate as an insect bite neutralizer. Therefore, the agency is retaining the Category II classification that was proposed for this ingredient as an insect bite neutralizer by the Miscellaneous External Panel (47 FR 39436 at 39448).

The Topical Analgesic Panel did not recommend any age or concentration limits for the use of sodium bicarbonate. The agency is not proposing any concentration limits for sodium bicarbonate in this amendment; however, it is including an age limitation. No data were provided on the use of sodium bicarbonate on infants for the requested uses. The agency is aware of one report of an adverse reaction in a 4-month-old infant after treatment of diaper rash with sodium bicarbonate (Ref. 7). The adverse reaction report states that liberal amounts of sodium bicarbonate and petrolatum had been applied to a severe diaper rash at every diaper change for more than a week.

The infant experienced hypokalemic metabolic alkalosis which the authors attributed to excessive sodium bicarbonate absorption from the baking soda that was applied to the diaper rash. The authors postulated that metabolic alkalosis occurred because the infant's immature renal system was not able to effectively excrete the excessive load of bicarbonate.

The agency notes that a marketed product containing sodium bicarbonate provides directions for emollient baths to relieve skin irritations (Ref. 1). Regarding the use of sodium bicarbonate for such baths, the submission (Ref. 1) cites the Merck Manual (Ref. 8) as recommending that 8 ounces of sodium bicarbonate be dissolved in about 30 gallons of warm water and that the patient should remain in the bath for 10 to 30 minutes or longer. The skin should be patted dry rather than rubbed so that a thin film of the drug remains on the skin. Other submitted data (Ref. 6) indicated that although there is variation regarding the recommended or optimal concentration of sodium bicarbonate for baths and solutions, a range of 1 to 5 percent would encompass most of the concentrations.

The following directions are being proposed for sodium bicarbonate for use as a skin protectant: Adults and children 2 years of age and over: Topical dosage is 1 to 100 percent sodium bicarbonate.

(i) *For use as a paste.* Add sufficient water to the sodium bicarbonate to form a paste and apply to the affected area of the skin as needed. Children under 2 years of age: Consult a doctor.

(ii) *For use as a soak in a tub.* Dissolve 1 to 2 cupfuls of this product in a tub of warm water and soak for 10 to 30 minutes as needed. Do not rub dry, but instead pat dry so that a thin layer of the sodium bicarbonate will be left on the skin. Children under 2 years of age: Consult a doctor.

(iii) *For use as a wet dressing.* Add sodium bicarbonate to water to make a solution. Use a container in which you can saturate a cloth. Saturate a clean, soft, white cloth (such as a diaper or torn sheet) in the solution, gently squeeze, and apply loosely to the affected area. Saturate the cloth in the solution every 15 to 30 minutes and apply to the affected area. Repeat as often as necessary. Discard remaining solution after use.

The agency has considered the warnings proposed for skin protectants in § 347.50(c) to determine which are applicable to sodium bicarbonate. In the tentative final monograph for OTC skin

protectant drug products (48 FR 6820 at 6830), a comment requested that sodium bicarbonate be exempted from the general warning for skin protectants "For external use only because it is both a food and an antacid and, thus, this warning would confuse consumers. The agency agrees that sodium bicarbonate can be exempted from the warning "For external use only. Further, the directions for using the ingredient as a skin protectant clearly indicate that the product is for external use. The comment also requested that sodium bicarbonate be exempted from the warning Avoid contact with the eyes. The comment contended that the drug is nonirritating according to the Draize rabbit eye irritation test, and it is used in swimming pools and baths.

The agency has reviewed the eye irritation study referred to by the comment (Ref. 1). Six rabbits were tested using sodium bicarbonate (0.086 grams) instilled into the right eye. All rabbits exhibited redness of the conjunctiva because of sodium bicarbonate, and two exhibited a slight discharge. However, as stated by the comment, the drug would not be considered an eye irritant according to the standards prescribed in the Draize testing methodology. Although sodium bicarbonate is not considered an eye irritant, it caused redness of the eye in rabbits. Because any product that might be used on the face could accidentally get into the eye and cause irritation, the agency believes that a general warning to avoid contact with the eyes is appropriate. Therefore, the warning is being retained for sodium bicarbonate. Thus, the following warnings proposed in § 347.50(c) (1) and (2) are applicable to sodium bicarbonate: (1) Avoid contact with the eyes, and (2) "If condition worsens or does not improve within 7 days, consult a doctor.

The use of sodium bicarbonate for other skin protectant uses will be discussed in future issues of the **Federal Register**.

References

- (1) OTC Volume 160032.
- (2) Comment C00027 Docket No. 78N-0021, Dockets Management Branch.
- (3) Comment C00050, Docket No. 78N-0021, Dockets Management Branch.
- (4) Comment C00047 Docket No. 78N-0301, Dockets Management Branch.
- (5) Comment C00085, Docket No. 78N-0301, Dockets Management Branch.
- (6) Eisenstat, B.A., "Dermatological Summary of Baking Soda, unpublished study, pp. 1-7 October 7 1983, in OTC Volume 06PISTFM, Docket No. 78N-021P Dockets Management Branch.
- (7) Gonzalez, J., and R.J. Hogg, "Metabolic Alkalosis Secondary to Baking Soda

Treatment of a Diaper Rash. *Pediatrics*, 67:820-822, 1981.

(8) Lyght, C.E., editor, "The Merck Manual, 9th Ed., Merck & Co., Rahway, NJ, p. 1756, 1956.

4. Two comments contended that limiting the statement of identity for different skin protectant drug products to the one term "skin protectant" is too restrictive, that other equally descriptive terms are appropriate, and that other statements of identity should be allowed for such products. One comment stated that the statement of identity should reflect the mode of action and suggested that the term "poison ivy and oak (dosage form)" be allowed for skin protectant drug products labeled for this use. The other comment argued that because the tentative final monograph provides separate and distinct indications for each group of skin protectant drug products, there should be equally separate and distinct statements of identity for each group. According to the comment, the large diversity of appropriate indications justifies an equally diverse list of appropriate statements of identity that would properly inform the consumer of the intended use of the product. The comment requested that additional statements of identity be included in the skin protectant monograph and suggested such statements as "poison ivy, oak, sumac treatment," "poison ivy, oak, sumac protectant," and "drying (dosage form)" for ingredients proposed in § 347.50(b)(3) and also for corn starch.

The agency agrees with one comment that the term "poison ivy, oak, sumac treatment" is an appropriate statement of identity for skin protectant drug products used for this purpose, including the ingredients colloidal oatmeal and sodium bicarbonate that are proposed for Category I status in this document (see comments 1 and 3 above.). However, the agency does not find the statements "poison ivy and oak (dosage form)" and "poison ivy, oak, sumac protectant" to be as descriptive and informative to consumers. Further, the agency believes that the word "protectant" in the latter statement is confusing and could be interpreted as protecting against poison ivy, oak, and sumac.

In addition, the agency believes that while the statement "drying (dosage form)" describes the principal intended action of skin protectant drug products used for the proposed indication ("Dries the oozing and weeping of poison ivy, poison oak, and poison sumac"), it is too general if used alone. If the concept of "drying" is combined with "poison ivy, oak, and sumac," it would be an acceptable statement of identity.

However, this statement of identity is not appropriate for the ingredients colloidal oatmeal and sodium bicarbonate, because the agency is not proposing that these ingredients be Category I for the indication "Dries the oozing and weeping of poison ivy, poison oak, and poison sumac." (See comments 1 and 3 above.) Accordingly, the agency is proposing that the statement of identity in § 347.50(a) for skin protectant drug products used to treat poison ivy, poison oak, and poison sumac be revised to read as follows: "(a) *Statement of Identity*. The labeling of the product contains the established names of the product, if any, and identifies the product with one or more of the following:

(1) "Skin protectant.

(2) *For products containing any ingredient in § 347.10 (b), (c), (g), (k), (l), or (m)*. "Poison ivy, oak, sumac drying" (insert dosage form, e.g., "cream," "lotion, or "ointment").

(3) *For products containing any ingredient in § 347.10 (b), (c), (g), (k), (l), (m), (t), or (u)*. "Poison ivy, oak, sumac treatment.

II. The Agency's Evaluation of the Submissions

The Miscellaneous External Panel discussed only the use of OTC drug products for the prevention of poison ivy, poison oak, and poison sumac and for use as insect bite neutralizers. The Panel recommended that the agency consider in appropriate rulemakings ingredients and labeling claims submitted for treating poison ivy, poison oak, poison sumac, and their related symptoms (47 FR 39436 at 39441).

In this document, the agency discusses the use of OTC skin protectant drug products for the treatment and/or prevention of poison ivy, poison oak, and poison sumac as well as for the treatment and/or neutralization of insect bites. The agency has evaluated a number of submissions (Ref. 1) that were not reviewed by the Panel. Some of the submissions include drug products that are no longer marketed or that have been reformulated to include active ingredients and/or conditions that were proposed in the tentative final monograph for OTC skin protectant drug products (48 FR 6820). The manufacturers of these drug products have requested that their submissions or portions of their submissions concerning these drug products be withdrawn from further consideration in this rulemaking, as follows:

1. Submissions (Ref. 2) concerning drug products containing stabilized aloe vera for topical use for numerous

indications including the symptoms of insect bites and poison ivy were withdrawn by the manufacturers (Refs. 3 and 4).

2. Submissions and portions of submissions (Ref. 5) concerning drug products containing zirconium oxide for the prevention and/or treatment of poison ivy, poison oak, and poison sumac were withdrawn by the manufacturers (Refs. 6 and 7).

References

(1) OTC Volumes 160032, 160074, 160152, and 160186.

(2) OTC Volumes 160143, 160196, 160252, 160261, 160273, and 160274.

(3) Letter from J.F. Girardi, Aloe Creme Laboratories, to W.E. Gilbertson, FDA, dated October 22, 1988, included in OTC Volume 06PISTFM, Docket No. 78N-021P Dockets Management Branch.

(4) Letters from A. Davis, Aloe Vera of America, to W.E. Gilbertson, FDA, dated October 24, 1986 and May 20, 1988, included in OTC Volume 06PISTFM, Docket No. 78N-021P Dockets Management Branch.

(5) OTC Volumes 160030, 160076, and 1600288.

(6) Letter from J. Wright, North Health Care, to W.E. Gilbertson, FDA, dated April 15, 1988, included in OTC Volume 06PISTFM, Docket No. 78N-021P Dockets Management Branch.

(7) Letter from R. Kirpitch, Warner-Lambert, to A. Mustafa, FDA, dated May 10, 1988, included in OTC Volume 06PISTFM, Docket No. 78N-021P Dockets Management Branch.

5. One manufacturer submitted information to the Miscellaneous External Panel requesting Category I status for a drug product containing 6 percent ferric chloride solution labeled as an astringent "for topical use only in prevention of ivy poisoning" and as a "preventative solution for poison ivy, poison oak, poison sumac" (Refs. 1, 2, and 3).

The Miscellaneous External Panel reviewed these submissions, but inadvertently did not cite one of them (Ref. 1) in its statement on OTC drug products for the prevention of poison ivy, oak, and sumac (47 FR 39412 at 39417 and 39441). The agency has reviewed these submissions and determined that the volume not cited by the Panel contains only labeling for the manufacturer's products and that one of the submissions that the Panel did review and cite (Ref. 2) contains all of the supporting information for the ferric chloride product.

The Panel stated that the submissions contained no substantial data to establish the safety and effectiveness of ferric chloride to prevent poison ivy, poison oak, or poison sumac and classified this ingredient in Category II

(47 FR 39412 at 39417 and 39436 at 39441). No additional data have been submitted. The agency concurs with the Panel's determination that the manufacturer's submissions do not contain substantial data in support of the safety or effectiveness of ferric chloride and with the Panel's recommendation that ferric chloride be classified Category II for the prevention of poison ivy, poison oak, or poison sumac.

References

- (1) OTC Volume 160074.
- (2) OTC Volume 160152.
- (3) OTC Volume 160132.

6. One submission (Ref. 1) contained a label for a spray product containing benzalkonium chloride and polyvinylpyrrolidone-vinyl acetate copolymers as active ingredients claimed to be effective for the treatment of itching and burning of poison ivy, poison oak, and poison sumac and "in reducing the swelling and itching of insect bites, from chiggers, mosquitoes, bees, wasps, etc.

The submission did not contain any data to support the claims made for these ingredients. Because no information has been submitted to the agency on the safety and effectiveness of polyvinylpyrrolidone-vinyl acetate copolymers, the agency is classifying this ingredient in Category II in this rulemaking. The agency proposed a Category III classification for benzalkonium chloride as a skin antiseptic and as a skin wound protectant in the tentative final monograph for OTC topical antimicrobial drug products (January 6, 1978; 43 FR 1210 at 1229). This ingredient will be discussed further in the tentative final monograph for OTC first aid antiseptic drug products in a future issue of the Federal Register.

Reference

- (1) OTC Volume 160186.

III. The Agency's Tentative Conclusions and Adoption of the Panel's Statements

A. Summary of Ingredient Categories and Testing of Category II and Category III Conditions

1. Summary of Ingredient Categories

In the Miscellaneous External Panel's advance notice of proposed rulemaking for skin protectant drug products (47 FR 39436 at 39440 and 39448), the Panel stated that, although the agency's call-for-data notices (38 FR 31697 and 40 FR 38179) requested the submission of data and information for a number of specific active ingredients (47 FR 39436 at 39440 and 39448) or any other active

ingredients used in OTC poison ivy and oak remedy drug products and insect bites drug products, the Panel reviewed only those ingredients with claims for preventing poison ivy, oak, or sumac or for treating insect bites by neutralization or inactivation of insect venom. As stated above, drug products for treatment of the symptoms of poison ivy-oak-sumac and insect bites are discussed in the external analgesic rulemaking published elsewhere in this issue of the Federal Register and will not be discussed further here.

The Panel received submissions for products containing a buffered mixture of cation and anion resins and for products containing ferric chloride that claimed to prevent poison ivy, oak, or sumac by complexing with the plant antigen before it enters the skin. The agency concurs with the Panel's determination that there are insufficient data to demonstrate the effectiveness of a buffered mixture of cation and anion resins in preventing poison ivy, poison oak, and poison sumac and agrees with the Panel's Category III classification of these ingredients. In addition, the agency concurs with the Panel's determination that there are no substantial data to support the safety and effectiveness of ferric chloride and agrees with the Panel's Category II classification of this ingredient.

The Panel also received submissions for products containing ammonium hydroxide and triethanolamine (trolamine) that claimed to neutralize or inactivate insect venom. The agency concurs with the Panel's determination that there are insufficient data to demonstrate the effectiveness of ammonium hydroxide and trolamine as insect bite neutralizers and concurs with the Panel's Category III classification of these ingredients.

Although the Miscellaneous External Panel mentioned the use of skin protectant ingredients for the prevention of poison ivy, poison oak, and poison sumac, and use as insect bite neutralizers, it did not review or classify all of the individual ingredients. Most of the ingredients in marketed products submitted to the Panel or ingredients that appeared in the call-for-data notices were simply listed in the Panel's statements on OTC drug products for the prevention of poison ivy, poison oak, and poison sumac (47 FR 39436 at 39440) and on OTC insect bite neutralizer drug products (47 FR 39448). The Panel noted at 47 FR 39440 that many of these ingredients labeled with claims as skin protectant drug products for symptoms of oozing or weeping due to contact dermatitis, poison ivy, or poison oak have been previously addressed by

another OTC panel, the Topical Analgesic Panel. The agency has further considered the recommendations of the Topical Analgesic Panel on OTC skin protectant drug products (43 FR 34628), the tentative final monograph on OTC skin protectant drug products (48 FR 6820), and the additional data and information available at this time. Based upon this information, the agency is adding several active ingredients to the "Summary of Ingredient Categories" table for skin protectant active ingredients that appeared in the tentative final monograph for OTC skin protectant drug products (48 FR 6820 at 6831). These ingredients are ammonium hydroxide, buffered mixtures of cation and anion exchange resins, colloidal oatmeal, ferric chloride, polyvinylpyrrolidone-vinyl acetate copolymers, and trolamine. In addition, the agency is amending the entries for two ingredients that were listed as deferred and transferred to other rulemakings. These ingredients (corn starch and sodium bicarbonate) are now classified as skin protectants in this rulemaking. An updated table appears below for the convenience of the reader.

Summary of Ingredient Categories

Skin protectant active ingredients	Category
Allantoin ¹	I
Aluminum hydroxide gel.....	I
Ammonium hydroxide.....	III
Bismuth subnitrate.....	II
Boric acid.....	II
Buffered mixture of cation and anion exchange resins.....	III
Calamine.....	I
Cocoa butter.....	I
Colloidal oatmeal.....	I
Corn starch.....	III
Dimethicone.....	I
Ferric Chloride.....	II
Glycerin.....	I
Kaolin.....	I
Live yeast cell derivative ³	III
Petrolatum.....	I
Polyvinylpyrrolidone-vinylacetate copolymers.....	II
Shark liver oil.....	I
Sodium bicarbonate.....	I
(a) for the temporary protection and relief of itching due to poison ivy/oak/sumac, and insect bites.....	I
(b) for drying oozing and weeping.....	III
(c) as an insect bite neutralizer.....	II
Sulfur.....	II
Tannic acid.....	II
Trolamine ⁴	III
White petrolatum.....	I
Zinc acetate.....	I
Zinc carbonate.....	I
Zinc oxide.....	I

Also classified by the Topical Analgesic Panel and the agency as a Category III wound healing agent.

² On condition that a standard chemical composition and concentration of the colloidal oatmeal can be established.

³ Classified only as wound healing agent.

⁴ Identified by the Miscellaneous External Panel as triethanolamine.

The Miscellaneous External Panel also listed a number of other ingredients in its statement that it said should be considered in other appropriate rulemakings for their use in treating poison ivy, poison oak, and poison sumac, and their related symptoms (47 FR 39436 at 39440). Except for the ingredients listed in the table above, no information has been provided on any of the other ingredients in the Panel's list. Accordingly, all of those ingredients are considered Category II.

The Miscellaneous External Panel also stated that it was not able to locate nor was it aware of data demonstrating the safety or effectiveness as OTC insect bite neutralizers of a number of active ingredients listed in its report (47 FR 39436 at 39448) and recommended a Category II classification for these ingredients. The agency concurs with the Panel's Category II classification of these ingredients for use as insect bite neutralizers.

2. Testing of Category II and Category III Conditions

The agency is not proposing specific testing guidelines in this document. Interested persons may communicate with the agency about the submission of data and information to demonstrate the safety or effectiveness of any skin protectant ingredient or conditions included in the review for the treatment and/or prevention of poison ivy, poison oak, and poison sumac as well as for the treatment and/or neutralization of insect bites, by following the procedures outlined in the agency's policy statement published in the *Federal Register* of September 29, 1981 (48 FR 47740) and clarified April 1, 1983 (48 FR 14050). That policy statement includes procedures for the submission and review of proposed protocols, agency meetings with industry or other interested persons, and agency communications on submitted test data and other information.

B. Summary of the Agency's Changes

FDA has considered comments submitted to the Topical Analgesic Panel and the Miscellaneous External Panel, the submissions to the Miscellaneous External Panel, and other relevant information and concludes that it will tentatively adopt the substance of the Miscellaneous External Panel's statements. This Panel did not recommend a specific monograph for skin protectant drug products for use in the treatment and/or prevention of poison ivy, poison oak, and poison sumac or for the treatment and/or

neutralization of insect bites. However, the Topical Analgesic Panel did recommend a monograph for skin protectant drug products (43 FR 34628), and the agency adopted this recommended monograph with some revisions in the tentative final monograph for OTC skin protectant drug products (48 FR 6820 at 6832). The agency is amending the tentative final monograph to include conditions for the treatment and/or prevention of poison ivy, poison oak, and poison sumac as well as for the treatment and/or neutralization of insect bites based on its evaluations of the data and its responses to the comments described above, and the other changes described in the summary below. A summary of the changes made by the agency follows.

1. The agency is proposing in § 347.3(d) of this tentative final monograph the following definition for poison ivy, poison oak, or poison sumac dermatitis: an allergic contact dermatitis (usually an intensely itching skin rash) due to exposure to plants of the genus *Rhus* (poison ivy, poison oak, poison sumac), which contain urushiol, a potent skin-sensitizing agent.

