AUTHENTICATED
U.S. GOVERNMENT
INFORMATION
GPO

4–28–93
Vol. 58 No. 80

federal register

Wednesday
April 28, 1993

United States
Government
Printing Office
SUPERINTENDENT
OF DOCUMENTS
Washington, DC 20402

OFFICIAL BUSINESS
Penalty for private use, $300

SECOND CLASS NEWSPAPER

Postage and Fees Paid
U.S. Government Printing Office
(ISSN 0097–6326)

4-28-93
Vol. 58 No. 80
Pages 25773-25928

federal register

Wednesday
April 28, 1993

Briefings on How To Use the Federal Register
For information on briefings in Washington, DC, and Philadelphia, PA, see announcement on the inside cover of this issue.

FEDERAL REGISTER Published daily, Monday through Friday, (not published on Saturdays, Sundays, or on official holidays), by the Office of the Federal Register, National Archives and Records Administration, Washington, DC 20408, under the Federal Register Act (49 Stat. 500, as amended; 44 U.S.C. Ch. 15) and the regulations of the Administrative Committee of the Federal Register (1 CFR Ch. I). Distribution is made only by the Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402.

The **Federal Register** provides a uniform system for making available to the public regulations and legal notices issued by Federal agencies. These include Presidential proclamations and Executive Orders and Federal agency documents having general applicability and legal effect, documents required to be published by act of Congress and other Federal agency documents of public interest. Documents are on file for public inspection in the Office of the Federal Register the day before they are published, unless earlier filing is requested by the issuing agency.

The seal of the National Archives and Records Administration authenticates this issue of the **Federal Register** as the official serial publication established under the Federal Register Act. 44 U.S.C. 1507 provides that the contents of the **Federal Register** shall be judicially noticed.

The **Federal Register** is published in paper, 24x microfiche format and magnetic tape. The annual subscription price for the **Federal Register** paper edition is $375, or $415 for a combined **Federal Register**, Federal Register Index and List of CFR Sections Affected (LSA) subscription; the microfiche edition of the **Federal Register** including the Federal Register Index and LSA is $353; and magnetic tape is $37,500. Six month subscriptions are available for one-half the annual rate. The charge for individual copies in paper form is $4.50 for each issue, or $4.50 for each group of pages as actually bound; or $1.50 for each issue in microfiche form; or $175.00 per magnetic tape. All prices include regular domestic postage and handling. International customers please add 25% for foreign handling. Remit check or money order, made payable to the Superintendent of Documents, or charge to your GPO Deposit Account, VISA or MasterCard. Mail to: New Orders, Superintendent of Documents, P.O. Box 371954, Pittsburgh, PA 15250–7954.

There are no restrictions on the republication of material appearing in the **Federal Register**.

How To Cite This Publication: Use the volume number and the page number. Example: 58 FR 12345.

SUBSCRIPTIONS AND COPIES

PUBLIC

Subscriptions:

Paper or fiche	202–783–3238
Magnetic tapes	512–1530
Problems with public subscriptions	512–2303

Single copies/back copies:

Paper or fiche	783–3238
Magnetic tapes	512–1530
Problems with public single copies	512–2457

FEDERAL AGENCIES

Subscriptions:

Paper or fiche	523–5243
Magnetic tapes	512–1530
Problems with Federal agency subscriptions	523–5243

For other telephone numbers, see the Reader Aids section at the end of this issue.

THE FEDERAL REGISTER
WHAT IT IS AND HOW TO USE IT

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: May 12 and June 15 at 9:00 am

WHERE: Office of the Federal Register, 7th Floor Conference Room, 800 North Capitol Street NW, Washington, DC (3 blocks north of Union Station Metro)

RESERVATIONS: 202–523–4538

PHILADELPHIA, PA

WHEN: May 25, at 1:00 pm

WHERE: William J. Green, Jr. Federal Building, Conference Room 6306–10, 600 Arch St. Philadelphia, PA

RESERVATIONS: Federal Information Center 1–800–347–1997

Printed on recycled paper containing 100% post consumer waste

Contents

Federal Register

Vol. 58, No. 80

Wednesday, April 28, 1993

Agricultural Marketing Service
PROPOSED RULES
Dairy products:
Promotion and research order, 25785
Fluid milk promotion program
Correction, 25900

Agriculture Department
See Agricultural Marketing Service
See Animal and Plant Health Inspection Service
See Forest Service
See Rural Electrification Administration

Animal and Plant Health Inspection Service
PROPOSED RULES
Viruses, serums, toxins, etc.:
Analogous products—
Packaging and labeling, 25786