2. After reviewing all of the information submitted on the uses of sodium bicarbonate, the agency has decided to address sodium bicarbonate in the skin protectant rulemaking, not in the external analgesic rulemaking. Although the agency stated in the tentative final monograph for skin protectant drug products (48 FR 6820 at 6830) that it would address this ingredient in the external analgesic rulemaking, the agency finds that, because of its mechanism of action in relieving itching, i.e., its ability to form a mechanical barrier, it is appropriate to address sodium bicarbonate in the skin protectant rulemaking. (See comment 3 above.)

3. Based on the agency's review of data on colloidal oatmeal and the available information on sodium bicarbonate, the agency is revising the tentative final monograph to include these two ingredients as Category I skin protectant drug products and is proposing the following indication for these two ingredients in § 347.50(b)(4): "Provides temporary skin protection and relieves minor irritation and itching due to poison ivy, poison oak, poison sumac, and insect bites. However, for colloidal oatmeal, the agency states that sufficient data on the composition and concentration of the different constituents of this ingredient need to be established before it can be included in

the final monograph. (See comments 1 and 3 above.)

4. The agency has added letter designations in § 347.10 *Skin protectant active ingredients* to include the addition of the ingredients colloidal oatmeal in paragraph (t) and sodium bicarbonate in paragraph (u). The agency has added these letter designations for these two active ingredients in appropriate paragraphs of § 347.50.

5. The agency is proposing to revise the statement of identity in § 347.50(a) to read as follows: (a) *Statement of identity*. The labeling of the product contains the established name of the drug, if any, and identifies the product with one or more of the following:

- (1) "Skin protectant.
- (2) *For products containing any ingredient in § 347.10 (b), (c), (g), (k), (l), or (m)*. "Poison ivy, oak, sumac drying" (insert dosage form, e.g., "cream, "lotion, or "ointment").
- (3) *For products containing any ingredient in § 347.10 (b), (c), (g), (k), (l), (m), (t), or (u)*. "Poison ivy, oak, sumac treatment. (See comment 4 above.)

As noted above, an OTC skin protectant drug product may be labeled for one or more uses. Other uses for skin protectant active ingredients will be added to this monograph in the future, e.g., claims for the treatment and prevention of diaper rash. When the labeling of the product contains more than one labeled use, it must contain the appropriate statement(s) of identity, indications, warnings, and directions for each labeled use. For multiple use skin protectant drug products, the labeling appropriate to different uses may be combined to eliminate duplicate words and phrases so that the resulting information is clear and understandable. Introductory text to § 347.50 has been added in this amendment to reflect the above labeling requirements.

6. The agency is proposing that the warning in § 347.50(c)(1) "For external use only" not be required for sodium bicarbonate because this ingredient can be used orally for other purposes. (See comment 3 above.)

7. Because colloidal oatmeal can be slippery in a tub of water, the agency is proposing a warning in § 347.50(c)(9) when colloidal oatmeal is labeled for use as a soak in a tub, to read "Take special care to avoid slipping when getting into and out of the tub. (See comment 1 above.)

8. The agency is proposing directions in § 347.50(d)(2) for the use of colloidal oatmeal as a skin protectant, to read "Adults and children 2 years of age and over: *For use as a soak in a tub*. Turn

tub warm water faucet on to full force, then slowly sprinkle 1 cupful of colloidal oatmeal directly under the faucet into the tub. Before entering the tub, stir any colloidal oatmeal that may have settled to the bottom of the tub. Soak the affected area for 15 to 20 minutes as needed. Do not rub area dry, but instead pat dry so that a thin layer of the colloidal oatmeal will be left on the skin. Soak once or twice daily, or as directed by your doctor. Children under 2 years of age: Consult a doctor. (See comment 1 above.)

9. The agency is proposing directions in § 347.50(d)(3) for the use of sodium bicarbonate as a skin protectant, to read: Adults and children 2 years of age and over: Topical dosage is 1 to 100 percent sodium bicarbonate.

(i) *For use as a paste.* Add sufficient water to the sodium bicarbonate to form a paste and apply to the affected area of the skin as needed. Children under 2 years of age: Consult a doctor.

(ii) *For use as a soak in a tub.* Dissolve 1 to 2 cupfuls of this product in a tub of warm water and soak for 10 to 30 minutes as needed. Do not rub dry, but instead pat dry so that a thin layer of the sodium bicarbonate will be left on the skin. Children under 2 years of age: Consult a doctor. (See comment 3 above.)

(iii) *For use as a wet dressing.* Add sodium bicarbonate to water to make a solution. Use a container in which you can saturate a cloth. Saturate a clean, soft, white cloth (such as a diaper or torn sheet) in the solution, gently squeeze, and apply loosely to the affected area. Saturate the cloth in the solution every 15 to 30 minutes and apply to the affected area. Repeat as often as necessary. Discard remaining solution after use.

The agency has examined the economic consequences of this proposed rulemaking in conjunction with other rules resulting from the OTC drug review. In a notice published in the *Federal Register* of February 8, 1983 (48 FR 5806), the agency announced the availability of an assessment of these economic impacts. The assessment determined that the combined impacts of all the rules resulting from the OTC drug review do not constitute a major rule according to the criteria established by Executive Order 12291. The agency therefore concludes that not one of these rules, including this proposed rule for OTC skin protectant drug products for the treatment and/or prevention of poison ivy, poison oak, and poison sumac, as well as for the treatment and/or neutralization of insect bites is a major rule.

The economic assessment also concluded that the overall OTC drug review was not likely to have a significant economic impact on a substantial number of small entities as defined in the Regulatory Flexibility Act (Pub. L. 96-354). That assessment included a discretionary Regulation Flexibility Analysis in the event that an individual rule might impose an unusual or disproportionate impact on small entities. However, this particular rulemaking for OTC skin protectant drug products for the treatment and/or prevention of poison ivy, poison oak, and poison sumac as well as the treatment and/or neutralization of insect bites is not expected to pose such an impact on small businesses. Therefore, the agency certifies that this proposed rule, if implemented, will not have a significant economic impact on a substantial number of small entities.

The agency invited public comment in the advance notice of proposed rulemaking regarding any impact that this rulemaking would have on OTC skin protectant drug products. No comments on economic impacts were received. Any comments on the agency's initial determination of the economic consequences of this proposed rulemaking should be submitted by January 31, 1990. The agency will evaluate any comments and supporting data that are received and will reassess the economic impact of this rulemaking in the preamble to the final rule.

The agency has determined under 21 CFR 25.24(c)(6) 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.

Interested persons may, on or before January 31, 1990, submit to the Dockets Management Branch (address above) written comments, objections, or requests for oral hearing before the Commissioner on the proposed regulation. A request for an oral hearing must specify points to be covered and time requested. Written comments on the agency's economic impact determination may be submitted on or before January 31, 1990. Three copies of all comments, objections, and requests are to be submitted, except that individuals may submit one copy. Comments, objections, and requests are to be identified with the docket number found in brackets in the heading of this document and may be accompanied by a supporting memorandum or brief. Comments, objections, and requests may be seen in the office above between 9 a.m. and 4 p.m., Monday through

Friday. Any scheduled oral hearing will be announced in the *Federal Register*.

Interested persons, on or before October 3, 1990, may also submit in writing new data demonstrating the safety and effectiveness of those conditions not classified in Category I. Written comments on the new data may be submitted on or before December 3, 1990. These dates are consistent with the time periods specified in the agency's final rule revising the procedural regulations for reviewing and classifying OTC drugs, published in the *Federal Register* of September 29, 1981 (46 FR 47730). Three copies of all data and comments on the data are to be submitted, except that individuals may submit one copy, and all data and comments are to be identified with the docket number found in brackets in the heading of this document. Data and comments should be addressed to the Dockets Management Branch. Received data and comments may also be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

In establishing a final monograph for OTC skin protectant drug products, the agency will ordinarily consider only data submitted prior to the closing of the administrative record on December 3, 1990. Data submitted after the closing of the administrative record will be reviewed by the agency only after a final monograph is published in the *Federal Register*, unless the Commissioner finds good cause has been shown that warrants earlier consideration.

List of Subjects in 21 CFR Part 347

Labeling, Over-the-counter drugs, Skin protectant drug products.

Therefore, under the Federal Food, Drug, and Cosmetic Act and the Administrative Procedure Act, it is proposed that subchapter D of chapter I of title 21 of the Code of Federal Regulations be amended in Part 347 as proposed in the *Federal Register* of February 15, 1983 (48 FR 6820) as follows:

PART 347—SKIN PROTECTANT DRUG PRODUCTS FOR OVER-THE-COUNTER HUMAN USE

1. The authority citation for 21 CFR Part 347 continues to read as follows:

Authority: Secs. 201(p), 502, 505, 701, 52 Stat. 1041-1042 as amended, 1050-1053 as amended, 1055-1056 as amended by 70 Stat. 919 and 72 Stat. 948 (21 U.S.C. 321(p), 352, 355, 371); 5 U.S.C. 553; 21 CFR 5.10 and 5.11.

2. Section 347.3 is amended by adding new paragraph (d) to read as follows:

§ 347.3 Definitions.

(d) *Poison ivy, poison oak, or poison sumac dermatitis.* An allergic contact dermatitis (usually an intensely itching skin rash) due to exposure to plants of the genus *Rhus* (poison ivy, poison oak, poison sumac), which contain urushiol, a potent skin-sensitizing agent.

3. Section 347.10 is amended by adding new paragraphs (n), (o), (p), (q), (r), and (s) and reserving them and by adding new paragraphs (t) and (u) to read as follows:

§ 347.10 Skin protectant active ingredients.

(n)–(s) [Reserved]

(t) Colloidal oatmeal.

(u) Sodium bicarbonate, 1 to 100 percent.

4. Section 347.50 is amended by adding an introductory text paragraph, by revising paragraph (a), by adding new paragraph (b)(4), by revising paragraphs (c)(1), (c)(2), and (c)(3), by adding new paragraph (c)(9), and by revising paragraph (d) to read as follows:

§ 347.50 Labeling of skin protectant drug products.

A skin protectant drug product may have more than one labeled use. When the labeling of the product contains more than one labeled use, then the appropriate statement(s) of identity, indications, warnings, and directions must be stated in the labeling. For multiple use skin protectant drug products, the labeling appropriate to different uses may be combined to eliminate duplicative words or phrases so that the resulting information is clear and understandable.

(a) *Statement of identity.* The labeling of the product contains the established name of the drug, if any, and identifies the product with one or more of the following:

(1) "Skin protectant."

(2) *For products containing any ingredient in § 347.10 (b), (c), (g), (k), (l), or (m).* "Poison ivy, oak, sumac drying" (insert dosage form, e.g., "cream, "lotion, or "ointment").

(3) *For products containing any ingredient in § 347.10 (b), (c), (g), (k), (l), (m), (t), or (u).* "Poison ivy, oak, sumac treatment.

(b)

(4) *For products containing any ingredient in § 347.10 (t) and (u).* "Provides temporary skin protection and relieves minor irritation and itching due to poison ivy, poison oak, poison sumac, and insect bites.

(c)

(1) Avoid contact with the eyes.

(2) "If condition worsens or does not improve within 7 days, consult a doctor."

(3) *For products containing any ingredient in § 347.10 (a), (b), (c), (d), (e), (f), (g), (h), (i), (j), (k), (l), (m), and (t).* "For external use only.

(9) *For products containing colloidal oatmeal identified in § 347.10(t) when labeled for use as a soak in a tub.* "Take special care to avoid slipping when getting into and out of the tub.

(d) *Directions.* The labeling of the product contains the following information under the heading "Directions":

(1) *For products containing any ingredient in § 347.10 (a), (b), (c), (d), (e), (f), (g), (h), (l), (j), (k), (l), or (m).* Apply liberally as often as necessary.

(2) *For products containing colloidal oatmeal identified in § 347.10(t).* Adults and children 2 years of age and over: *For use as a soak in a tub.* Turn tub warm water faucet on to full force, then slowly sprinkle 1 cupful of colloidal oatmeal directly under the faucet into the tub. Before entering the tub, stir any colloidal oatmeal that may have settled to the bottom of the tub. Soak the affected area for 15 to 20 minutes as needed. Do not rub area dry, but instead pat dry so that a thin layer of the colloidal oatmeal will be left on the skin. Soak once or twice daily, or as directed by your doctor. Children under 2 years of age: Consult a doctor.

(3) *For products containing sodium bicarbonate identified in § 347.10(u).* Adults and children 2 years of age and over: Topical dosage is 1 to 100 percent sodium bicarbonate.

(i) *For use as a paste.* Add sufficient water to the sodium bicarbonate to form a paste and apply to the affected area of the skin as needed. Children under 2 years of age: Consult a doctor.

(ii) *For use as a soak in a tub.* Dissolve 1 to 2 cupfuls of this product in a tub of warm water and soak for 10 to 30 minutes as needed. Do not rub dry, but instead pat dry so that a thin layer of the sodium bicarbonate will be left on the skin. Children under 2 years of age: Consult a doctor.

(iii) *For use as a wet dressing.* Add sodium bicarbonate to water to make a solution. Use a container in which you can saturate a cloth. Saturate a clean, soft, white cloth (such as a diaper or torn sheet) in the solution, gently squeeze, and apply loosely to the affected area. Saturate the cloth in the

solution every 15 to 30 minutes and apply to the affected area. Repeat as often as necessary. Discard remaining solution after use.

Dated: August 26, 1989.

Frank E. Young,

Commissioner of Food and Drugs.

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21 CFR Part 348

[Docket No. 78N-301P]

RIN 0905-AA06

External Analgesic Drug Products for Over-the-Counter Human Use; Proposed Rulemaking for Poison Ivy, Poison Oak, Poison Sumac, and Insect Bites Drug Products

AGENCY: Food and Drug Administration.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Food and Drug Administration (FDA) is issuing a notice of proposed rulemaking amending the tentative final monograph (proposed rule) for over-the-counter (OTC) external analgesic drug products. The proposed rulemaking would establish conditions under which OTC external analgesic drug products for the treatment of the symptoms of poison ivy, poison oak, poison sumac, and insect bites are generally recognized as safe and effective and not misbranded. FDA is issuing this notice of proposed rulemaking after considering the statements on OTC drug products for poison ivy, poison oak, and poison sumac, and for use as insect bite neutralizers of the Advisory Review Panel on OTC Miscellaneous External Drug Products, public comments on an advance notice of proposed rulemaking that was based on those statements, and public comments on the notice of proposed rulemaking for OTC external analgesic drug products. (See the *Federal Register* of February 8, 1983; 48 FR 5852.) The agency's proposals concerning the use of other OTC drug products for the treatment and/or prevention of poison ivy, poison oak, and poison sumac and for the treatment and/or neutralization of insect bites are being published elsewhere in this issue of the *Federal Register*. These proposals are part of the ongoing review of OTC drug products conducted by FDA.

DATES: Written comments, objections, or requests for oral hearing on the proposed rulemaking before the Commissioner of Food and Drugs by

January 31, 1990. The agency is allowing a period of 120 days for comments and objections instead of the normal 60 days for the following reasons: (1) The concurrent publication of two rulemakings regarding OTC drug products for poison ivy, poison oak, poison sumac, and insect bites and (2) this document contains the first published evaluation of several submissions of data on OTC drug products for the treatment of symptoms of these conditions that were made to, but not reviewed by, the Advisory Review Panel on OTC Miscellaneous External Drug Products (Miscellaneous External Panel). New data by October 3, 1990. Comments on the new data by December 3, 1990. Written comments on the agency's economic impact determination by January 31, 1990.

ADDRESS: Written comments, objections, new data, or requests for oral hearing to the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857

FOR FURTHER INFORMATION CONTACT: William E. Gilbertson, Center for Drug Evaluation and Research (HFD-210), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857 301-295-8000.

SUPPLEMENTARY INFORMATION: In the Federal Register of September 7 1982, FDA published, under § 330.10(a)(6) (21 CFR 330.10(a)(6)), advance notices of proposed rulemaking and reopened the administrative records for OTC external analgesic drug products (47 FR 39412) and skin protectant drug products (47 FR 39436). The notices were published to allow for consideration of statements on OTC drug products for the prevention of poison ivy, poison oak, poison sumac, and for use as insect bite neutralizers. The statements were prepared by the Miscellaneous External Panel, which was the advisory review panel responsible for evaluating data on the active ingredients used for these conditions. Interested persons were invited to submit comments by December 6, 1982. Reply comments in response to comments filed in the initial comment period could be submitted by January 5, 1983.

In the Federal Register of December 28, 1982 (47 FR 57738), in response to a request for an extension of time, the comment period and reply comment period for OTC external analgesic drug products were extended to February 4, 1983, and to March 7 1983, respectively.

In accordance with § 330.10(a)(10), the data and information considered by the Panel were put on public display in the Dockets Management Branch (address

above), after deletion of a small amount of trade secret information.

One trade association and five drug manufacturers submitted comments concerning the use of external analgesic drug products for poison ivy, poison oak, poison sumac, and insect bites (poison ivy-oak-sumac and insect bites). Some of these comments were submitted to both the external analgesic and skin protectant rulemakings. In those cases where the same comments were submitted to both rulemakings, the comments will be addressed only in the appropriate amendment to either the proposed rule for OTC external analgesic drug products or for OTC skin protectant drug products published elsewhere in this issue of the Federal Register. Copies of the comments received are on public display in the Dockets Management Branch.

The Panel provided general statements on OTC drug products for the prevention of poison ivy, poison oak, poison sumac, and for use as insect bite neutralizers. However, the Panel did not review all of the submitted individual ingredients nor develop labeling for drug products for these indications. Also, the Panel reviewed only ingredients with labeling claims for prevention of poison ivy, poison oak, or poison sumac, or for treatment of insect bites by neutralization or inactivation of insect venom. However, many submissions to the Panel were for drug products used to treat the symptoms (i.e., itching, minor irritations) of poison ivy-oak-sumac and insect bites by the mechanism of depressing or stimulating cutaneous sensory receptors. Additionally, a number of external analgesic drug products labeled for the treatment of poison ivy-oak-sumac and insect bites were not submitted to the Miscellaneous External Panel. Therefore, the agency is expanding the scope of this segment of the external analgesic rulemaking to include all OTC external analgesic drug products labeled for any of these uses.

In this document, the agency is addressing comments concerning drug products for the treatment of symptoms of poison ivy-oak-sumac and insect bites when the mechanism of action involves the depression or stimulation of cutaneous sensory receptors. In the skin protectant rulemaking (published elsewhere in this issue of the Federal Register), the agency is addressing the claims for the treatment and/or prevention of poison ivy, poison oak, and poison sumac and for the treatment and/or neutralization of insect bites when the mechanism of action for these claims involves the ingredient's ability to neutralize or inactivate insect venom or the ingredient's ability to provide a

mechanism barrier to protect the exposed skin surfaces from harmful or annoying stimuli.

In the Federal Register of February 8, 1983 (48 FR 5852), the agency published a tentative final monograph (proposed rule) for OTC external analgesic drug products. The agency issued this notice after considering the report and recommendations of the Advisory Review Panel on OTC Topical Analgesic, Antirheumatic, Otic, Burn, and Sunburn Prevention and Treatment Drug Products (Topical Analgesic Panel) and public comments on an advance notice of proposed rulemaking that was based on those recommendations.

Interested persons were invited to submit comments by April 11, 1983, new data by February 8, 1984, and comments on new data by April 9, 1984. In response to that notice, one manufacturer's association and five drug manufacturers submitted comments concerning the use of external analgesic ingredients for the treatment of poison ivy-oak-sumac and insect bites. The agency is also addressing these comments in this notice of proposed rulemaking. Copies of the comments received are on public display in the Dockets Management Branch (address above).

In this notice of proposed rulemaking, FDA responds to public comment and further discusses its position on OTC external analgesic drug products for the treatment of poison ivy-oak-sumac and insect bites. Final agency action on this matter will occur with the publication at a future date of a final rule relating to OTC external analgesic drug products for the treatment of these conditions.

The OTC drug procedural regulations (21 CFR 330.10) now provide that any testing necessary to resolve the safety or effectiveness issues that formerly resulted in a Category III classification, and submission to FDA of the results of that testing or any other data, must be done during the OTC drug rulemaking process before the establishment of a final monograph. Accordingly, FDA will no longer use the terms "Category I" (generally recognized as safe and effective and not misbranded), "Category II" (not generally recognized as safe and effective or misbranded), and "Category III" (available data are insufficient to classify as safe and effective, and further testing is required) at the final monograph stage, but will use instead the terms "monograph conditions" (old Category I) and "nonmonograph conditions" (old Categories II and III). This document retains the concepts of Categories I, II,

and III at the tentative final monograph stage.

The agency advises that the conditions under which the drug products that are subject to this monograph would be generally recognized as safe and effective and not misbranded (monograph conditions) will be effective 12 months after the date of publication of the final monograph in the **Federal Register**. On or after that date, no OTC drug product that is subject to the monograph and that contains a nonmonograph condition, i.e., a condition that would cause the drug to be not generally recognized as safe and effective or to be misbranded, may be initially introduced or initially delivered for introduction into interstate commerce unless it is the subject of an approved application. Further, any OTC drug product subject to this monograph that is repackaged or relabeled after the effective date of the monograph must be in compliance with the monograph regardless of the date the product was initially introduced or initially delivered for introduction into interstate commerce. Manufacturers are encouraged to comply voluntarily with the monograph at the earliest possible date.

If the agency determines that any labeling for a condition included in the final monograph should be implemented sooner than the 12-month effective date, a shorter deadline may be established. Similarly, if a safety problem is identified for a particular nonmonograph condition, a shorter deadline may be set for removal of that condition from OTC drug products.

All "OTC Volumes" cited throughout this document refer to the submissions made by interested persons pursuant to the call-for-data notices published in the **Federal Register** on December 12, 1972 (37 FR 26456), November 16, 1973 (38 FR 31697), and August 27, 1975 (40 FR 38179), or to additional information that has come to the agency's attention since publication of the advance notices of proposed rulemaking. The volumes are on public display in the Dockets Management Branch (address above).

I. The Agency's Tentative Conclusions on the Comments

The agency has reviewed the comments submitted to this rulemaking. As noted above, most of the comments were also submitted to the skin protectant rulemaking. Several of these comments are general in scope and will be addressed in this rulemaking for external analgesic drug products. Any of these general comments that are applicable to the skin protectant

rulemaking are incorporated into that rulemaking.

1. One comment contended that OTC drug monographs are interpretive, as opposed to substantive, regulations. The comment referred to statements on this issue submitted earlier to other OTC drug rulemaking proceedings.

The agency addressed this issue in paragraphs 85 through 91 of the preamble to the procedures for classification of OTC drug products, published in the **Federal Register** of May 11, 1972 (37 FR 9464), and in paragraph 3 of the preamble to the tentative final monograph for antacid drug products, published in the **Federal Register** on November 12, 1973 (38 FR 31280). FDA reaffirms the conclusions stated in those documents. Court decisions have confirmed the agency's authority to issue substantive regulations by rulemaking. (See, e.g., *National Nutritional Foods Association v. Weinberger*, 512 F.2d 688, 696-98 (2d Cir. 1975) and *National Association of Pharmaceutical Manufacturers v. FDA*, 487 F Supp. 412 (S.D.N.Y. 1980), *aff'd*, 637 F.2d 887 (2d Cir. 1981).)

2. Noting its continued opposition to FDA's exclusivity of labeling policy for OTC drugs, one comment stated that FDA should not prohibit the use of alternative OTC labeling terminology that is truthful, not misleading, and intelligible to the consumer. Another comment stated that its objections to FDA's "exclusivity" policy were presented at the agency's hearing on this subject on September 29, 1982.

In the **Federal Register** of May 1, 1986 (51 FR 16258), the agency published a final rule changing its labeling policy for stating the indications for use of OTC drug products. Under 21 CFR 330.1(c)(2), the label and labeling of OTC drug products are required to contain in a prominent and conspicuous location, either (1) the specific wording on indications for use established under an OTC drug monograph, which may appear within a boxed area designated

"Approved Uses"; (2) other wording describing such indications for use that meets the statutory prohibitions against false or misleading labeling, which shall neither appear within a boxed area nor be designated "Approved Uses"; or (3) the approved monograph language on indications, which may appear within a boxed area designated "Approved Uses", plus alternative language describing indications for use that is not false or misleading, which shall appear elsewhere in the labeling. All other OTC drug labeling required by a monograph or other regulation (e.g., statement of identity, warnings, and directions) must

appear in the specific wording established under the OTC drug monograph or other regulation where exact language has been established and identified by quotation marks, e.g., 21 CFR 201.63 or 330.1(g). The proposed rule in this document is subject to the labeling provisions of § 330.1(c)(2).

3. Two comments in response to the tentative final monograph for OTC external analgesic drug products (48 FR 5852) requested that specific indications for rashes caused by poison ivy be added to the monograph. One comment stated that the phrase "and rashes due to poison ivy, poison oak, or poison sumac" should be added to the indication "for the temporary relief of itching associated with sunburn, insect bites, or minor skin irritations." The comment requested that the agency revise this indication for external analgesic ingredients identified in § 348.10 (a), (b), and (c) to read "For the temporary relief of" (select one of the following: "pain, "itching, or "pain and itching") which may be followed by: "associated with" (select one or more of the following: "minor burns, "sunburn, "minor cuts, "scrapes, "insect bites, "minor skin irritations, or "rashes due to poison ivy, poison oak, or poison sumac"). The comment used the example of Category I combination products containing an external analgesic (antihistamine) and a skin protectant to support its request. The comment noted that the agency proposed the indication "Dries the oozing and weeping of poison ivy, poison oak, and poison sumac" in the skin protectant tentative final monograph (February 15, 1983; 48 FR 6820 at 6832). According to the comment, the purpose of a combination product containing a topical antihistamine and a skin protectant is both to help dry the poison ivy, poison oak, or poison sumac lesions and to relieve the itch associated with these conditions. The comment argued that not permitting an indication for the relief of itch associated with rashes due to poison ivy, poison oak, and poison sumac in the external analgesic monograph is not only inconsistent with the allowed combination but also misleading and would cause confusion to consumers.

The second comment stated that the proposed indication for external analgesic ingredients identified in § 348.10 (a), (b), and (c) of the tentative final monograph is too restrictive for the broad range of uses for these products. The comment proposed the following as an example of a truthful statement that is an appropriate indication for external analgesic drug products: "For the

temporary relief of pain and itching associated with poison ivy, poison oak, and poison sumac.

The agency agrees that indications for the relief of pain and itching associated with rashes due to poison ivy, poison oak, and poison sumac are appropriate for external analgesic ingredients identified in § 348.10 (a), (b), and (c).

The Topical Analgesic Panel recognized that the causes of pain and itch are multivariied but did not provide an exhaustive list of these causes in its report on OTC external analgesic drug products (December 4, 1979; 44 FR 69768 at 69776 and 69777). The Panel stated that itching is amenable to topically applied OTC external analgesic drug products that have antipruritic activity. The Panel explained that the anatomic pathways subserving pain and itch are identical and that itching results when cutaneous pain fibers are weakly stimulated, i.e., the difference between stimuli causing pain and itch is one of intensity. Further, the Panel stated that since the sensation of itch is mediated via pain fibers, local anesthetics and analgesics that block conduction along the axonal membranes, such as the nitrogenous drugs of the "caine" type and of the alcohol type, all have antipruritic activity. In addition, itching due to chemomediators can be relieved by drugs such as antihistamines that act competitively or combine with chemical agents released by trauma and other factors. The Panel recommended the following indication for external analgesic ingredients with antipruritic activity: "For the temporary relief of pain and itching due to minor burns, sunburn, minor cuts, abrasions, insect bites, and minor skin irritations.

In the tentative final monograph for OTC external analgesic drug products, the agency revised the Topical Analgesic Panel's recommended indication to allow the claim "For the temporary relief of itching" without listing examples of causes of itching (48 FR 5852 at 5863). The agency stated that such labeling would be clearly recognizable and meaningful to a consumer who was experiencing itching without knowing the cause. The agency also proposed in § 348.50(b)(2) the Topical Analgesic Panel's recommended list of examples of causes of itching as optional labeling as follows: "For the temporary relief of" (select one of the following: "pain," "itching," or "pain and itching") (which may be followed by: "associated with" (select one or more of the following: "minor burns," "sunburn," "minor cuts," "scrapes," "insect bites," or "minor skin irritations.")) At that time, the agency

did not expand the Panel's recommended list of causes of itching to include poison ivy, poison oak, and poison sumac because it had not evaluated the Miscellaneous External Panel's recommendations on products for that use.

The agency believes that, as with other conditions that cause pain and itching, external analgesic drug products with antipruritic activity will help to relieve the pain and itching associated with rashes due to poison ivy, poison oak, and poison sumac. Poison ivy, poison oak, and poison sumac dermatitis is an allergic contact dermatitis that usually causes an intensely itching skin rash due to exposure to plants of the genus *Rhus* (poison ivy, poison oak, and poison sumac), which contain urushiol, a potent skin-sensitizing agent (Refs. 1 and 2). The agency believes that the pain and itching of rashes caused by contact of the skin with poison ivy, poison oak, or poison sumac are readily recognizable by the consumer. The agency accepts one comment's suggestion that the phrase "rashes due to" be included in the indications statement. However, because manifestations of contact with poison ivy, oak, or sumac or other than a rash, such as blistering, may be present and not all manufacturers may want to use the phrase "rashes due to" in the indications statement, the agency is proposing that the use of this phrase be optional.

The agency is therefore proposing that the indication in § 348.50(b)(2) be revised to read "For the temporary relief of" (select one of the following: "pain," "itching" or "pain and itching,") (which may be followed by: "associated with" (select one or more of the following: "minor burns," "sunburn," "minor cuts," "scrapes," "insect bites," "minor skin irritations," (optional, may include the following: "rashes due to") "poison ivy," "poison oak," or "poison sumac.")) This revised indication will also provide for consistent labeling of a combination product containing an external analgesic and a skin protectant, as noted by one comment.

In addition, the agency is proposing in § 348.3(g) of the tentative final monograph the following definition for poison ivy, poison oak, or poison sumac dermatitis: an allergic contact dermatitis (usually an intensely itching skin rash) due to exposure to plants of the genus *Rhus* (poison ivy, poison oak, poison sumac), which contain urushiol, a potent skin-sensitizing agent.

References

- (1) "Dorland's Illustrated Medical Dictionary," 27th Ed., W. B. Saunders Co., Philadelphia, 1988, s.v. "rhus dermatitis."
- (2) "Webster's New Collegiate Dictionary," G. & C. Merriam Co., Springfield, MA, 1979, s.v. "poison ivy."

4. One comment submitted data to the agency in support of claims for 3.6 percent ammonium hydroxide for the "relief of pain and itching from insect bites and discomfort due to nettle and berry bush scratches" (Ref. 1). In a later submission (Ref. 2), the company stated that the ingredient does not work by reducing inflammation or wheal size, nor is there any indication that it neutralizes insect venom. The company described a possible mechanism of action and concluded that the ingredient has a generalized antipruritic effect in relieving pain and itching that follow insect bites. The company noted the Topical Analgesic Panel's Category I classification of 1 to 2.5 percent ammonium hydroxide as a counterirritant (44 FR 69768 at 69792) and stated that the transcripts of the Panel's meetings show that members of that Panel recognized that ammonium hydroxide was effective for relief of itching due to insect bites. The company requested that 3.6 percent ammonium hydroxide be classified as a Category I antipruritic external analgesic ingredient in the final monograph for OTC external analgesic drug products.

Because the company has requested an antipruritic claim for all conditions included in the external analgesic tentative final monograph, the agency is not addressing the data in this document, which addresses only poison ivy-oak-sumac and insect bite claims. The agency will discuss the data regarding ammonium hydroxide in the final monograph for OTC external analgesic drug products in a future issue of the Federal Register.

References

- (1) Comment No. C00046, Docket No. 78N-0301, Dockets Management Branch.
- (2) Comment coded HER, Docket No. 78N-0301, Dockets Management Branch.

II. The Agency's Evaluation of the Submissions

The Miscellaneous External Panel reviewed only the use of OTC drug products for the prevention of poison ivy, poison oak, and poison sumac and for use as insect bite neutralizers. The Panel recommended that the agency consider in appropriate rulemakings ingredients and labeling claims submitted for treating poison ivy, poison oak, poison sumac, and their related symptoms (47 FR 39412 at 39417).

In this document, the agency discusses the use of OTC external analgesic drug products for the treatment of poison ivy-oak-sumac and insect bites. The agency has evaluated a number of submissions (Ref. 1) that were not reviewed by the Panel. Some of the submissions include drug products that are no longer marketed or that have been reformulated to include active ingredients and/or conditions that were proposed in the tentative final monograph for OTC external analgesic drug products (48 FR 5852). The manufacturers of these drug products have requested that their submissions or portions of their submissions concerning these drug products be withdrawn from further consideration in this rulemaking, as follows:

(1) Submissions (Ref. 2) concerning drug products containing pyrilamine maleate for the treatment of the symptoms of insect bites and/or poison ivy, poison oak, and poison sumac were withdrawn by the manufacturers (Refs. 3 and 4).

(2) A submission (Ref. 5) concerning a combination drug product containing chlorobutanol, glycerin, boric acid, salicylic acid, resorcinol, phenol, oxyquinoline sulfate, camphor, and 28 percent alcohol for the treatment of the symptoms of insect bites and poison ivy was withdrawn by the manufacturer (Ref. 6).

(3) A submission (Ref. 7) concerning a combination drug product containing benzocaine, phenol, and iodine for the treatment of the symptoms of insect bites and poison ivy was withdrawn by the manufacturer (Ref. 8).

(4) A submission (Ref. 9) concerning a combination drug product containing ethyl alcohol, gum camphor, oil of eucalyptus, and boric acid for the itch of insect bites and poison ivy, poison oak, and poison sumac was withdrawn by the manufacturer (Ref. 10).

(5) A portion of two submissions (Ref. 11) concerning drug products containing dexpanthenol in lotion form for the treatment of the symptoms of insect bites, poison ivy, and poison sumac was withdrawn by the manufacturer (Ref. 12).

References

(1) OTC Volumes 160006, 160076, 160104, 160124, 160204, and 160288.

(2) OTC Volumes 160074, 160080, 160132, 160156, and 160216.

(3) Letter from J. Wright, North Health Care, to W.E. Gilbertson, FDA, dated April 15, 1988, included in OTC Volume 06PIETFM.

(4) Letter from W.E. Byerley, Law Offices of W.E. Byerly, to H. Cothran, FDA, dated April 29, 1988, included in OTC Volume 06PIETFM.

(5) OTC Volume 160059.

(6) Letter from S. Smith, Dep Corp., to W.E. Gilbertson, FDA, dated May 3, 1988, included in OTC Volume 06PIETFM.

(7) OTC Volume 160278.

(8) Letter from M.H. Davis, Whitehall Laboratories, to W.E. Gilbertson, FDA, dated July 13, 1988, included in OTC Volume 06PIETFM.

(9) OTC Volume 160084.

(10) Letter from L. Sonopp, Clairol, to W.E. Gilbertson, FDA, dated June 9, 1987 included in OTC Volume 06PIETFM.

(11) OTC Volumes 160104 and 160204.

(12) Letter from A. Ryan, Armour Pharmaceutical Co., to L. Geismar, FDA, dated January 7 1987 included in OTC Volume 06PIETFM.

5. One manufacturer submitted data in 1975 (Refs. 1 and 2) in support of the safety and efficacy of the combination of 2 percent dexpanthenol, 0.1 percent camphor, and 0.1 percent menthol "for use in mild eczemas and dermatoses; itching skin, minor wounds, stings, bites, poison ivy and poison oak (dry stage), minor skin irritations. The current labeling (submitted in 1987) contains the same indications, but lists dexpanthenol 2 percent as the only active ingredient (Ref. 3)

Because camphor and menthol are no longer listed as active ingredients in the product, the agency is addressing only dexpanthenol for use in the treatment of poison ivy-oak-sumac and insect bites in this comment. Dexpanthenol was not reviewed by any OTC advisory review panel for these uses.

The agency has evaluated one study on acute oral toxicity of dexpanthenol in male rats (Ref. 1). In a 14-day study, three preparations containing 2 percent dexpanthenol were orally administered to groups of six rats at a dose level of 50 milliliters per kilogram; no toxic or untoward effects, mortality, or loss of body weight occurred. However, the data provided no detailed information, and were neither blinded nor well-controlled. Dixon and Mastin (Ref. 4) treated 69 patients with various skin conditions of the lower extremities with a 2-percent dexpanthenol cream and reported that no evidence of sensitization was encountered. Likewise, no evidence of sensitization with the topical use of 2 percent dexpanthenol was observed by Welsh and Ede (Ref. 5) in 54 patients treated for dermatoses of various causes, by Kline and Caldwell (Ref. 6) in 31 patients treated for a variety of dermatoses, or by Kline (Ref. 7) in 500 dermatologic patients.

Regarding effectiveness, Dixon and Mastin (Ref. 4) cited 17 representative cases out of 69 patients and summarized the results in a table. In the table, the authors report some clinical evidence of relief of irritation and pruritus in a

variety of skin diseases. However, none of the subjects had poison ivy, poison oak, poison sumac, or insect bites. Kline and Caldwell (Ref. 6) summarized 31 cases of various dermatoses treated with topical application of 2 and/or 5-percent dexpanthenol. The authors reported that many of the patients with skin diseases that cause itching obtained excellent results. However, none of the subjects had poison ivy, poison oak, poison sumac, or insect bites. The authors did state that further investigation of the topical application of this drug in other types of dermatoses is indicated. Kline (Ref. 7) reported 12 years of experience with topical dexpanthenol treatment of 500 dermatologic patients with a variety of itching dermatoses, including 64 patients with acute or chronic contact dermatitis (412 patients out of 500 or 82.4 percent obtained satisfactory results). However, none of the above studies were either blinded or well-controlled. Because no well-controlled safety or efficacy data were submitted to support topical use of 2 percent dexpanthenol for itching, such as that associated with poison ivy-oak-sumac or insect bites, the agency is classifying 2 percent dexpanthenol in Category III for safety and effectiveness for these uses.

Although the submitted labeling lists dexpanthenol as the active ingredient in the drug product, the United States Pharmacopeia recognizes both panthenol, which is a racemic mixture, and dexpanthenol, which is the dextro-form of panthenol (Ref. 8). Therefore, the agency is classifying both dexpanthenol and panthenol in Category III.

References

(1) OTC Volume 160104.

(2) OTC Volume 160204.

(3) Letter from A. Ryan, Armour Pharmaceutical Co., to L. Geismar, FDA, dated January 7 1987 in OTC Volume 06PIETFM.

(4) Dixon, F. C., and M. N. Mastin, "The Use of Panthothenylol in Lower Extremity Lesions, *Journal of the National Association of Chiropractors*, 47:61-62 and 108, 1957

(5) Welsh, A. L., and M. Ede, "Panthoderm: A Topical Therapeutic Adjuvant, *A.M.A. Archives of Dermatology and Syphilology*, 69:732-734, 1945.

(6) Kline, P. R., and A. Caldwell, "Treatment of Various Dermatoses with Topical Application of Panthenol, *New York State Journal of Medicine*, 52:1141-1143, 1952.

(7) Kline, P. R., "12 Years Experience Using Pantothenylol Topically, *Western Medicine*, 4:78-81, 1963.

(8) "United States Pharmacopeia XXI—National Formulary XVI, United States Pharmacopeial Convention, Inc., Rockville; MD, pp. 296 and 781, 1985.

6. One comment submitted data to the Miscellaneous External Panel to support the safety and effectiveness of 1 to 2 percent diphenhydramine hydrochloride applied topically "for relief of itching due to insect bites, mild cases of sunburn, poison ivy or oak, and other minor skin irritations" and "for relief of itching due to mild poison ivy or oak, insect bites, or other minor skin irritations, and soothing relief of mild sunburn" (Ref. 1). The data included the results of three studies of a test product containing 1 percent diphenhydramine hydrochloride, calamine lotion, camphor, and 2 percent alcohol for the relief of itching caused by poison ivy/oak. In these studies, the antipruritic effect of diphenhydramine hydrochloride in the test product was compared with the antipruritic effect of calamine lotion alone as a control. The control did not contain diphenhydramine, camphor, or alcohol. According to the comment, the principal difference between the test product and the control is the presence of 1 percent diphenhydramine hydrochloride in the test product. No adverse reactions were reported in any of the studies.

The agency has evaluated the following three studies:

(1) Protocol 282-15 (Ref. 2) is a double-blind controlled study which included 45 subjects with a history of contact dermatitis (poison ivy/oak) with a pruritic component. To induce a contact dermatitis, poison ivy antigen patches were applied to both forearms and removed after 24 to 48 hours of contact with the skin. Both subjective and objective evaluations and examinations of the contact dermatitis were made. Subjects then applied the test product on one arm and the control containing calamine on the other arm every 3 hours and at night, as desired, for 3 consecutive days after development of contact dermatitis. After 3 days of observation, 84 percent preferred the test product for relief of itching. The investigators concluded that the test product reduced pruritus more than the control.