Army Department
NOTICES
Privacy Act:
Systems of records, 25813

Commerce Department
See Export Administration Bureau
See International Trade Administration
See National Oceanic and Atmospheric Administration

Commodity Futures Trading Commission
NOTICES
Committees; establishment, renewal, termination, etc.:
Financial Products Advisory Committee, 25812
Meetings:
Agricultural Advisory Committee, 25813

Defense Department
See Army Department
See Defense Logistics Agency
RULES
DOD cooperation with civilian law enforcement officials; American Forces Radio and Television Service (AFRTS); Armed Forces Institute of Pathology (AFIP); CFR Parts removed, 25776
NOTICES
Privacy Act:
Systems of records, 25813

Defense Logistics Agency
NOTICES
Privacy Act:
Systems of records, 25819

Drug Enforcement Administration
PROPOSED RULES
Schedules of controlled substances:
Levo-alphacetylmethadol, 25790
Methcathinone, 25788
NOTICES
Applications, hearings, determinations, etc.:
Johnson Matthey Inc., 25848
Prust, James, 25848

Education Department
NOTICES
Grants and cooperative agreements; availability, etc.:
Postsecondary education improvement fund—
Special focus competition (invitational priority; higher education collaboration and exchange between United States and European Community), 25821
Meetings:
National Education Commission on Time and Learning, 25822

Energy Department
See Federal Energy Regulatory Commission
NOTICES
Environmental restoration and waste management:
Interim mixed waste inventory report; waste streams, treatment capacities, and technologies; availability, 25822

Environmental Protection Agency
RULES
Air quality implementation plans; approval and promulgation; various States:
Tennessee, 25776, 25777
Pesticides; tolerances in food, animal feeds, and raw agricultural commodities:
Acrylic acid-sodium acrylate-sodium-2-methylpropanesulfonate copolymer, 25782
Ethoxylated polyarylalkylphenols, 25780
Sodium bisulfate, 25779
Spod-X bioinsecticide, 25783
PROPOSED RULES
Air programs:
Stratospheric ozone protection—
Ozone-depleting substances; accelerated phaseout schedule, 25793
Pesticides; tolerances in food, animal feeds, and raw agricultural commodities:
Cross-linked polyurea-type encapsulating polymer, 25792
NOTICES
Agency information collection activities under OMB review, 25830
Meetings:
Science Advisory Board, 25831
Pesticide registration, cancellation, etc.:
Ciba-Geigy Corp., 25832
Sandoz Agro, Inc., 25832
Pesticides; emergency exemptions, etc.:
Tebuconazole, 25833
Superfund; response and remedial actions, proposed settlements, etc.:
Old City of York Site, PA, 25834
Superfund program:
Confidential business information and data transfer to contractors, 25834

Export Administration Bureau
NOTICES
Export privileges, actions affecting:
Zandian, Reza, et al., 25800

Federal Communications Commission
PROPOSED RULES
Radio broadcasting:
Low power television service; application acceptance standard; major changes definition; four-letter call signs, 25794
NOTICES
Agency information collection activities under OMB review, 25835

Federal Emergency Management Agency
NOTICES
Disaster and emergency areas:
Georgia, 25835
Nebraska, 25835
Tennessee, 25836

Federal Energy Regulatory Commission
RULES
Public Utility Holding Company Act:
Filing requirements and ministerial procedures for persons seeking exempt wholesale generator status Correction, 25900
NOTICES
Electric rate, small power production, and interlocking directorate filings, etc.:
PacifiCorp et al.; correction, 25900
Puget Sound Power & Light Co. et al., 25824
Interstate natural gas pipelines, oil pipelines, and electric utilities; incentive ratemaking, 25825
Natural gas certificate filings:
United Gas Pipe Line Co. et al., 25826
Natural Gas Policy Act:
State jurisdictional agencies tight formation recommendations; preliminary findings—
Wyoming Oil and Gas Conservation Commission, 25827
Applications, hearings, determinations, etc.:
Algonquin LNG, Inc., 25828
ANR Pipeline Co., 25828
Belize Electric Co., Ltd., 25828
Mississippi River Transmission Corp., 25828
National Fuel Gas Supply Corp., 25829
Seagull Shoreline System, 25829
South Carolina Electric & Gas Co., 25829
Superior Offshore Pipeline Co., 25829
Tennessee Gas Pipeline Co., 25829
Texas Eastern Transmission Corp.; correction, 25900
Transwestern Pipeline Co., 25830
Williams Natural Gas Co., 25830

Federal Maritime Commission
NOTICES
Freight forwarder licenses:
SCAC California Inc. et al., 25836
Seaway Forwarding Corp. et al.; correction, 25837
U.S. International Transport, Inc., et al., 25837