(2) Protocol 282-12 (Ref. 3) is a double-blind, randomized, controlled study. Poison ivy was induced with challenge patches in 50 subjects with a history of hypersensitivity to poison ivy. Twenty subjects with the most severe itching after the application of challenge patches were selected for the study. The test product was applied to one arm, and the control was applied to the other arm every 3 hours in six applications over a 24-hour period. Pruritus was assessed after each application. The investigator stated that a statistical

analysis utilizing a t-test ($t_{19} = 3.75$, $p < 0.01$) strongly indicates that the antipruritic response with the use of the test product is significantly superior to the control.

(3) Protocol 282-10 (Ref. 4) is a double-blind, randomized, controlled study. Sixteen out of 29 subjects with artificially-induced poison ivy were studied after developing moderate to severely pruritic lesions. The test product was applied to one arm and the control was applied to the other arm every 3 hours for 48 hours. Pruritus was assessed after each application. The investigators found a significant difference ($p < 0.05$) in favor of the test product.

The agency has determined that these studies were inappropriately designed because the test product contained camphor and alcohol but the control did not contain camphor and alcohol. The Topical Analgesic Panel has recommended (December 4, 1979; 44 FR 69768) and the agency has proposed (February 8, 1983; 48 FR 5852) that camphor be a Category I analgesic, anesthetic, and antipruritic at a 0.1- to 0.3-percent concentration. Because of the nature of the studies, it cannot be determined whether the 1 percent diphenhydramine hydrochloride, the camphor, or both provided the relief obtained. Although there is a problem with the study design, based on other information discussed below concerning the antipruritic properties of diphenhydramine hydrochloride, the agency believes that the above studies provide supporting evidence that 1 percent diphenhydramine hydrochloride relieves itching caused by poison ivy or oak.

The above data were not examined by the Miscellaneous External Panel in its statement on OTC drug products for the prevention of poison ivy, poison oak, and poison sumac. That Panel stated that ingredients such as diphenhydramine hydrochloride should be considered in other appropriate rulemakings for their use in treating poison ivy, poison oak, poison sumac, and their related symptoms. (See 47 FR 39412 at 39417 and 39440.) The Miscellaneous External Panel was aware that the Topical Analgesic Panel had reviewed similar data (Ref. 5) concerning the antipruritic effectiveness of 1 to 2 percent diphenhydramine hydrochloride and had recommended Category I status for this ingredient in its proposed monograph with the indication "For the temporary relief of pain and itching due to minor burns, sunburn, minor cuts, abrasions, insect bites, and minor skin irritations" (44 FR

69768 at 69865). In the tentative final monograph for OTC external analgesic drug products (48 FR 5852), the agency concurred with the Topical Analgesic Panel's recommendations and also agreed with a comment to that Panel's report that products containing antipruritic ingredients (including diphenhydramine hydrochloride) should be allowed to use the general indication "For the temporary relief of itching" without listing specific examples of the causes of the itching, or for itching associated with one or more causes. (See comment 28 at 48 FR 5863.) Section 348.50(b)(2) of the external analgesic tentative final monograph already provides the option of listing specific causes of itching such as "insect bites, "sunburn, and "minor skin irritations."

After reviewing the above data, the agency is now proposing to amend § 348.50(b)(2) to expand the list of optional causes of itching by adding "poison ivy, "poison oak, and "poison sumac. As revised, proposed § 348.50(b)(2) will now read as follows: *For products containing any external analgesic active ingredients identified in § 348.10 (a), (b), and (c).* "For the temporary relief of" (select one of the following: "pain, "itching, or "pain and itching") (which may be followed by: "associated with" (select one or more of the following: "minor burns, "sunburn, "minor cuts, "scrapes, "insect bites, "minor skin irritations, (optional, may include the following: "rashes due to") "poison ivy, "poison oak, or "poison sumac.")) (See also comment 3 above.)

References

- (1) OTC Volume 160124.
- (2) Protocol 282-15, draft of unpublished data, in OTC Volume 160124.
- (3) Protocol 282-12, draft of unpublished data, in OTC Volume 160124.
- (4) Protocol 282-10, draft of unpublished data, in OTC Volume 160124.
- (5) OTC Volume 060095.

7 One manufacturer submitted data and information (Refs. 1 and 2) to the Miscellaneous External Panel on three combination drug products containing either 8 or 10 percent tannic acid and requested that these combinations be Category I for the temporary relief of itching associated with poison ivy, poison oak, or poison sumac. In addition to 10 percent tannic acid, one product contains 12.5 percent isopropanol as an active ingredient and is labeled "for temporary relief of itching associated with poison ivy, oak or sumac. A second product contains the following active ingredients: 10 percent tannic acid, 1.25 percent benzocaine, 0.4

percent camphor, 0.2 percent menthol, and 35 percent isopropanol, and is labeled "for the temporary relief of poison ivy-oak-sumac, sunburn, insect bites and other minor irritations." The third product contains the active ingredients 8 percent tannic acid, 0.5 percent benzocaine, 0.4 percent menthol, and 0.6 percent camphor, and is labeled "for the relief of minor pain and itching caused by poison ivy, poison oak, insect bites, sunburn and other minor skin irritations. The manufacturer stated that the tannic acid-isopropanol combination has been marketed since 1943, based on the findings of Schwartz and Warren (Ref. 3) and on informal testing by "local physicians, as a "safe, simple and economical product which helped to dry the blisters and relieved the itching due to poison ivy rash. The submissions included a 1949 "Federal Security Agency Public Health Service Health Information Series No. 65" publication that describes a method of using a 10-percent alcoholic solution of tannic acid to treat mild cases of poison ivy (Ref. 1). The manufacturer stated that the multicomponent combination drug products "were added as additional forms [of the original drug product] for the convenience of the users, and that all of the active and inactive components of the products have been acceptable to the medical profession and have been used in OTC drugs for many years. The manufacturer submitted several letters from consumers supporting the safety and effectiveness of these products and stated that it has an extensive file containing testimonials from satisfied customers confirming the effectiveness of its products. The submissions contained several studies on the safety of tannic acid or tannin and a table of summaries of several studies on the carcinogenicity of tannic acid (Refs. 2 and 4 through 8). The manufacturer concluded that 35 years of marketing experience with no serious complaints other than staining of the skin or clothing substantiates the fact that the products are safe and effective for the labeling claims. The manufacturer added that over this period of time its tannic acid-isopropanol product "has proven to be a mild, safe product to alleviate the discomforts of mild cases of poison ivy, sunburn, insect bites and minor skin irritations due to its astringent and protein precipitating properties. The manufacturer noted that it had compared its product "subjectively to every other leading OTC product on the market" and found its product to be at least as effective and generally more effective than other

products, with no undesirable side effects.

The Topical Analgesic Panel reviewed tannic acid and stated that this ingredient is not safe for use as an OTC skin protectant (August 4, 1978; 43 FR 34628 at 34644). The Panel reviewed studies concerning the safety of topical use of tannic acid (Refs. 9, 10, and 11) and stated that the documented hepatotoxicity of tannic acid with repeated topical applications over large areas of damaged skin make this ingredient unsuitable for use as a skin protectant. In addition, the Panel stated that the desired effect of tannic acid, i.e., to produce a protein precipitate which would act as a protective coat (43 FR 34628 at 34644), causes the formation of an outer crust under which bacterial growth may flourish. The Miscellaneous External Panel and the agency concurred with the Topical Analgesic Panel's conclusions regarding the safety of tannic acid (47 FR 39412 at 39426 and 48 FR 6820 at 6825).

The manufacturer's summaries of some of the studies cited in support of the safety of tannic acid (Ref. 1) indicate that either no data were presented in the studies (Refs. 2 and 7) or the studies concerned the carcinogenic effect of tannic acid (Refs. 4, 6, and 8). One other study cited by the manufacturer (Ref. 5) was reviewed by the Topical Analgesic Panel in its discussion of tannic acid (43 FR 34628 at 34644). The Panel's evaluation of this study did not change its view that tannic acid is not safe for use as an OTC skin protectant. The studies cited in the submissions do not address the issues raised by the Panel, i.e., (1) that repeated use of tannic acid over large areas of damaged skin can cause liver damage, or (2) that formation of an outer crust on the skin (produced by the tannin's ability to precipitate protein) may allow bacteria to grow and flourish under the crust.

In addition, the information submitted on the effectiveness of 10 percent tannic acid to relieve itching of poison ivy-oak-sumac or insect bites is inadequate. The 1949 Public Health Service publication (Ref. 1) describes the use of a 10-percent alcoholic solution of tannic acid to treat mild cases of poison ivy, but does not present any data concerning the effectiveness of this solution. The 1941 Schwartz and Warren study (Ref. 3) involved "only 11 patients having dermatitis presumably caused by poison ivy, one of whom failed to return for final observation. The authors state that itching and discomfort in nine of the patients stopped within 1 or 2 days and all nine had recovered at the end of 1 week. The authors go on to state that the

10th patient, who did not fully recover for 2 weeks, was suspected of having dermatitis caused by crab grass, not poison ivy. This study does not support the effectiveness of 10 percent tannic acid because it is uncontrolled, the etiology of the dermatitis is uncertain, and objective methods of determining the effectiveness of the treatment are not described. In fact, the authors state that this treatment is reported in the hope that other physicians will give it a trial, and either confirm or disprove the efficacy of this treatment on a larger number of patients.

The testimonials included in the submissions are not adequate to establish effectiveness. The standards for establishing effectiveness in the OTC drug review state that isolated case reports, random experience, and reports lacking the details which permit scientific evaluation will not be considered. (See 21 CFR 330.10(a)(4)(ii).)

Based on the above, the agency is placing 8 to 10 percent tannic acid in Category III for the temporary relief of itching associated with poison ivy-oak-sumac and insect bites. Therefore, any combination drug product that contains 8 to 10 percent tannic acid for these uses is also Category III.

With respect to the other active ingredients in the submitted combination drug products, 0.2 percent menthol and 0.4 percent camphor are Category I external analgesics and may be combined; isopropanol has not been classified as an external analgesic or as a skin protectant and would require adequate data to support its safety and effectiveness for such use; and although 5 to 20 percent benzocaine is Category I as an external analgesic, 0.5 to 1.25 percent benzocaine and any combination containing 0.5 to 1.25 percent benzocaine are Category III and would require adequate data to demonstrate effectiveness.

References

- (1) OTC Volume 160076.
- (2) OTC Volume 160288.
- (3) Schwartz, L., and L. H. Warren, "Tannic Acid Treatment of Poison Ivy (*Rhus* Spp.) Dermatitis, *Public Health Reports*, 56:1039-1041, 1941.
- (4) Armstrong, D. M. G., E. G. C. Clark, and E. Cotchin, "A Note on the Acute Toxicity of Hydrolyzable and Condensed Tannins, *The Journal of Pharmacy and Pharmacology*, 9:98-101, 1957.
- (5) Korpassy, B., and M. Mosonyi, "The Carcinogenic Action of Tannic Acid: Effect of Casein on the Development of Liver Tumors, *Acta Morphologica Academiae Scientiarum Hungaricae*, 1:37-54, 1951.
- (6) Krezanoski, J. Z., "Tannic Acid: Chemistry, Analysis, and Toxicology, *Radiology*, 87:655-657 1966.

(7) Korpassy, B., and M. Mosonyi, "The Carcinogenic Activity of Tannic Acid; Liver Tumors Induced in Rats by Prolonged Subcutaneous Administration of Tannic Acid Solutions," *British Journal of Cancer*, 4:411-420, 1950.

(8) Robinson, H. J., and O. E. Graessle, "Toxicity of Tannic Acid," *Journal of Pharmacology*, 77:63-69, 1943.

(9) Wells, D. B., H. D. Humphrey, and J. J. Coll, "The Relation of Tannic Acid to Liver Necrosis Occurring in Burns," *The New England Journal of Medicine*, 226:629-636, 1942.

(10) Barnes, J. M., and R. J. Rossiter, "Toxicity of Tannic Acid," *The Lancet*, 2:218-222, 1943.

(11) McClure, R. D., C. R. Lam, and H. Romence, "Tannic Acid and the Treatment of Burns: An Obsequy," *Annals of Surgery*, 120:387-398, 1944.

8. One manufacturer (Ref. 1) submitted data and information for a product containing 0.5 percent tripeleannamine hydrochloride, and 0.5 percent methapyrilene hydrochloride, and 0.1 percent menthol in combination with 0.0495 percent benzalkonium chloride with the labeling claims "Relieves itch and discomforts of skin allergies, hives, bee stings, nonpoisonous insect bites, poison ivy and oak, sunburn and minor skin disorders, and "Helps prevent skin infection. The comment subsequently informed the agency that it had reformulated its product by substituting 1 percent diphenhydramine hydrochloride for the 0.5 percent methapyrilene hydrochloride, but did not submit any additional data on the reformulated product (Ref. 2). The company subsequently submitted updated labeling stating that the active ingredients are diphenhydramine hydrochloride 1.0 percent, tripeleannamine hydrochloride 0.5 percent, and benzalkonium chloride 0.12 percent and that menthol is an inactive ingredient (Ref. 3).

Two of the three active ingredients (tripeleannamine hydrochloride and diphenhydramine hydrochloride) have been proposed as Category I for the temporary relief of pain and/or itching associated with insect bites and minor skin irritations in the tentative final monograph for OTC external analgesic drug products (48 FR 5852 at 5868). The Topical Analgesic Panel stated that there is evidence that topical creams containing 2 to 3 percent tripeleannamine hydrochloride are effective in temporarily relieving the pruritus of poison ivy eruptions (44 FR 69768 at 69839). Based on the agency's discussion of poison ivy, poison oak, and poison sumac claims for all Category I antipruritic ingredients in comments 3 and 6 above, tripeleannamine

hydrochloride and diphenhydramine hydrochloride are being proposed as Category I ingredients for the temporary relief of pain and/or itch associated with poison ivy-oak-sumac, insect bites, and minor skin irritations. The agency proposed that benzalkonium chloride, the third active ingredient in the product, be classified Category III for use as a skin antiseptic and as a skin wound protectant in the tentative final monograph for OTC topical antimicrobial drug products (January 6, 1978; 43 FR 1210 at 1229). This ingredient will be discussed further in the tentative final monograph for OTC first aid antiseptic drug products in a future issue of the **Federal Register**.

Proposed § 348.20(b)(2) of the external analgesic tentative final monograph provides for the combination of the antihistamine tripeleannamine hydrochloride or diphenhydramine hydrochloride and any Category I topical antimicrobial active ingredient or combination identified in Part 333, when labeled for concurrent symptoms (48 FR 5852 at 5868). However, because the product described above contains two antihistamines, it does not qualify as a permitted combination included in § 348.20, nor does it meet the agency's combination policy for OTC drugs as stated in 21 CFR 330.10(a)(4)(iv) and in the agency's general guidelines for OTC drug combination products (Ref. 4). These guidelines state that Category I active ingredients from the same therapeutic category (antihistamines, in this case) that have the same mechanism of action should not ordinarily be combined unless there is some advantage over the single ingredients in terms of enhancing effectiveness, safety, patient acceptance, or quality of formulation. No data have been submitted demonstrating any of these advantages. Therefore, such a combination of ingredients is classified as Category III for treating poison ivy-oak-sumac and insect bites. Further, in a telephone conversation between representatives of the agency and the company, a company representative indicated that the diphenhydramine "was likely to be deleted" from the product at the time that a final order goes into effect (Ref. 5).

References

- (1) OTC Volume 160006.
- (2) Letter from H.W. Gordon, Commerce Drug Co., Inc., to W.E. Gilbertson, FDA, dated January 14, 1983, included in OTC Volume 06PIETFM.
- (3) Letter from H.W. Gordon, Commerce Drug Co., Inc., to M. Benson, FDA, dated April 20, 1988, included in OTC Volume 06PIETFM.

(4) "Food and Drug Administration General Guidelines for OTC Drug Combination Products," September 1978, Docket No. 78D-0322, Dockets Management Branch.

(5) Memorandum of telephone conversation between H.W. Gordon, Commerce Drug Co., Inc., and M. Benson, FDA, dated March 3, 1983, included in OTC Volume 06PIETFM.

III. The Agency's Tentative Conclusions and Adoption of the Panel's Statements

A. Summary of Ingredient Categories and Testing of Category II and Category III Conditions

1. Summary of Ingredient Categories

In the Miscellaneous External Panel's advance notice of proposed rulemaking for external analgesic drug products (47 FR 39412 at 39416 and 39430), the Panel stated that, although the agency's call-for-data notices (38 FR 31697 and 40 FR 38179) requested the submission of data and information for a number of specific active ingredients (47 FR 39412 at 39416 and 39430) or any other active ingredients used in OTC poison ivy and oak remedy drug products and insect bites drug products, the Panel reviewed only those ingredients with claims for preventing poison ivy, poison oak, or poison sumac or for treating insect bites by neutralization or inactivation of insect venom. As stated above, drug products for the treatment and/or prevention of poison ivy, poison oak, and poison sumac and for the treatment and/or neutralization of insect bites are discussed in the skin protectant rulemaking published elsewhere in this issue of the **Federal Register** and will not be discussed further here.

Although the Miscellaneous External Panel mentioned the use of external analgesic ingredients for the treatment of poison ivy-oak-sumac and insect bites, it did not review or classify all of the individual ingredients. Most of the ingredients in marketed products submitted to the Panel or ingredients that appeared in the call-for-data notices were simply listed in the Panel's statements on OTC drug products for the prevention of poison ivy, poison oak, and poison sumac (47 FR 39412 at 39416) and on OTC insect bite neutralizer drug products (47 FR 39412 at 39430). The Panel noted at 47 FR 39417 that many of these ingredients labeled with claims for the relief of minor skin irritations, itching, and rashes due to poison ivy, poison oak, and poison sumac have been previously addressed by another OTC panel, the Topical Analgesic Panel. The agency has further considered the recommendations of the Topical Analgesic Panel on OTC external analgesic drug products (44 FR 69768), the tentative final monograph on OTC

external analgesic drug products (48 FR 5852), and the additional data and information available at this time. Based upon this information, the agency is adding several active ingredients to the "Summary of Ingredient Categories" table for analgesic, anesthetic, and antipruritic active ingredients that appeared in the tentative final monograph for OTC external analgesic drug products (48 FR 5852 at 5865). These ingredients are benzocaine 0.5 to 1.25 percent, dexpanthenol, panthenol, and tannic acid. An updated table appears below for the convenience of the reader.

SUMMARY OF INGREDIENT CATEGORIES

Analgesic, anesthetic, and antipruritic active ingredients	Category
Aspirin.....	III
Benzocaine	I
(a) 5 to 20 percent.....	I
(b) 0.5 to 1.25 percent.....	III
Benzyl alcohol.....	I
Butamben picrate.....	I
Camphor.....	I
Camphorated metacresol.....	I
Chloral hydrate.....	II
Chlorobutanol.....	III
Cyclomethycaine sulfate.....	III
Dexpanthenol.....	III
Dibucaine.....	I
Dibucaine hydrochloride.....	I
Dimethisoquin hydrochloride.....	I
Diphenhydramine hydrochloride.....	I
Dyclonine hydrochloride.....	I
Eugenol.....	III
Glycol salicylate.....	III
Hexylresorcinol.....	III
Hydrocortisone.....	I
Hydrocortisone acetate.....	I
Juniper tar.....	I
Lidocaine.....	I
Lidocaine hydrochloride.....	I
Menthol.....	I
Methapyrilene hydrochloride.....	II
Panthenol.....	III
Phenol.....	III
Phenolate sodium.....	I
Pramoxine hydrochloride.....	I
Resorcinol.....	I
Salicylamide.....	III
Tannic acid.....	I
Tetracaine.....	I
Tetracaine hydrochloride.....	I
Thymol.....	III
Trolamine salicylate.....	III
Tripeleennamine hydrochloride.....	I

Hydrocortisone and hydrocortisone acetate are OTC external analgesics only for use as topical antipruritics.
Identified by the Topical Analgesic Panel as triethanolamine salicylate.

The Miscellaneous External Panel's list of ingredients in marketed products for treating poison ivy, poison oak, poison sumac, and their related symptoms (47 FR 39412 at 39417) included a number of ingredients, with the exception of sodium bicarbonate, for which no information was provided. These ingredients are considered Category II. The agency is addressing sodium bicarbonate in the skin

protectant document published elsewhere in this issue of the **Federal Register** because the mechanism of action of sodium bicarbonate involves the ingredient providing a mechanical barrier to protect the exposed skin surfaces from harmful or annoying stimuli.

2. Testing of Category II and Category III Conditions

The agency is not proposing specific testing guidelines in this document. Interested persons may communicate with the agency about the submission of data and information to demonstrate the safety or effectiveness of any external analgesic ingredients or conditions included in the review for the treatment of poison ivy-oak-sumac and insect bites by following the procedures outlined in the agency's policy statement published in the **Federal Register** of September 29, 1981 (46 FR 47740) and clarified April 1, 1983 (48 FR 14050). That policy statement includes procedures for the submission and review of proposed protocols, agency meetings with industry or other interested persons, and agency communications on submitted test data and other information.

B. Summary of the Agency's Changes

FDA has considered comments submitted to the Topical Analgesic Panel and the Miscellaneous External Panel, the submissions to the Miscellaneous External Panel, and other relevant information and concludes that it will tentatively adopt the substance of the Miscellaneous External Panel's statements. This Panel did not recommend a specific monograph for external analgesic drug products for use in the treatment of poison ivy-oak-sumac and insect bites. However, the Topical Analgesic Panel did recommend a monograph for external analgesic drug products (44 FR 69768), and the agency adopted this recommended monograph with some revisions in the tentative final monograph for OTC external analgesic drug products (48 FR 5852 at 5867). In this document, the agency is amending that tentative final monograph to include conditions for the treatment of poison ivy-oak-sumac and insect bites based on its evaluations of the data and its responses to the comments described above. A summary of the changes made by the agency follows.

1. The agency is proposing in § 348.3(g) to add a definition for poison ivy, poison oak, or poison sumac dermatitis to the tentative final monograph. (See comment 3 above.)

2. The agency is amending proposed § 348.50(b)(2) ("Indications") by expanding the optional list of causes of

itching to include "poison ivy, "poison oak, and "poison sumac" to read: "For the temporary relief of" (select one of the following: "pain," "itching, or "pain and itching") (which may be followed by: "associated with" (select one or more of the following: "minor burns, "sunburn, "minor cuts, "scrapes," "insect bites, "minor skin irritations," (optional, may include the following: "rashes due to") "poison ivy," "poison oak, or "poison sumac.")) (See comment 3 above.)

The agency has examined the economic consequences of this proposed rulemaking in conjunction with other rules resulting from the OTC drug review. In a notice published in the **Federal Register** of February 8, 1983 (48 FR 5806), the agency announced the availability of an assessment of these economic impacts. The assessment determined that the combined impacts of all the rules resulting from the OTC drug review do not constitute a major rule according to the criteria established by Executive Order 12291. The agency therefore concludes that not one of these rules, including this proposed rule for OTC external analgesic drug products for the treatment of poison ivy-oak-sumac and insect bites, is a major rule.

The economic assessment also concluded that the overall OTC drug review was not likely to have a significant economic impact on a substantial number of small entities as defined in the Regulatory Flexibility Act (Pub. L. 96-354). That assessment included a discretionary Regulatory Flexibility Analysis in the event that an individual rule might impose an unusual or disproportionate impact on small entities. However, this particular rulemaking for OTC external analgesic drug products for the treatment of poison ivy-oak-sumac and insect bites is not expected to pose such an impact on small businesses. Therefore, the agency certifies that this proposed rule, if implemented, will not have a significant economic impact on a substantial number of small entities.

The agency invited public comment in the advance notice of proposed rulemaking regarding any impact that this rulemaking would have on OTC external analgesic drug products. No comments on economic impacts were received. Any comments on the agency's initial determination of the economic consequences of this proposed rulemaking should be submitted by January 31, 1990. The agency will evaluate any comments and supporting data that are received and will reassess the economic impact of this rulemaking in the preamble to the final rule.

The agency has determined under 21 CFR 25.24(c)(6) 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.

Interested persons may, on or before January 31, 1990, submit to the Dockets Management Branch (address above) written comments, objections, or requests for oral hearing before the Commissioner on the proposed regulation. A request for an oral hearing must specify points to be covered and time requested. Written comments on the agency's economic impact determination may be submitted on or before January 31, 1990. Three copies of all comments, objections, and requests are to be submitted, except that individuals may submit one copy. Comments, objections, and requests are to be identified with the docket number found in brackets in the heading of this document and may be accompanied by a supporting memorandum or brief. Comments, objections, and requests may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday. Any scheduled oral hearing will be announced in the *Federal Register*.

Interested persons, on or before October 3, 1990, may also submit in writing new data demonstrating the safety and effectiveness of those conditions not classified in Category I. Written comments on the new data may be submitted on or before December 3, 1990. These dates are consistent with the time periods specified in the agency's final rule revising the procedural regulations for reviewing and classifying OTC drugs, published in the

Federal Register of September 29, 1981 (46 FR 47730). Three copies of all data and comments on the data are to be submitted, except that individuals may submit one copy, and all data and comments are to be identified with the docket number found in brackets in the heading of this document. Data and comments should be addressed to the Dockets Management Branch. Received data and comments may also be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

In establishing a final monograph for OTC external analgesic drug products, the agency will ordinarily consider only data submitted prior to the closing of the administrative record on December 3, 1990. Data submitted after the closing of the administrative record will be reviewed by the agency only after a final monograph is published in the *Federal Register*, unless the Commissioner finds good cause has been shown that warrants earlier consideration.

List of Subjects in 21 CFR Part 348

External analgesic drug products, Labeling, Over-the-counter drugs.

Therefore, under the Federal Food, Drug, and Cosmetic Act and the Administrative Procedure Act, it is proposed that subchapter D of chapter I of title 21 of the Code of Federal Regulations be amended in part 348 as proposed in the *Federal Register* of February 8, 1983 (48 FR 5852) as follows:

PART 348—EXTERNAL ANALGESIC DRUG PRODUCTS FOR OVER-THE-COUNTER HUMAN USE

1. The authority citation for 21 CFR Part 348 continues to read as follows:

Authority: Secs. 201(p), 502, 505, 701, 52 Stat. 1041-1042 as amended, 1050-1053 as amended, 1055-1056 as amended by 70 Stat. 919 and 72 Stat. 948 (21 U.S.C. 321(p), 352, 355, 371); 5 U.S.C. 553; 21 CFR 5.10 and 5.11.

2. Section 348.3 is amended by adding new paragraph (g) to read as follows:

§ 348.3 Definitions.

(g) *Poison ivy, poison oak, or poison sumac dermatitis.* An allergic contact dermatitis (usually an intensely itching skin rash) due to exposure to plants of the genus *Rhus* (poison ivy, poison oak, poison sumac), which contain urushiol, a potent skin-sensitizing agent.

3. Section 348.50 is amended by revising paragraph (b)(2) to read as follows:

§ 348.50 Labeling of external analgesic drug products.

(b)

(2) *For products containing any external analgesic active ingredients identified in § 348.10 (a), (b), and (c).* "For the temporary relief of" (select one of the following: "Pain, "itching, or "pain and itching") (which may be followed by: "associated with" (select one or more of the following: "minor burns," "sunburn," "minor cuts, "scrapes, "insect bites, "minor skin irritations, (optional, may include the following: "rashes due to") "poison ivy," "poison oak," or "poison sumac."))

Dated: August 26, 1989.

Frank E. Young,

Commissioner of Food and Drugs.

[FR Doc. 89-23261 Filed 10-2-89; 8:45 am]

BILLING CODE 4160-01-M

Final Rule

**Tuesday
October 3, 1989**

Part VI

**Department of the
Treasury**

**Bureau of the Public Debt and
Fiscal Service**

31 CFR Part 317

**U.S. Savings Bonds; Use of Regional
Delivery System for Issuance of Over-
the-Counter Purchases of Series EE
Bonds and Revised Fee Schedule; Final
Rule and Notice**

DEPARTMENT OF THE TREASURY**Fiscal Service****Bureau of the Public Debt****31 CFR Part 317**

[Dept. of the Treasury Circ., Public Debt Series No. 4-67, Second Rev.]

U.S. Savings Bonds; Use of Regional Delivery System for Issuance of Over-the-Counter Purchases of Series EE Bonds

AGENCY: Bureau of the Public Debt, Fiscal Service, Department of the Treasury.

ACTION: Final rule.

SUMMARY: This final rule is being promulgated to authorize use of the Regional Delivery System (RDS) for issuance of over-the-counter purchases of Series EE United States Savings Bonds. Under RDS, the actual inscription of and delivery arrangements for the bonds will be made by the Federal Reserve Banks. This rule also contains changes which will enhance the Bureau's cash management program by requiring the earlier remittance of sales proceeds, and will correct an omission in the appendix to § 317.8, by providing for the remission of bond registration stubs.

EFFECTIVE DATE: October 1, 1989.

FOR FURTHER INFORMATION CONTACT: Dean A. Adams, Assistant Chief Counsel, Bureau of the Public Debt, Parkersburg, West Virginia 26106-1328.

SUPPLEMENTARY INFORMATION: The Regional Delivery System (RDS) is a program developed by the Bureau of the Public Debt to automate the inscription; and provide for the delivery of Series EE savings bonds sold over-the-counter and through Bond-a-Month plans. When the Regional Delivery System is fully operational in all Federal Reserve Districts, most issuing agents heretofore qualified to sell and inscribe over-the-counter bonds will no longer conduct all phases of such transactions. They will continue to accept purchase orders and payments from customers, but will not inscribe the bonds. Instead, they will transmit funds and purchase order information to designated Federal Reserve Banks that will inscribe the bonds in an automated environment. Special arrangements will be made for large-volume issuing agents, where authorized by the Bureau, to inscribe bonds sold over-the-counter and report sales on magnetic tape.

Issuing agents that are not yet authorized RDS participants and agents that are authorized to inscribe bonds

sold over-the-counter and report such sales on magnetic tape, will continue to inscribe and deliver bonds.

An audit by the Inspector General's Office and a study conducted by the Savings Bond Operations Office of its Cash Remittance/Interest Assessment System resulted in recommendations to modify agent reporting requirements, thereby necessitating revisions of the regulations prior to implementation. These changes relate to issuing agent remittance requirements and the submission of savings bond registration records. One change, in particular, should be noted with respect to Treasury Tax and Loan Accounts. As a result of the study, credits to Treasury Tax and Loan Accounts may no longer be used for savings bond sales payments. The provision has therefore been eliminated from § 317.2(f).

In the past several years, there has been a substantial change in the investment patterns of bondholders. As bonds became more competitive and appealing to investors, issuing agents began experiencing individual sales at face amounts of \$30,000 or more. Investors can use different inscriptions to purchase bonds in excess of \$30,000 face amounts. Many monthly agents are now occasionally holding large sums of sales proceeds until their scheduled remittance date.

The revisions will both clarify and strengthen the requirements for agent submission of sales proceeds. They will further enhance the Department's cash management program by requiring agents to submit accumulations of sales proceeds of \$5,000 or more prior to their scheduled remittance.

The changes will also include correction of an oversight in the current regulations which resulted in the omission of instructions for remitting bond registration stubs. Issuing agents will now be required to submit bond registration records (stubs or tape) within 30 days following the month of issue. This will facilitate reconciliation of agent activity in an earlier time frame.

Procedural Requirements

Because this final rule relates to public contracts, the notice and public comment and delayed effective date provisions of the Administrative procedure Act are inapplicable pursuant to 5 U.S.C. 553(a)(2). This final rule is not a "major rule" as defined in executive Order 12291, "Federal Regulations" A regulatory impact analysis is, therefore, not required. Because no notice of proposed rulemaking is required, the provisions of

the Regulatory Flexibility Act do not apply.

List of Subjects in 31 CFR Parts 352, 353, 332, and 315

Bonds, Federal Reserve System, Government securities.

Dated: September 28, 1989.

Gerald Murphy,
Fiscal Assistant Secretary.

31 CFR chapter II, part 317
Department of the Treasury Circular, Public Debt Series No. 4-67 Revised, is hereby further revised and issued as a Second Revision, to read as follows:

PART 317—REGULATIONS GOVERNING AGENCIES FOR ISSUE OF UNITED STATES SAVINGS BONDS

- Sec.
- 317.0 Purpose and effective date.
 - 317.1 Definitions.
 - 317.2 Organizations authorized to act.
 - 317.3 Procedure for qualifying and serving as issuing agent.
 - 317.4 Issuing agents currently qualified.
 - 317.5 Termination of qualification.
 - 317.6 Issuance of bonds.
 - 317.7 Obtaining and accounting for bond stock.
 - 317.8 Remittance of sales proceeds and registration records.
 - 317.9 Role of Federal Reserve Banks.
 - 317.10 Reservation.

Authority: Sec. 22 of the Second Liberty Bond Act, as amended, 49 Stat. 21 (31 U.S.C. 3105) and 5 U.S.C. 301.

§ 317.0 Purpose and effective date.

The regulations in this part govern the manner in which an organization may qualify and act as an agent for the sale and issue of Series EE United States Savings Bonds.

§ 317.1 Definitions.

(a) "Bond(s)" means Series EE United States Savings Bonds.

(b) "Federal Reserve Bank" refers to the Federal Reserve Bank of the district in which the issuing agent or the applicant organization is located, and includes the Branch(es) of the Reserve Bank, where appropriate.

(c) "Issuing agent" refers to an organization that has been granted a certificate of qualification by a Federal Reserve Bank to sell savings bonds. The definition encompasses (1) each organization that accepts and processes purchase orders for bonds sold over-the-counter, but does not inscribe bonds, and (2) each organization that is authorized to inscribe bonds sold over-the-counter or through payroll savings plans.

(d) "Offering circular" refers to Department of the Treasury Circular,

Public Debt Series No. 1-80, current revision.

(e) "Organization" means an entity, as described in § 317.2, which may qualify as an issuing agent of bonds.

§ 317.2 Organizations authorized to act.

Organizations eligible to apply for qualification and serve as savings bond issuing agents include:

(a) Banks, trust companies and savings institutions chartered by or incorporated under the laws of the United States, or those of any State or Territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico;

(b) Agencies of the United States and of State and local governments; and

(c) Employers operating payroll savings plans for the purchase of United States Savings Bonds.

§ 317.3 Procedure for qualifying and serving as issuing agent.

(a) *Execution of application-agreement.* The applicant-organization shall obtain from, duly execute, and file with a Federal Reserve Bank an application-agreement form. The terms of each application-agreement shall include the provisions prescribed by section 202 of Executive Order No. 11246, entitled "Equal Employment Opportunity" (3 CFR, subchapter B, 42 U.S.C. 2000e note).

(b) *Certificate of qualification.* Upon approval of an application-agreement, the Federal Reserve Bank will issue a certificate of qualification to the organization. Until the receipt of such a certificate, an organization shall not perform any act as an issuing agent, or advertise in any manner that it is authorized to so act or that it has applied for qualification as an issuing agent. After receipt of a certificate of qualification, an organization may perform the functions of an issuing agent. Under the terms of the application-agreement, the proceeds of the sale of bonds are at all times the property of the United States for which the organization shall be fully accountable.

(c) *Adverse action or change in qualification.* An organization will be notified by the Federal Reserve Bank if its application-agreement to act as issuing agent is not approved, or if, after issuance, its certificate of qualification is terminated.

§ 317.4 Issuing agents currently qualified.

Each organization, qualified as an issuing agent under a trust agreement currently in effect, is authorized to continue to act in that capacity without requalification. By so acting, it shall be

subject to the terms and conditions of the previously executed application-agreement and these regulations in the same manner and to the same extent as though it had requalified hereunder.

§ 317.5 Termination of qualification.

(a) *By the United States.* The Secretary of the Treasury or a delegate may terminate the qualification of an issuing agent at any time, upon due notice to the agent. If this action is taken, the agent will be required to make a final accounting for the balance of savings bond stock for which it is charged, based on the records of the Federal Reserve Bank. The agent must surrender all unissued bonds and remit the issue price of any remaining bonds included in its accountability.

(b) *At request of issuing agent.* A Federal Reserve Bank will terminate the qualification of an issuing agent upon its request, provided the agent is in full compliance with the terms of its agreement and the applicable regulations and instructions, and renders a final accounting.

§ 317.6 Issuance of bonds.

(a) *General.* Each issuing agent shall comply with all regulations and instructions issued by the Department of the Treasury directly, or through the Federal Reserve Bank, concerning the sale, inscription, dating, and validation of bonds; the acceptance, processing, and transmittal of over-the-counter purchase orders; the remittance of sales proceeds; and the disposition of paper and electronic registration records. No issuing agent shall have authority to sell bonds other than as provided in the offering circular.

(b) *Fees.* Each issuing agent, other than a Federal agency, will be paid a fee for each savings bond transaction. Fee payments for bonds issued through payroll savings plans, and by agents authorized to inscribe bonds sold over-the-counter, will be based on the number of individual issues transmitted to a Federal Reserve Bank. Fee payments for over-the-counter sales, where the agent is not authorized to inscribe the bonds, will be based on the number of purchase orders forwarded to a Federal Reserve Bank. A schedule reflecting the amount of the fees and the basis upon which they are computed will be published separately in the **Federal Register**.

(c) *No charge to customers.* Any issuing agent that accepts fees from the Department of the Treasury for selling savings bonds, and/or accepting over-the-counter purchase orders, shall not make any charge to customers for the same service.

§ 317.7 Obtaining and accounting for bond stock.

An issuing agent that is authorized to inscribe bonds sold over-the-counter or through payroll savings plans may obtain bond stock from a Federal Reserve Bank. The bond stock is, at all times, the property of the United States. The organization shall be fully accountable for the bond stock consigned to it in accordance with all regulations and instructions issued by the Department of the Treasury.

§ 317.8 Remittance of sales proceeds and registration records.

An issuing agent shall account for and remit bond sales proceeds and registration records promptly in accordance with regulations and instructions issued by the Department of the Treasury, either directly or through the Federal Reserve Banks. Failure to comply with these instructions may subject an agent to penalties, including termination of its qualification as an issuing agent.

Appendix to § 317.8—Remittance of Sales Proceeds and Registration Records, Department of the Treasury Circular, Public Debt Series No. 4-67, Second Revision (31 CFR Part 317) Fiscal Service, Bureau of the Public Debt

Subpart A—General Information

1. *Purpose.* This appendix is issued for the guidance of organizations qualified as issuing agents of Series EE United States Savings Bonds under the provisions of Department of the Treasury Circular, Public Debt Series No. 4-67 current revision. Its purpose is to supplement the provisions of § 317.8 of the Circular relating to the remittance of savings bond sales proceeds and registration records, including the interest charge to be collected for late remittances.

2. *Definition of terms.* As used in this appendix:

(a) "Issue Date" is the date as of which a bond begins to earn interest. It is the date entered by the issuing agent in the upper right corner of the bond.

(b) "Validation Date" is the date as of which a bond is actually inscribed for issue. It is entered by the issuing agent immediately below the "Issue Date" in the area marked "Issuing Agent's Dating Stamp"

(c) "Over-the-counter sale" includes all sales of savings bonds (i) on the basis of individual purchase applications received over-the-counter or by mail, and (ii) on Bond-a-Month plans.

(d) "Payroll sale" includes all issues of savings bonds paid for with deductions, withheld from the pay of employees of organizations which maintain (i) payroll savings plans or (ii) thrift, savings, vacation, or similar plans.

(e) "Issuing agent" as provided in § 317.1(c) of the Circular, refers to an organization which has been granted a certificate of qualification by a Federal

Reserve Bank to accept over-the-counter purchase orders for, or, heretofore, to sell and issue savings bonds.

(f) "Immediately available funds" are remittances of funds which are available for the use by the Department of the Treasury immediately upon receipt by the Department or its fiscal agents, and include, but are not limited to:

(1) A change to the remitter's (or a correspondent depository institution's) reserve account with a Federal Reserve Bank;

(2) A Federal funds check;

(3) A United States Government check; or

(4) A postal money order.

(g) "Financial institutions" refers to banks, trust companies, credit unions, and savings institutions chartered by or incorporated under the laws of the United States, or those of any State or Territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico.

(h) "Nonfinancial institutions" refers to any issuing agent not described under paragraph (g) of this appendix.

3. *Determination of issue date.* The obligation of the United States to pay interest on a savings bond is determined by its issue date. That date is the first day of the month in which a qualified issuing agent receives or accumulates the full purchase price of the bond. In the case of a bond purchased under a payroll savings plan operated by an organization which is not an issuing agent, the issue date should be fixed as of the month in which the organization accumulates the full purchase price of the bond. Such funds must, however, be remitted to the issuing agent in time to permit such dating.

4. *Forms of remittance.* Issuing agents shall remit sales proceeds in timely fashion as follows:

(a) Issuing agents which are financial institutions must remit in immediately available funds.

(b) Issuing agents which are nonfinancial institutions should remit in immediately available funds.

(c) The Commissioner of the Public Debt, as designee of the Secretary of the Treasury, may waive or modify this provision. The Commissioner may do so in any particular case or class of cases for the convenience of the United States or in order to relieve any agent or agents of unusual hardship:

(1) If such action would not be inconsistent with law or equity,

(2) If it does not impair any existing rights, and

(3) If the Commissioner is satisfied that such action would not subject the United States to any substantial expense or liability.

5. *Remittance date.* Sales proceeds should be remitted on the date shown on the transmittal document, i.e., PD F 3252-OC or PD F 5255-RDS for over-the-counter sales or PD F 4848 for payroll sales. If there is a significant time difference between the date on the transmittal document and the date of receipt in the Federal Reserve Bank, the transmittal date may be determined, for purposes of this appendix, by the postmark, if the remittance is mailed, or the receipt date, if the remittance is forwarded by courier, messenger, or similar means.

Subpart B—Over-the-Counter Sales

1. *Regional Delivery (RDS) participants.* An agent participating in the Regional Delivery System (RDS) is authorized to sell bonds over-the-counter. It will accept and review customer purchase orders, but it will not inscribe the bonds. Purchase order information will be forwarded to a Federal Reserve Bank for inscription of the bonds. An authorized RDS participant shall remit sales proceeds and purchase orders (on paper or in an electronically processible format) to a Federal Reserve Bank within five (5) business days of receipt from the customer.

2. *Issues-on-Tape Program participants.* An agent that has been authorized by the Bureau of the Public Debt to inscribe bonds sold over-the-counter and report such sales on magnetic tape shall remit sales proceeds and electronic issue records no less often than once a week on a schedule established by the Federal Reserve Bank.

3. *Agents not participating in RDS.* An agent that has not been authorized to participate in RDS by a Federal Reserve Bank shall remit sales proceeds and paper registration records, as directed by the Federal Reserve Bank, in accordance with one of the schedules set forth below, based on a periodic determination by the Bureau of the Public Debt of the average monthly over-the-counter sales remitted by the agent.

(a) *Agents with average monthly sales of less than \$5,000.* Each agent with average monthly over-the-counter sales of less than \$5,000 (issue price) shall remit the proceeds of such sales no less often than once each month on a schedule established by the Federal Reserve Bank. The agent will be allowed two (2) business days to prepare the remittance; sales during those two (2) business days may be included in the following month's remittance. If an agent accumulates monthly over-the-counter sales of \$5,000 (issue price) or more prior to its scheduled remittance date, those sales proceeds shall be remitted within two (2) business days; the agent will also report on its normal reporting date.

(b) *Agents with average monthly sales of \$5,000 or more.* Each agent with average monthly over-the-counter sales of \$5,000 (issue price) or more shall remit the proceeds of such sales no less often than once a week on a schedule established by the Federal Reserve Bank. The agent will be allowed two (2) business days to prepare the remittance; sales during those two (2) business days may be included in the following week's remittance. At the end of each calendar month, the agent shall remit within two (2) business days all remaining sales made during that calendar month, even though the last business day of the month may not coincide with the established reporting date.

Subpart C—Remittance of Payroll Sales Proceeds

1. *Application of requirements.* The remittance requirements on payroll sales apply to the agent that issues the bonds. That agent may be either (a) an employer organization that maintains a payroll savings plan, or (b) a financial institution that services an employer organization. An organization that maintains a payroll savings

plan but does not issue bonds should be notified by the servicing issuing agent that it must remit sales proceeds to the agent in sufficient time to permit compliance with the requirements.

2. *Remittance of payroll sales deductions.* Payroll agents shall remit sales proceeds throughout the month shown in the issue date as soon as the full amount of the purchase price of the bonds has been received or accumulated. In no case should such proceeds be remitted later than the second business day of the month following the month shown in the issue date. The agent shall ensure that its system properly accounts for and recognizes when the full purchase price is received, or is accumulated, so that timely remittance is made. The agent shall transmit registration records, on paper or on magnetic tape, within thirty (30) days following the month shown on the issue date.

Subpart D—Interest on Late Remittances

1. *Rate of Interest.* Interest will be assessed for each day's delay in the remittance of sales proceeds, based on the actual date of remittance. The rate of interest to be used will be the current value of funds to the Department of the Treasury, as set forth each quarter in the Treasury Fiscal Requirements Manual. The rate applied will be that in effect during the entire period in which the remittance is late. The interest assessment will be collected by the Federal Reserve Bank.

2. *Waiver.* Interest will be waived in the situations described below as well as in any specific case where, in the judgment of the Commissioner of the Public Debt, the circumstances warrant such action. The Commissioner's decision on any waiver action shall be final.

(a) *Bonds inscribed by issuing agent.—(i) Payroll or book-entry issues.* If, during any three (3) month period, the interest assessed on an agent's late remittance of payroll or book entry sales proceeds accumulates to less than \$50 for each type of sales, the interest assessed for the first month will be waived. The interest assessed for each type of sales for the remaining two (2) months will then be carried forward to the next period of three (3) consecutive months.

(ii) *Over-the-counter issues.* The interest assessed on an agent's late remittance of over-the-counter sales proceeds transmitted during a given month will be waived if it is less than \$50.

(b) *Bonds inscribed by Federal Reserve Bank.* The interest assessed on late remittance of over-the-counter sales proceeds transmitted by a financial institution's parent and branch offices during a given month will be waived if it is less than \$25. The interest assessed on late remittances of payroll or book-entry sales proceeds transmitted by a financial institution or employer during a given month will be waived if it is less than \$25.

(c) *Suspension of waiver.* The Commissioner may suspend the application of the waiver in the case of any agent that consistently fails to meet the remittance requirements.

§ 317.9 Role of Federal Reserve Banks.

(a) *Role as fiscal agent.* In their capacity as fiscal agents of the United States, the Federal Reserve Banks are authorized to perform such duties, including the issuance of instructions and forms, as may be necessary to fulfill the purposes and requirements of these regulations.

(b) *Specific activities of Federal Reserve Banks.* The specific activities of Federal Reserve Banks include:

(1) Qualifying issuing agents;

(2) Supplying agents with bond stock, maintaining records of agent accountability, and monitoring compliance with stock consignment rules;

(3) Instructing agents regarding the sale and issue of bonds, the custody and control of bond stock, and the accounting for and remittance of sales proceeds; and

(4) Providing guidelines covering the amount of bond stock agents may ordinarily requisition and maintain.

§ 317.10 Reservation.

The Secretary of the Treasury may at any time, or from time to time, supplement or amend the terms of these regulations.

[FR Doc. 89-23367 Filed 9-29-89; 10:03 am]

BILLING CODE 4810-40-M

DEPARTMENT OF THE TREASURY**Fiscal Service**

[Dept. of the Treasury Circ., Public Debt Series No. 4-67, Second Rev.]

U.S. Savings Bonds; Revised Fee Schedule

AGENCY: Bureau of the Public Debt, Fiscal Service, Department of the Treasury.

ACTION: Notice of change in the method of calculation of issuing agent fees and payment date for fees for over-the-counter sales.

SUMMARY: This notice is being published to set out a revised schedule for fees payable to eligible issuing agents for United States Savings Bonds sold over-the-counter and through Bond-a-Month plans and to establish payment dates for such fees. The revised fee schedule applies to issue records transferred to the Bureau of the Public Debt and over-the-counter purchase orders received by Federal Reserve Banks on and after the effective date of this notice. The change is required due to the implementation of the Regional Delivery System (RDS).

EFFECTIVE DATE: October 1, 1989.

FOR FURTHER INFORMATION CONTACT: Dean A. Adams, Assistant Chief Counsel, Bureau of the Public Debt, Savings Bond Operations Office, Parkersburg, WV 26106-1328 (304) 420-6505.

SUPPLEMENTARY INFORMATION: Department of the Treasury Circular, Public Debt Series No. 4-67 Second Revision (31 CFR part 317), at § 317.6(b), provides that issuing agents, other than Federal agencies, will be paid a fee for each savings bond transaction. The Circular further provides that a schedule of fees and the basis on which the fees are computed and paid will be separately published in the *Federal Register*.

The Regional Delivery System (RDS) is a program developed by the Bureau of the Public Debt to automate the inscription and to arrange delivery of Series EE savings bonds sold over-the-counter and through Bond-a-Month plans. When the Regional Delivery System is fully operational in all Federal Reserve Districts, most issuing agents heretofore qualified to sell and inscribe over-the-counter bonds will no longer conduct all phases of such transactions. They will continue to accept purchase orders and remit sales proceeds received from customers, but they will not inscribe the bonds. Instead, they will

transmit funds and purchase order information to designated Federal Reserve Banks that will then complete the process in an automated environment. Special arrangements will be made for large-volume issuing agents authorized by the Bureau to inscribe bonds sold over-the-counter and report sales on magnetic tape.

Issuing agents that are not yet authorized RDS participants and agents that are authorized to inscribe bonds sold over-the-counter and report such sales on magnetic tape will continue to receive a fee of \$.85 for each bond issued during a calendar quarter; such fees will be paid quarterly by the Bureau of the Public Debt based on transfer dates assigned to transmittals by the Federal Reserve Bank. As set forth in a notice published in the *Federal Register* on June 30, 1989 (54 FR 27853), such payments will be made by the Bureau within sixty (60) days after the close of the quarter.

Fees for over-the-counter bonds, sold by agents authorized to participate in the Regional Delivery System, will be based on the number of purchase orders received by a Reserve Bank during a calendar month; such fees will be paid monthly by the Reserve Bank within forty-five (45) days after the close of the month. Authorized RDS participants will receive a fee of \$.50 for each hard-copy purchase order received by a Reserve Bank. Such amount has been determined to be appropriate compensation for agents' lessened responsibilities in conducting over-the-counter transactions. In recognition of additional processing costs, RDS participants that elect to prepare electronic records of purchase order information will receive a fee of \$.85 per purchase order record received by a Reserve Bank. Heretofore, issuing agents that provided electronic input to Reserve Banks for inscription of bonds sold over-the-counter have not received fees, since they were not the issuing agent of record.

No changes have been made to the schedule of fees paid to issuing agents for bonds issued through payroll savings plans or reissued to effect distribution to participants in thrift, savings, vacation, or similar plans; provisions related thereto are included here for ease of reference. The fee schedules are included by reference in all issuing agent agreements and Bureau regulations, as well as the Issuing Agent Fee Statement (PD F 4982) distributed to issuing agents.

Dated: September 28, 1989.

Gerald Murphy,
Fiscal Assistant Secretary.

Schedules of Fees

The schedules of fees for the issue of Series EE savings bonds are hereby set forth below.

Eligible organizations, qualified as issuing agents by Federal Reserve Banks and Branches under the provisions of Department of the Treasury Circular, Public Debt Series No. 4-67 Second Revision (31 CFR part 317), will receive a fee for each savings bond issued or, in the case of agents authorized to participate in the Regional Delivery System, for each over-the-counter purchase order received from them by a Federal Reserve Bank.

Fee Schedule—Over-the-Counter Issues

Qualified issuing agents, other than Federal agencies, will be paid a fee for each over-the-counter savings bond transaction based on the method used to transmit purchase information to a Federal Reserve Bank.

(a) *Class 1 Fee:* Each issuing agent that (1) has not yet been authorized to participate in the Regional Delivery System or (2) is authorized under a special arrangement to inscribe bonds sold over-the-counter and report sales on magnetic tape will be paid a fee of \$.85 for each Series EE bond issue record transmitted to the Bureau of the Public Debt during a calendar quarter based on transfer dates assigned to the transmittals by a Federal Reserve Bank. Class 1 fees will be paid to each issuing agent by the Bureau of the Public Debt within sixty (60) days after the close of the quarter via check or direct deposit (electronic funds transfer).

(b) *Class 2 Fee:* Each issuing agent authorized to participate in the Regional Delivery System will be paid a fee of \$.50 for each paper Series EE purchase order received from them by a Federal Reserve Bank during a calendar month. Class 2 fees will be paid to each depository financial institution by the Reserve Bank, within forty-five (45) days after the close of the month, via a credit to the institution's reserve account.

(c) *Class 3 Fee:* Each issuing agent, authorized to participate in the Regional Delivery System, that elects to prepare electronic records of Series EE purchase order information and transmit such information to a Federal Reserve Bank for inscription of the bonds will be paid a fee of \$.85 for each purchase order record received by the Reserve Bank during a calendar month. Class 3 fees will be paid to each depository financial institution by the Reserve Bank within

forty-five (45) days after the close of the month via a credit to the institution's reserve account.

Coverage of Over-the-Counter Fees

Class 1 fees are intended to recompense issuing agents that are authorized to inscribe bonds sold over-the-counter for costs associated with obtaining and controlling unissued bond stock and inscribing and delivering bonds, exclusive of the cost of postage for bonds mailed in envelopes provided by a Federal Reserve Bank. Class 2 fees are intended to recompense authorized RDS participants for costs associated with accepting and reviewing purchase orders and preparing transmittals to a Reserve Bank. Class 3 fees are intended to recompense authorized RDS participants for costs associated with accepting and reviewing purchase orders, generating electronic records of purchase orders, and transmitting such information to a Reserve Bank.

Fee Schedule—Payroll and Other Issues

Qualified issuing agents, other than Federal agencies, will be paid a fee for each Series EE savings bond issued on

the basis of deductions under a payroll savings plan, on the following scale:

(a) For the first 1,500 bonds issued in a calendar quarter, \$.32.

(b) For the next 8,500 bonds issued in a calendar quarter, \$.11.

(c) For all Series EE bonds over 10,000 issued in a calendar quarter, \$.06.

Qualified issuing agents, other than Federal agencies, will be paid a fee of \$.05 for each Series E or EE savings bond issued on reissue during a calendar quarter to effect distribution to participants in thrift, savings, vacation, or similar plans.

Payroll fee payments will be based on the number of individual bond issue records transmitted by an issuing agent to the Bureau of the Public Debt during a calendar quarter, according to transfer dates assigned to the transmittals by a Federal Reserve Bank. Payroll fees will be paid to each eligible issuing agent by the Bureau within sixty (60) days after the close of the quarter via check or direct deposit (electronic funds transfer).

Coverage of Payroll Fees

In establishing and paying a fee for savings bonds issued via payroll or other savings plans, the Department of

the Treasury is recompensing issuing agents for costs associated with obtaining and controlling bond stock and inscribing and delivering bonds. The fee does not include the cost of postage for bonds mailed in envelopes provided by a Federal Reserve Bank. The amount of the fee is generally based on alternative costs to the Department for obtaining or providing this issuing service.

Charges to Customers

A financial institution that accepts fees from the Department of the Treasury for issuing savings bonds or accepting over-the-counter purchase orders shall not make any charge to customers for the same service. Customers, in this context, include employers that provide a payroll savings plan for employees and have arranged for a financial institution to issue the bonds. Individuals who purchase savings bonds over-the-counter, through Bond-a-Month plans, or through payroll deduction, may not be charged a fee by either the issuing agent or the employer.

[FR Doc. 89-23368 Filed 9-29-89; 10:03 am]

BILLING CODE 4810-40-M

Federal Register

Tuesday
October 3, 1989

Part VII

The President

Proclamations 6030-6033

Presidential Documents

Title 3—

Proclamation 6030 of September 28, 1989

The President

To Provide for the Tariff Treatment of Goods From the Freely Associated States, To Implement Tariff Reductions on Certain Tropical Products, and for Other Purposes

By the President of the United States of America

A Proclamation

1. Section 242 of the Compact of Free Association (the Compact) entered into by the Government of the United States and the Governments of the Marshall Islands and of the Federated States of Micronesia (the freely associated states), as given effect by section 401(a) of the Compact of Free Association Act of 1985 (the Association Act) (Public Law No. 99-239, 99 Stat. 1770), provides that upon implementation of the Compact the President shall proclaim duty-free treatment for most products of the freely associated states, subject to the limitations provided in sections 503(b) and 504(c) of the Trade Act of 1974, as amended (the 1974 Act) (19 U.S.C. 2463(b) and 2464(c)).

2. Section 243 of the Compact, as given effect by section 401(b) of the Association Act, provides that certain articles imported from the freely associated states are to be excluded from the duty-free treatment proclaimed by the President and are to receive most-favored-nation treatment. In addition, section 401(a) of the Association Act sets restrictions on the aggregate quantity of canned tuna that may be entered free of duty in any calendar year. The foregoing exclusions and restrictions were set forth in terms of the former Tariff Schedules of the United States (TSUS) (19 U.S.C. 1202). The United States converted the TSUS to the Harmonized Tariff Schedule of the United States (HTS) effective January 1, 1989. Accordingly, the exclusions and restrictions set out in section 401 of the Association Act must be incorporated into the HTS. Further, certain technical rectifications to particular HTS provisions are necessary in order to designate such provisions correctly

3. In accordance with section 401 of the Association Act, I have determined that the existing preferential tariff treatment provided under the Generalized System of Preferences (GSP), pursuant to Title V of the 1974 Act, to products of the freely associated states should be terminated and that certain modifications and rectifications to the HTS are necessary in order to reflect the appropriate treatment of such articles under the Compact.

4. Pursuant to section 1102(a) of the Omnibus Trade and Competitiveness Act of 1988 (the 1988 Act) (19 U.S.C. 2902(a)), I have determined that one or more existing duties or other import restrictions of the United States are unduly burdening and restricting the foreign trade of the United States and that the purposes, policies, and objectives of Title I of the 1988 Act (19 U.S.C. 2901 *et seq.*) will be promoted by entering into a trade agreement providing for the reduction of rates of duty applicable to imports of certain tropical products.

5. The requirements set forth in sections 125, 126(a), 131-135, and 161(b) of the 1974 Act (19 U.S.C. 2135, 2136(a), 2151-2155, and 2211(b)) have been complied with.

6. Pursuant to section 1102(a) of the 1988 Act, the President, through his duly empowered representative, on December 5, 1988, entered into a trade agreement with other contracting parties to the General Agreement on Tariffs and Trade (GATT) (61 Stat. (pts. 5 and 6)), as amended, consisting of a statement

of negotiating results and schedules of concessions agreed upon by parties thereto, and implementing on a provisional basis tariff reductions on enumerated tropical products. A copy of the agreement and the attached schedule of United States concessions on such products is annexed to this Proclamation as part (b) of Annex II.

7 Pursuant to the 1988 Act, I hereby determine that the modification or continuance of existing duties hereinafter proclaimed is required or appropriate to carry out the trade agreement on tropical products. Pending the successful conclusion of the Uruguay Round of Multilateral Trade Negotiations, I have decided to implement the United States tropical products concessions on a temporary basis.

8. Section 201(a) of the United States-Canada Free-Trade Agreement Implementation Act of 1988 (the Implementation Act) (Public Law No. 100-449, 102 Stat. 1851) authorizes the President to proclaim such modifications or continuance of any existing duty, such continuance of existing duty-free or excise treatment, or such additional duties, as the President determines to be necessary or appropriate to carry out Article 401 of the United States-Canada Free-Trade Agreement and the schedule of duty reductions with respect to goods originating in the territory of Canada set forth in Annexes 401.2 and 401.7 to the Agreement.

9. Pursuant to section 201(a) of the Implementation Act, I have determined that it is necessary to provide for the staged reduction in duties on certain plywood and certain motor vehicle equipment originating in the territory of Canada, and to correct an omission in Proclamation 5978 of May 12, 1989, of the staged reduction in duties on certain puzzles originating in the territory of Canada.

10. Section 1204(b) of the 1988 Act (19 U.S.C. 3004(b)) directs the President to proclaim such modifications to the HTS as are necessary or appropriate to implement the applicable provisions of executive actions taken after January 1, 1988, and before the effective date of the HTS, and such technical rectifications as the President considers necessary Pursuant to the terms of section 1204(b)(1) of the 1988 Act (19 U.S.C. 3004(b)(1)), I have determined that certain technical rectifications to the HTS are necessary.

11. Section 604 of the 1974 Act (19 U.S.C. 2483) authorizes the President to embody in the HTS the substance of the provisions of that Act, and other Acts affecting import treatment, and actions thereunder.

NOW THEREFORE, I, GEORGE BUSH, President of the United States of America, acting under the authority vested in me by the Constitution and the statutes of the United States, including but not limited to section 401 of the Association Act, section 201 of the Implementation Act, sections 1102 and 1204(b) of the 1988 Act, and Title V and section 604 of the 1974 Act, do proclaim that:

(1) In order to provide for the tariff treatment of goods from the freely associated states, general note 3 to the HTS is modified as set forth in Annex I to this Proclamation.

(2) In order to implement the agreement on tropical products on a provisional basis, chapter 99 of the HTS is modified as set forth in Annex II(a) to this Proclamation.

(3) In order to implement the duty treatment provided by the United States-Canada Free-Trade Agreement for certain motor vehicle equipment, certain plywood, and certain puzzles originating in the territory of Canada, the HTS is modified as provided in Annex III to this Proclamation.

(4) In order to make technical rectifications in particular provisions, the HTS is modified as set forth in Annex IV to this Proclamation.

(5) Any provisions of previous proclamations and Executive orders inconsistent with the provisions of this Proclamation are hereby superseded to the extent of such inconsistency.

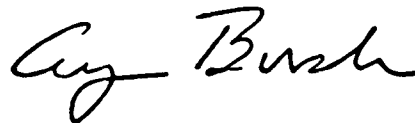
(6)(a) The amendments made by Annex I and IV(b) of this Proclamation shall be effective with respect to articles entered, or withdrawn from warehouse for consumption, on or after the date that is 15 days after the publication of this Proclamation in the **Federal Register**.

(b) The amendments made by Annex II(a) of this Proclamation shall be effective with respect to articles entered, or withdrawn from warehouse for consumption, on or after the dates specified in such Annex.

(c) The amendments made by Annex III of this Proclamation shall be effective with respect to goods originating in the territory of Canada which are entered, or withdrawn from warehouse for consumption, on or after the dates specified in such Annex.

(d) The amendments made by Annex IV(a) of this Proclamation shall be effective with respect to articles entered, or withdrawn from warehouse for consumption, on or after January 1, 1989.

IN WITNESS WHEREOF I have hereunto set my hand this twenty-eighth day of September, in the year of our Lord nineteen hundred and eighty-nine, and of the Independence of the United States of America the two hundred and fourteenth.



ANNEX I

Modifications to General Note 3 to the HTS

Effective with respect to articles entered, or withdrawn from warehouse for consumption, on or after the date that is fifteen days after the publication of this Proclamation in the Federal Register, general note 3(c) to the HTS is modified as follows:

(a) by striking out, from the enumeration in general note 3(c)(ii)(A) of independent countries designated as beneficiary developing countries for purposes of the Generalized System of Preferences, "Marshall Islands, Republic of" and "Micronesia, Federated States of" and

(b) by inserting in appropriate sequence the following new subdivision (viii):

"(viii) Products of Freely Associated States.

(A) Pursuant to sections 101 and 401 of the Compact of Free Association Act of 1985 (99 Stat. 1773 and 1838) the following countries shall be eligible for treatment as freely associated states:

Marshall Islands
Micronesia, Federated States of

(B) Except as provided in subparagraphs (D) and (E) of this paragraph, any article the product of freely associated state shall enter the customs territory of the United States free of duty if--

- (1) such article is imported directly from the freely associated state, and
- (2) the sum of (I) the cost or value of the materials produced in the freely associated state, plus (II) the direct costs of processing operations performed in the freely associated state is not less than 35 percent of the appraised value of such article at the time of its entry into the customs territory of the United States.

If the cost or value of materials produced in the customs territory of the United States is included with respect to an article the product of freely associated state and not described in subparagraph (D) of this paragraph, an amount not to exceed 15 percent of the appraised value of such article at the time it is entered that is attributed to such United States cost or value may be applied toward determining the percentage referred to in subparagraph (B)(2)(II) above.

(C) Tuna of subheading 1604.14.20 in an aggregate quantity entered in any calendar year from the freely associated states not to exceed 10 percent of United States consumption of canned tuna during the immediately preceding calendar year, as reported by the National Marine Fisheries Service, may enter the customs territory free of duty provided that such imports shall be counted against the aggregate quantity of tuna that is dutiable under the general subcolumn of rate of duty column 1 for subheading 1604.14.20 for that calendar year.

(D) The duty-free treatment provided under subparagraph (B) of this paragraph shall not apply to--

- (1) tuna of subheading 1604.14.20 (except tuna in an aggregate quantity entered in any calendar year from the freely associated states not to exceed 10 percent of United States consumption of canned tuna during the immediately preceding calendar year, as reported by the National Marine Fisheries Service);
- (2) textile and apparel articles which are subject to textile agreements;
- (3) footwear, handbags, luggage, flat goods, work gloves and leather wearing apparel, the foregoing which were not eligible articles for purposes of the Generalized System of Preferences on April 1, 1984;
- (4) watches, clocks and timing apparatus of chapter 91 (except such articles incorporating an optoelectronic display and no other type of display) and
- (5) buttons of subheading 9606.21.40 or 9606.29.20.

(E) No article the product of freely associated state and not excluded from duty-free treatment in subparagraph (D) of this paragraph shall enter the customs territory free of duty during calendar year if the freely associated state--

- (1) has exported (directly or indirectly) to the United States during the calendar year quantity of such article having an appraised value in excess of an amount which bears the same ratio to \$25,000,000 as the gross national product of the United States for the preceding calendar year (as determined by the Department of Commerce) bears to the gross national product of the United States for calendar year 1974 (as determined for purposes of section 504(c)(1)(A) of the Trade Act of 1974 (19 U.S.C. 2464(c)(1)(A)) or
- (2) has exported (either directly or indirectly) to the United States quantity of such article equal to or exceeding 50 percent of the appraised value of the total imports of such article into the United States during the preceding calendar year.

(F) Any article the product of freely associated state and excluded from duty-free treatment pursuant to subparagraphs (D) or (E) of this paragraph shall be dutiable at the rate provided in the general subcolumn of rate of duty column 1 for the appropriate heading or subheading.

ANNEX II
TEMPORARY REDUCTIONS IN RATES OF DUTY
FOR CERTAIN TROPICAL PRODUCTS

Note: The following supersedes provisions now in the Harmonized Tariff Schedule of the United States (HTS). The provisions are set forth in columnar format, and material in such columns is inserted in the columns of the HTS designated "Heading/Subheading" "Article Description" "Rates of Duty 1-General" "Rates of Duty 1-Special" and "Rates of Duty 2" respectively.

(a)(1) Effective with respect to articles entered, or withdrawn from warehouse for consumption, on or after the date that is fifteen days after the publication of this Proclamation in the Federal Register and before the close of December 31, 1992, the following new provisions are inserted in chapter 99 of the HTS:

9903.10.01	Other live herbaceous perennials, with soil attached to roots (provided for in subheading 0602.99.30)	1.7%	No change	No change
9903.10.02	Other live plants, with soil attached to roots (provided for in subheading 0602.99.60).	2.3%	No change	No change
9903.10.03	Cassava (manioc) fresh or dried (provided for in subheading 0714.10.00).	22%	No change	No change
9903.10.04	Fresh dasheens (provided for in subheading 0714.90.10).	3.8%	No change	No change
9903.10.05	Pignolia nuts, fresh or dried, in shell (provided for in subheading 0802.90.20)	1.1¢/kg	No change	No change
9903.10.06	Pignolia nuts, fresh or dried, shelled (provided for in subheading 0802.90.25).	1.7¢/kg	No change	No change
9903.10.07	Plantains, dried (provided for in subheading 0803.00.40).	2.3%	No change	No change
	Fruit and nuts, uncooked or cooked by steaming or boiling in water, frozen, whether or not containing added sugar or other sweetening matter:			
9903.10.08	Bananas and plantains (provided for in subheading 0811.90.10).	5.6%	No change	No change
9903.10.09	Cashew apples, mameyes colorados, sapodillas, soursops and sweetsops (provided for in subheading 0811.90.25).	5.3%	No change	No change
9903.10.10	Barberries, dried (provided for in subheading 0813.40.15)	4.1¢/kg	No change	No change
9903.10.11	Bombay or wild mace, ground (provided for in subheading 0908.20.20)	12.4¢/kg	No change	No change
9903.10.12	Ginger, ground (provided for in subheading 0910.10.40)	1.7¢/kg	No change	No change
9903.10.13	Thyme, other than crude or not manufactured (provided for in subheading 0910.40.30)	5.6%	No change	No change
9903.10.14	Origanum, other than crude or not manufactured (provided for in subheading 0910.99.40).	5.6%	No change	No change
9903.10.15	Other spices (provided for in subheading 0910.99.60).	2.3%	No change	No change
9903.10.16	Mint leaves, other than crude or not manufactured (provided for in subheading 1211.90.40)	5.6%	No change	No change
9903.10.17	Turpentine gum (oleoresinous exudate from living trees) (provided for in subheading 1301.90.40)	3.8%	No change	No change
9903.10.18	Other rattans of kind used primarily for plaiting (provided for in subheading 1401.20.40)	2.3%	No change	No change
9903.10.19	Other vegetable materials of kind used primarily for plaiting (provided for in subheading 1401.90.40)	3.8%	No change	No change
9903.10.20	Vegetable hair of kind used primarily as stuffing or as padding (provided for in subheading 1402.91.00)	0.8¢/kg	No change	No change
	Glycerol (glycerine), whether or not pure; glycerol waters and glycerol lyes:			
9903.10.21	Glycerol (glycerins) crude; glycerol waters and glycerol lyes (provided for in subheading 1520.10.00).	0.3¢/kg	No change	No change
9903.10.22	Other, including synthetic glycerol (provided for in subheading 1520.90.00).	0.8¢/kg	No change	No change
9903.10.23	Cocoa paste, wholly or partly defatted (provided for in subheading 1803.20.00)	0.62¢/kg	No change	No change
9903.10.24	Cocoa powder, not containing added sugar or other sweetening matter (provided for in heading 1805.00.00).	0.62¢/kg	No change	No change

ANNEX II (con.)

(a)(1) (con.):

9903.10.25	Other tapioca and substitutes therefor prepared from starch (provided for in subheading 1903.00.40)	0.9c/kg	No change	No change
9903.10.26	Chestnuts, prepared or preserved by vinegar or acetic acid (provided for in subheading 2001.90.42).	5.8c/kg	No change	No change
	Fruits, nuts and other edible parts of plants, otherwise prepared or preserved, whether or not containing added sugar or other sweetening matter:			
9903.10.27	Coconuts (provided for in subheading 2008.19.15).	3I	No change	No change
9903.10.28	Palm hearts (provided for in subheading 2008.91.00).	2.6I	No change	No change
9903.10.29	Banana pulp (provided for in subheading 2008.99.13).	5.6I	No change	No change
9903.10.30	Bananas, other than pulp (provided for in subheading 2008.99.15).	2.3I	No change	No change
9903.10.31	Cashew apples, mameyes colorados, sapodillas, soursops and sweetsops (provided for in subheading 2008.99.23).	2.1I	No change	No change
9903.10.32	Yucca (provided for in subheading 2008.99.65).	14.5I	No change	No change
9903.10.33	Oilcake and other solid residues whether or not ground or in the form of pellets, resulting from the extraction of fats or oils from palm nuts or kernels (provided for in subheading 2306.60.00).	0.5c/kg	No change	No change
9903.10.34	Essential oils of eucalyptus (provided for in subheading 3301.29.10)	2.1I	No change	No change
9903.10.35	Essential oils of orris (provided for in subheading 3301.29.20).	1.9I	No change	No change
9903.10.36	Rattan webbing (provided for in subheading 4601.20.20).	2.3I	No change	No change
9903.10.37	Other baskets and bags, whether or not lined, of rattan or of palm leaf (provided for in subheading 4602.10.13)...	7.5I	No change	No change
9903.10.38	Other basketwork, wickerwork and other articles, made directly to from plaiting materials or made up from articles of heading 4601 (provided for in subheading 4602.10.50).	2.3I	No change	No change
9903.10.39	Single yarn of jute or of other textile bast fibers of heading 5303 (provided for in subheading 5307.10.00).	2.3I	No change	No change
9903.10.40	Multiple (folded) or cabled yarn of jute or of other textile bast fibers of heading 5303 (provided for in subheading 5307.20.00).	3.0I	No change	No change
9903.10.41	Woven fabrics of jute or of other textile bast fibers of heading 5303, other than unbleached (provided for in subheading 5310.90.00).	0.8I	No change	No change
9903.10.42	Seats (other than those of heading 9402) of cane, osier, bamboo or similar materials (provided for in subheading 9401.50.00).	5.6I	No change	No change"

(a)(2) Effective with respect to articles entered, or withdrawn from warehouse for consumption, on or after the dates specified below for the enumerated provisions, the rate of duty in the general subcolumn of column 1 for such provisions is stricken from the HTS and the corresponding new rate of duty is inserted in lieu thereof:

9903.10.03	July 1, 1990---19I
	July 1, 1991---18.8I
9903.10.32	July 1, 1990---13.1I

ANNEX II (con)

- (b) Text of the Agreement identified in the sixth recital of this proclamation

MULTILATERAL TRADE
NEGOTIATIONS
THE URUGUAY ROUND

MTN GNG/17
5 December 1988

Group of Negotiations on Goods (GATT)

TROPICAL PRODUCTS

Specific Negotiating Results for the Uruguay Round Mid-Term Review Submitted by Australia, Austria, Brazil, Canada, Central American Countries, Colombia, European Communities, Finland, Japan, Malaysia, Mexico, New Zealand, Norway, Philippines, Sweden, Switzerland, Thailand, United States

1 The present document contains a first result obtained thus far in the negotiations. It consists of contributions by a number of participants towards the achievements of the objectives established by the Ministerial Declaration of Punta del Este for negotiations on tropical products in the Uruguay Round. This result will be further improved and extended in the course of continuing negotiations in the light of paragraphs 2 and 3 under the heading "Tropical Products" in Section III of the Report of the Group of Negotiations on Goods to the Trade Negotiations Committee

2 These contributions are made under the following terms and conditions

- (a) Participants undertake to apply the measures indicated by them on a provisional basis for the duration of the round, it being understood that if any participant finds it necessary to withdraw any or all of its contributions other participants may wish to reassess their own contributions
- (b) in relation to m.f.n. contributions individual participants undertake to consider binding concessions at the end of the Round in the light of the overall results achieved.

List of Attachments

1	Australia	10	Malaysia
2	Austria	11	Mexico
3	Brazil	12	New Zealand
4	Canada	13	Norway
5	Central American Countries	14	Philippines
6	Colombia	15	Sweden
7	European Communities	16	Switzerland
8	Finland	17	Thailand
9	Japan	18	United States

ANNEX III

TARIFF TREATMENT OF CERTAIN MOTOR VEHICLE EQUIPMENT,
OF CERTAIN PLYWOOD, AND OF CERTAIN PUZZLES
ORIGINATING IN THE TERRITORY OF CANADA

(a) Effective with respect to goods originating in the territory of Canada entered, or withdrawn from warehouse for consumption, on or after January 1, 1989, subchapter V of chapter 99 of the HTS is modified as follows:

1. U.S. note 3 to subchapter V of chapter 99 is renumbered as 5, and the following new U.S. notes 3 and 4 are inserted in subchapter V of chapter 99:

"3. For the following subheadings, the percentage set forth in the "Special" subcolumn of rate of duty column 1 for heading 9905.00.00 which is applicable to goods originating in the territory of Canada shall be applied to the rate of duty set opposite such subheading instead of the column 1-general rate of duty--

7419.99.30	8.5%
8308.90.60	4.8%
8708.50.50	2.6%
8708.50.80	2.6%
8708.60.50	2.6%
8708.60.80	2.6%
8708.80.50	2.6%

4. On or after January 1 of each of the following years, the rate of duty in the Rates of Duty 1-Special subcolumn in HTS headings 9905.00.10 and 9905.00.20 that is followed by the symbol "CA" in parentheses is deleted and the following rates of duty are inserted in such subheadings in lieu thereof:

	1990	1991	1992	1993	1994	1995	1996	1997	1998
9905.00.10	.1.7¢/kg + 1.3%	.1.1¢/kg + 0.9%	:0.5¢/kg + 0.4%	:Free	:Free	:Free	:Free	:Free	:Free
9905.00.20	.2.3¢/kg + 1.8%	.2¢/kg + 1.6%	.1.7¢/kg + 1.3%	.1.4¢/kg + 1.1%	.1.1¢/kg 0.9%	:0.8¢/kg 0.6%	:0.5¢/kg + 0.4%	:0.2¢/kg + 0.2%	:Free"

2. The rate of duty in the Rates of Duty 1-Special subcolumn for HTS heading 9905.00.00 is modified by striking out the rate of duty followed by the symbol "CA" in parentheses and inserting "80 percent of the column 1-general rate of duty (except as otherwise noted in U.S. note 3 to this subchapter) applicable under the respective listed subheading" in lieu thereof.

(b) Effective with respect to goods originating in the territory of Canada which are entered, or withdrawn from warehouse for consumption, on or after May 30, 1989, the Rates of Duty 1-Special subcolumn for HTS subheading 9503.60.20 is modified by inserting "6.1% (CA)" for such subheading.

(c) Effective with respect to goods originating in the territory of Canada entered, or withdrawn from warehouse for consumption, on or after the date that is fifteen days after the publication of this Proclamation in the Federal Register, subchapter V of chapter 99 of the HTS is modified by inserting the following new provisions:

"9905.00.10	Articles provided for in subheadings 4412.11, 4412.12, 4412.21, 4412.29 or 4412.91, if tongued, grooved or rabbetted continuously along any edge and of type used in the construction of walls, ceilings or other parts of buildings.	No change	No change (A, E, IL) 2.3¢/kg + 1.8% (CA)	No change
9905.00.20	Articles provided for in subheadings 4412.19 or 4412.99, if tongued, grooved or rabbetted continuously along any edge and of type used in the construction of walls, ceilings or other parts of buildings...	No change	No change (A, E, IL) 2.6¢/kg + 2% (CA)	No change"

(d) On or after January 1 of each of the following years, the rate of duty in the Rates of Duty 1-Special subcolumn in HTS subheading 9503.60.20 that is followed by the symbol "CA" in parentheses is deleted and the following rates of duty are inserted in such subheadings in lieu thereof:

	1990	1991	1992	1993	1994	1995	1996	1997	1998
9503.60.20	:5.4%	:4.7%	:4%	:3.4%	:2.7%	:2%	:1.3%	:0.6%	:Free

ANNEX IV

TECHNICAL RECTIFICATIONS TO THE HTS

(a) Effective with respect to articles entered, or withdrawn from warehouse for consumption, on or after January 1, 1989, the HTS is modified as follows:

1. General note 3(c)(ii)(A) to the HTS, setting forth those beneficiary developing countries designated as eligible for benefits of the Generalized System of Preferences, is modified by striking out, from the enumeration of members of the Association of South East Asian Nations (ASEAN), "Philippines" and by inserting in lieu thereof "Philippines" and by inserting "Bahamas, The" in the enumeration of member countries of the Caribbean Common Market (CARICOM).

2. General note 3(c)(vii)(L) to the HTS is modified by inserting "of" before "Canada"

3. Additional U.S. note 3(c)(i) to chapter 17 is modified by striking out, from the table setting forth allocations of quantities of sugar to supplying countries, "8. Panama 2.9" and by renumbering the subsequent allocations in the table accordingly

ANNEX IV (con.)

(a) (con.):

4. The article description of subheading 2007.91.10 is modified by striking out "Paste and purees" and by inserting in lieu thereof "Pastes and purees"
5. The article description of subheading 2106.90.05 is modified by striking out "0403.90.20" and by inserting in lieu thereof "0403.90.40"
6. Subheading 4016.99.03 is modified by striking out the word "the" appearing immediately before the word "pecking"
7. Additional U.S. note 2 to chapter 49 of the HTS is modified by striking out "\$5,000" and by inserting in lieu thereof "\$10,000"
8. The column 2 rate of duty for subheading 4105.11.00 is modified by striking out "kg"
9. Subheading 6911.10.39 is modified by inserting, in the parenthetical expression in the "Rates of Duty 1-Special" subcolumn, the symbol "A," immediately before "E,"
10. Additional U.S. note 2 to chapter 71 of the HTS is modified by striking out "\$5,000" and by inserting in lieu thereof "\$10,000"
11. The article description of subheading 7211.41.50 is modified by striking out "less than" and inserting "not exceeding" in lieu thereof.
12. Additional U.S. note 2 to chapter 73 of the HTS is modified by striking out "7303.19.30" and by inserting in lieu thereof "7307.19.30"
13. Heading 7416.00.00 of the HTS is modified by striking out the column 2 duty rate of "5%" and by inserting in lieu thereof "45%"
14. Subheading 8483.50.80 of the HTS is modified by inserting in alphabetical sequence in the parenthetical enumeration in the "Rates of Duty 1-Special" subcolumn the symbol "B,"
15. Subheading 8706.00.15 of the HTS is modified by inserting in alphabetical sequence in the parenthetical enumeration in the "Rates of Duty 1-Special" subcolumn the symbol "B,"
16. U.S. note 4, subchapter II, chapter 98 is modified by striking out the word "heading" and by inserting in lieu thereof the word "text"
17. U.S. note 1, subchapter X, chapter 98 is modified by striking out the word "subheadings" and by inserting in lieu thereof "subheading" by striking out the comma after "9810.00.20" and by inserting "and headings" immediately thereafter, by striking out "any subheading" and by inserting in lieu thereof "any provision" and by inserting "heading" before the second appearance of "9810.00.70."
18. U.S. note 6(a)(xvii), subchapter X, chapter 98 is further modified by inserting "subheadings" after "except"
19. U.S. note 6(a)(xviii), subchapter X, chapter 98 is further modified by inserting "subheadings" after "except" at the first appearance.
20. U.S. note 6(a)(xix) subchapter X, chapter 98 is modified by inserting "subheading" after "except."
21. U.S. note 2(ad) subchapter XVII, chapter 98 is modified by striking out "subheadings 9603.50, 9604.00, 9605.00 and 9616.10" and by inserting in lieu thereof "subheading 9603.50.00, headings 9604.00.00 and 9605.00.00 and subheading 9616.10.00"
22. U.S. note 8, subchapter II, chapter 99 is modified by striking out the word "subheadings" at the first appearance and by inserting in lieu thereof the word "provisions" by striking out the word "subheading" at the first appearance and by inserting in lieu thereof the word "provision" and by striking out "subheading or subheadings" and by inserting in lieu thereof "provisions"
23. Heading 9902.29.94 of the HTS is modified by striking out the words "for in" at their first appearance, and by striking out "change" from the column 2 rate of duty
24. The article description of heading 9902.29.95 is modified by striking out "2922.50.25" and by inserting in lieu thereof "2922.19.15"
25. Heading 9902.29.97 is modified by striking out "change" from the column 2 rate of duty
26. The article description of heading 9902.36.06 is modified by inserting after "subheading" the reference "2912.50.00,"
27. The article description of heading 9902.37.07 is modified by striking out the parenthetical expression and by inserting in lieu thereof the following: "(however provided for in chapter 29 or in subheading 3707.90.30 or 3707.90.60)"
28. The article description of heading 9902.40.11 is modified by striking out "4012.90.30" and by inserting in lieu thereof "4012.90.50"
29. The article description of heading 9902.48.23 is modified by striking out "or 8448.59.50" and by inserting in lieu thereof "8448.11.00 or 8448.49.00"
30. Heading 9902.71.13 is modified by striking out "9505.90.00" and by inserting in lieu thereof "9505.90"
31. Heading 9902.79.02 is modified by striking out "subheading 7902.00" and by inserting in lieu thereof "heading 7902.00.00"
32. The article description of heading 9902.81.05 is modified by striking out "cobalt" and by inserting in lieu thereof "cobalt"
33. Headings 9902.84.48 and 9902.84.49 are each modified by striking out "8448.19" and by inserting in lieu thereof "8448.19.00"
34. U.S. note 6, subchapter III, chapter 99 is modified by striking out "through 9903.04.55" and by inserting in lieu thereof "and 9903.04.10, headings 9903.04.15 through 9903.04.55"

ANNEX IV (con.)

(a) (con.):

35. The article description of heading 9903.04.35 is modified by striking out "1602.42.40" and by inserting in lieu thereof "1602.42.20"

36. U.S. note 4(d) to subchapter IV of chapter 99 is modified by striking out "subheadings 9904.20.10 and 9904.40.40" and by inserting in lieu thereof "subheading 9904.40.40"

37. Subheading 9904.10.66 is modified by striking out "1806.90, and by inserting in lieu thereof "1806.90.00 and" and by striking out "2105.00" and by inserting in lieu thereof "heading 2105.00.00"

38. The article description of subheading 9904.10.75 is modified by striking out "2106.90.05 and 2106.90.50" and by inserting in lieu thereof "and 2106.90.05"

39. Heading 9905.00.00 is modified by inserting "headings and" after "following" and by inserting "heading or" after "listed"

40. The following general and U.S. notes are modified by striking out at each instance the word "subheading" and by inserting in lieu thereof the word "provision":

general note 3(c)(1)(D)
 general note 3(c)(ii)(C)
 general note 3(c)(v)(C)
 general note 3(c)(v)(D)
 general note 3(c)(vi)(A)
 general note 3(c)(vii)(A)
 general note 3(c)(vii)(G)(2)
 U.S. note 5, subchapter II, chapter 98

41. The following general and U.S. notes are modified by striking out at each instance the word "subheadings" and by inserting in lieu thereof the word "provisions":

U.S. note 1 (at the first appearance) subchapter I, chapter 98
 U.S. note 6(a)(xvii) subchapter X, chapter 98
 U.S. note 6(a)(xviii), subchapter X, chapter 98

42. The following U.S. notes and tariff provisions are modified by striking out at each instance the word "subheading" and by inserting in lieu thereof the word "heading":

U.S. note 1(c), subchapter I, chapter 98
 9801.00.70
 U.S. note 1(d), subchapter II, chapter 98
 U.S. note 4, subchapter II, chapter 98
 U.S. note 2(b), subchapter III, chapter 98
 U.S. note 3, subchapter IV, chapter 98
 U.S. note 2, subchapter VI, chapter 98
 U.S. note 6(a)(iii), subchapter X, chapter 98
 U.S. note 6(a)(ix), subchapter X, chapter 98
 9810.00.85
 U.S. note 2, subchapter XI, chapter 98
 9811.00.60
 U.S. note 1, subchapter XII, chapter 98
 U.S. note 2, subchapter XII, chapter 98
 U.S. note 1(a) and (b) subchapter XIII, chapter 98
 U.S. note 2, subchapter XIII, chapter 98
 U.S. note 3, subchapter XIII, chapter 98
 U.S. note 4, subchapter XIII, chapter 98
 U.S. note 5, subchapter XIII, chapter 98
 9813.00.50
 U.S. note 1, subchapter XIV, chapter 98
 U.S. note 1, subchapter XVII, chapter 98
 9817.00.30
 9817.00.60
 U.S. note 2, subchapter I, chapter 99
 U.S. note 2, subchapter II, chapter 99
 U.S. note 3(a) and (b), subchapter II, chapter 99
 U.S. note 9, subchapter II, chapter 99
 9902.26.11
 9902.30.03
 9902.39.14
 9902.50.05
 9902.70.12
 9902.84.44
 U.S. note 3(c), subchapter IV, chapter 99
 9904.10.72
 U.S. note 1, subchapter V, chapter 99
 U.S. note 2, subchapter V, chapter 99

43. The following provisions are modified by striking out at each instance the word "subheadings" and inserting in lieu thereof the word "headings":

U.S. note 2, subchapter XV, chapter 98
 U.S. note 2, subchapter XVII, chapter 98
 immediately superior text to subheading 9904.60.20

44. The following U.S. notes are modified by striking out the word "subheading" and by inserting in lieu thereof the word "text":

U.S. note 5, subchapter II, chapter 98
 U.S. note 6, subchapter II, chapter 98
 U.S. note 7, subchapter II, chapter 98

(b) Effective with respect to articles entered, or withdrawn from warehouse for consumption, on or after the date that is fifteen days after the publication of this proclamation in the Federal Register, HTS subheading 2915.39.10 is modified by striking out "20%" and by inserting in lieu thereof "23.5%"

[FR Doc. 89-23496

Filed 9-29-89; 4:29 pm]

Billing code 3190-01-C

Presidential Documents

Proclamation 6031 of September 29, 1989

National Quality Month, 1989

By the President of the United States of America

A Proclamation

Producing quality goods and services is crucial not only to the continued economic growth of the United States, but also to our national security and the well-being of each American family. Our Nation has long been recognized for its leadership in producing quality products. However, in recent years, the position of the United States as quality leader has been challenged by foreign competition in domestic and overseas markets.

Reasserting our leadership position will require a firm commitment to total quality management and the principle of continuous quality improvement. The United States can, and must, excel in this area, setting new standards for world-class quality and competing vigorously in international markets.

Improving quality takes time and resources and can only be achieved through a combination of factors. It takes a long-term commitment by management that involves working with suppliers to improve performance; educating, training, and motivating workers; developing accurate and responsive information systems; and establishing targets for quality improvement.

Quality improvement principles apply to small companies as well as large corporations, to service industries as well as manufacturing, and to the public sector as well as private enterprise. Improving the quality of goods and services goes hand in hand with improving productivity and lowering costs. It is also essential to enhancing worker fulfillment and customer satisfaction.

Private sector organizations and government institutions across the country are joining forces to promote a national commitment to excellence. At the national, regional, and local level, business executives and public officials are working together to develop the skills and techniques needed for producing quality goods and services.

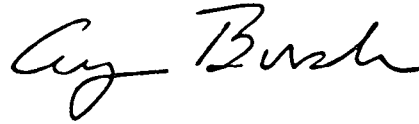
As part of this important effort, the Federal Government is promoting quality through such programs as the Malcolm Baldrige National Quality Award of the Department of Commerce, the Federal Quality Institute, the President's Council on Management Improvement, the Productivity Improvement Plan of the Department of Defense, and the NASA Excellence Award for Quality and Productivity.

The American Society for Quality Control—together with other national professional organizations, businesses, industries, government agencies, and academic institutions—is sponsoring activities in observance of "National Quality Month." These activities, focused on the theme of "Quality First," are designed to promote awareness of the importance of quality to production and services throughout the United States.

The Congress, by House Joint Resolution 204, has designated October as "National Quality Month" and has authorized and requested the President to issue a proclamation in observance of this month.

NOW THEREFORE, I, GEORGE BUSH, President of the United States of America, do hereby proclaim October 1989 as National Quality Month. I call upon the people of the United States to observe this occasion with appropriate ceremonies and activities.

IN WITNESS WHEREOF I have hereunto set my hand this twenty-ninth day of September, in the year of our Lord nineteen hundred and eighty-nine, and of the Independence of the United States of America the two hundred and fourteenth.

A handwritten signature in black ink, reading "George Bush". The signature is written in a cursive style with a large, sweeping initial "G".

[FR Doc. 89-23560
Filed 10-2-89; 10:53 am]
Billing code 3195-01-M

Presidential Documents

Proclamation 6032 of September 29, 1989

Mental Illness Awareness Week, 1989

By the President of the United States of America

A Proclamation

The 20th century has been marked by major advances in medical research and technology. Today, we can easily prevent or cure many diseases that once proved to be debilitating or even deadly. Because this remarkable scientific progress has included the study of mental illness, scientists and health care professionals now have a much greater understanding of such afflictions as depression, schizophrenia, phobias, and anxiety disorders.

During the past 10 years alone, our knowledge of mental illness has increased dramatically. Indeed, our ever-expanding knowledge of the brain might well be considered one of the most profound accomplishments of our time. That is why continued failure to diagnose or treat mental illness—and to accept and understand those who suffer from it—is so needless and so regrettable. Far too many mentally ill Americans are also victims of fear, prejudice, and distrust. Mental illness not only inhibits their ability to function normally in society, but also inflicts untold personal anguish upon them and their loved ones.

Frequently the result of biological or chemical disorders in the brain, mental illness can affect anyone—regardless of age, gender, race, or economic status. For a child or adolescent, a mental illness left untreated can mean years of torment, as well as lost opportunities to learn and grow. Adults who suffer from mental illness may not only lose their independence and ability to contribute, but also become strangers to their families and friends. Elderly victims can enjoy neither the comforts of retirement nor the well-earned respect and dignity rightfully afforded to our senior citizens. Tragically, the confusion, alienation, and loss of hope felt by some victims of mental illness— young and old alike—have even led them to take their own lives.

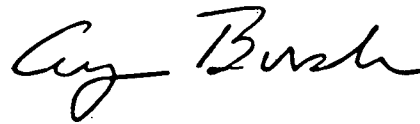
We can—and we must—help the victims of mental illness. Of the millions of Americans who suffer from depression, well over half could benefit from proper treatment. Scientific research has produced treatments that can alleviate the hallucinations and delusions that haunt victims of schizophrenia. There are also treatments, including medications and various forms of psychotherapy, to allay crippling panic and anxiety disorders and to help patients overcome dysfunctional behavior patterns. Today, improved methods of diagnosis and care can offer hope and healing to millions of people with mental disorders.

This week, we salute the dedicated scientists, health care professionals, and volunteers who are working hard to help solve the mysteries of mental illness and alleviate the suffering of its victims. In academic institutions, hospitals, and community-based mental health programs across the country, they are helping to destroy the myths and fears that prevent too many victims of mental illness from obtaining the help and compassion they need. All of us can assist their efforts by learning more about mental illness and by supporting continued research and effective treatment programs. Most important, however, we can help victims of mental illness and their families by giving them our encouragement and understanding.

In recognition of the importance of informing the public about mental illness and the needs of those who suffer from it, the Congress, by Senate Joint Resolution 55, has designated the week beginning October 1, 1989, as "Mental Illness Awareness Week" and has authorized and requested the President to issue a proclamation in observance of this event.

NOW THEREFORE, I, GEORGE BUSH, President of the United States of America, do hereby proclaim the week of October 1 through October 7, 1989, as Mental Illness Awareness Week. I call upon all citizens of the United States to observe this week with appropriate ceremonies and activities designed to promote greater understanding of mental illness and its victims' need for effective treatment and rehabilitation.

IN WITNESS WHEREOF I have hereunto set my hand this twenty-ninth day of September, in the year of our Lord nineteen hundred and eighty-nine, and of the Independence of the United States of America the two hundred and fourteenth.



Presidential Documents

Proclamation 6033 of September 29, 1989

Child Health Day 1989

By the President of the United States of America

A Proclamation

In this most fortunate of nations, millions of us can look with pride and gratitude upon happy, healthy children and grandchildren—children who are able to enjoy all the wonderful opportunities life offers. However, we cannot afford to forget that each year tens of thousands of children in this country die before reaching their first birthday.

Our hearts ache over this country's high rate of infant mortality, a rate that is all the more tragic because it occurs in a Nation that boasts one of the highest standards of living in the world. The statistics cannot reveal the suffering of bereaved parents, for their anguish is immeasurable. Nor can numbers reflect the costs incurred by our entire country. When the life of a child is destroyed, so, too, is the promise that he or she holds for our Nation's future. A society that fails to protect its most vulnerable members from harm suffers untold losses itself.

The failure of pregnant women to obtain adequate prenatal care is a major factor in our Nation's high infant mortality rate. While the government must not usurp the role of the family—and while it cannot fulfill parents' responsibilities in caring for their children—public officials at the Federal and State level are examining ways to help improve child health in the United States. Together with health care providers, insurers, and other concerned Americans, government officials have been working to develop ways to encourage more pregnant women to protect the lives of their unborn children through proper nutrition and prenatal care.

Already, advances in technology have enabled us to save the lives of babies who are born prematurely, or who develop dangerous illnesses and conditions while still in the womb. Scientific discoveries have helped us to reduce the incidence of some debilitating and life-threatening childhood diseases, and even eliminate others. Thanks to effective immunization programs, fear of the spread of diseases such as polio and smallpox is virtually a thing of the past. Nevertheless, we still face great challenges and responsibilities in the area of child health.

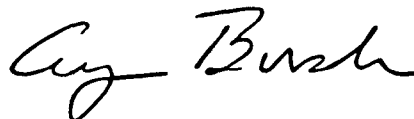
We must continue to encourage parents to have their children immunized, and we must promote education in child nutrition, safety, and hygiene. We must also recognize that our fight against drug abuse is a life-and-death struggle for the fate of a generation—in hospital nurseries and foster homes across the country, infants who were born addicted to drugs or infected with the AIDS virus provide heartrending evidence of the devastation wrought by chemical dependency. Children who grow up in homes torn apart by drug and alcohol abuse are also at grave risk. For their sake, for the sake of their families, and for the sake of our Nation's future, we must redouble our efforts in the war on substance abuse.

Today, as we begin the 7th decade of this national observance for children, let us resolve to ensure that every American child receives the best possible start in life—beginning with quality health care throughout pregnancy for expectant mothers and extending through each child's formative years.

The Congress, by Joint Resolution approved May 18, 1928, as amended (36 U.S.C. 143), has called for the designation of the first Monday in October as "Child Health Day" and has authorized and requested the President to issue annually a proclamation in observance of this event.

NOW THEREFORE, I, GEORGE BUSH, President of the United States of America, do hereby proclaim Monday, October 2, 1989, as Child Health Day. I urge all Americans to rededicate themselves to protecting the lives and health of our youngest and most vulnerable citizens.

IN WITNESS WHEREOF I have hereunto set my hand this twenty-ninth day of September, in the year of our Lord nineteen hundred and eighty-nine, and of the Independence of the United States of America the two hundred and fourteenth.



[FR Doc. 89-23562

Filed 10-2-89; 10:55 am]

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Federal Railroad Register

**Tuesday
October 3, 1989**

Part VIII

Department of Transportation

Federal Railroad Administration

**49 CFR Parts 217, 219, and 225
Alcohol/Drug Regulations; Public Hearing;
Notice of Public Hearing on Proposed
Rulemaking**

DEPARTMENT OF TRANSPORTATION

Federal Railroad Administration

49 CFR Parts 217, 219, 225

[FRA Docket No. RSOR-6, Notice No. 27]

RIN 2130-AA43

Alcohol/Drug Regulations; Public Hearing

AGENCY: Federal Railroad Administration (FRA), DOT.

ACTION: Notice of public hearing on proposed rulemaking.

SUMMARY: FRA announces a public hearing on its notice of proposed rulemaking with respect to its rule on Control of Alcohol and Drug Use in Railroad Operations and related provisions of other rules.

DATES: The public hearing will be held at 9:30 a.m. on Tuesday, October 17 1989. FRA requests that prepared statements for the public hearing be submitted to the Docket Clerk at the address set forth below not later than Friday, October 13, 1989. As previously announced, written comments on the notice of proposed rulemaking must be received no later than October 27 1989.

Comments received after that date will be considered to the extent possible without incurring additional expense or delay.

ADDRESSES: The hearing will be held in Room 6244, Nassif Building, Washington, DC. Prepared statements for the hearing and written comments should be submitted to the Docket Clerk, Office of the Chief Counsel (RCC-30), FRA, Room 8201, 400 7th Street SW., Washington, DC 20590. Persons desiring to be notified that their written comments have been received by the FRA should submit a stamped, self-addressed postcard with their comments. The Docket Clerk will indicate on the postcard the date on which the comments were received and will return the card to the addressee. Written comments will be available for examination, both before and after the closing date for comments, during regular business hours in Room 8201 of the Nassif Building at the above address.

FOR FURTHER INFORMATION CONTACT: Mr. Walter C. Rockey, Jr., Executive Assistant to the Associate Administrator for Safety (RRS-3), FRA, Washington, DC 20590 (Telephone: (202) 366-0897), Dr. Sam Holley, Alcohol &

Drug Program Manager (RRS-10), Office of Safety Enforcement, FRA, Washington, DC 20590 (Telephone: (202) 366-0501) or Grady Cothen, Special Counsel (RCC-4) FRA, Washington, DC 20590 (Telephone: (202) 366-0767).

SUPPLEMENTARY INFORMATION: On September 27 1989, FRA published in the **Federal Register** a notice of proposed rulemaking concerning miscellaneous amendments to conform and update its alcohol/drug regulations (Docket No. RSOR-6, Notice No. 24) (54 FR 39646). That notice indicated that an opportunity for oral presentations would be provided at a date to be announced. The public hearing will be held at 9:30 a.m. on Tuesday, October 17 1989 in room 6244, Nassif Building, Washington, D.C. Persons wishing to attend and make oral presentations are requested to submit prepared statements to the Docket Clerk at the address indicated above prior to the hearing.

Issued in Washington, DC, on September 28, 1989.

Susan M. Coughlin,
Deputy Administrator.

[FR Doc. 89-23520 Filed 10-2-89; 8:45 am]

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Update Service) on 523-6641. The text of laws is not published in the **Federal Register** but may be ordered in individual pamphlet form (referred to as "slip laws") from the Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402 (phone 202-275-3030).

H.J. Res. 407/Pub. L. 101-100

Making continuing appropriations for the fiscal year 1990, and for other purposes (Sept. 29, 1989; 103 Stat. 638; 3 pages) Price: \$1.00

LIST OF PUBLIC LAWS

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