Federal Mine Safety and Health Review Commission
NOTICES
Meetings; Sunshine Act, 25898

Federal Reserve System
NOTICES
Meetings; Sunshine Act, 25898

Financial Management Service
See Fiscal Service

Fiscal Service
RULES
Payment of unclaimed interest on certain awards of Mixed Claims Commission, U.S. and Germany; CFR Part removed, 25774
Payment on amount of awards and appraisals in favor of U.S. Nationals on claims against Mexico; CFR Part removed, 25775
Payment under Act of Congress approved August 30, 1962, on unpaid balances of awards of Philippine War Damage Commission; CFR Part removed, 25774
Refugee Relief Act of 1953; loans to public or private agencies; CFR Part removed, 25775

Food and Drug Administration
RULES
Human drugs:
Bioavailability and bioequivalence testing samples retention, 25918
PROPOSED RULES
Medical devices:
Gastroenterology-urology devices; penile inflatable implant; premarket approval requirement, 25902
NOTICES
Food for human consumption:
Food labeling—
Foods derived from new plant varieties; policy statement, 25837

Forest Service
NOTICES
Appealable decisions; legal notice:
Southern Region, 25797
Environmental statements; availability, etc.:
Tahoe National Forest, CA, 25799

General Accounting Office
PROPOSED RULES
Practice and procedure:
Personnel Appeals Board, 25785

Health and Human Services Department
See Food and Drug Administration
See Health Care Financing Administration
See Health Resources and Services Administration

Health Care Financing Administration
RULES
Medicare and medicaid:
Nursing facilities; individuals with mental illness and mental retardation; preadmission screening and annual resident review; correction, 25784

Health Resources and Services Administration
NOTICES
Grants and cooperative agreements; availability, etc.:
Family medicine—
Graduate training, 25842
General internal medicine and pediatrics—
Residency training, 25841

Interior Department
See Land Management Bureau
See National Park Service
See Reclamation Bureau
NOTICES
Meetings:
Exxon Valdez Oil Spill Public Advisory Group, 25843

Internal Revenue Service
PROPOSED RULES
Excise taxes:
Ozone layer depleting chemicals; exports, 25791

International Trade Administration
NOTICES
Antidumping:
Gray portland cement and clinker from Mexico, 25803
Antidumping and countervailing duties:
Administrative review requests, 25802

Interstate Commerce Commission
NOTICES
Rail carriers:
Declaratory order petitions—
Hanson Natural Resources Co., 25848

Justice Department
See Drug Enforcement Administration
See Parole Commission

Land Management Bureau
NOTICES
Environmental statements; availability, etc.:
Kettle River Key Project, WA, 25844
Meetings:
Uinta Southwestern Utah Regional Coal Team, 25844
Realty actions; sales, leases, etc.:
Idaho, 25845
Utah, 25845

Libraries and Information Science, National Commission
See National Commission on Libraries and Information Science

Martin Luther King, Jr. Federal Holiday Commission
NOTICES
Meetings, 25849

Mine Safety and Health Federal Review Commission
See Federal Mine Safety and Health Review Commission

National Aeronautics and Space Administration
NOTICES
Meetings:
Space Station Redesign Advisory Committee, 25849

National Commission on Libraries and Information Science
NOTICES
Meetings; Sunshine Act, 25899

National Highway Traffic Safety Administration
RULES
Motor vehicle safety standards:
Child restraint systems—
Built-in child restraint system; correction, 25900

National Oceanic and Atmospheric Administration
NOTICES
Permits:
Endangered and threatened species, 25810, 25811
Marine mammals, 25812

National Park Service
NOTICES
Meetings:
Mississippi River Coordinating Commission, 25846
National Register of Historic Places:
Pending nominations, 25846

Nuclear Regulatory Commission
NOTICES
Meetings:
Reactor Safeguards Advisory Committee, 25849
Operating licenses, amendments; no significant hazards considerations; biweekly notices, 25851
Applications, hearings, determinations, etc.:
Florida Power & Light Co., 25874

Parole Commission
NOTICES
Meetings; Sunshine Act, 25898

Physician Payment Review Commission
NOTICES
Meetings, 25874

Public Health Service
See Food and Drug Administration
See Health Resources and Services Administration

Reclamation Bureau
NOTICES
Environmental statements; availability, etc.:
Central Valley Project, CA, 25846, 25847

Rural Electrification Administration
PROPOSED RULES
Electric and telephone loans:
Borrower fidelity and insurance requirements, 25786

Securities and Exchange Commission
RULES
Organization, functions, and authority delegations:
Director, Market Regulation Division, 25773
NOTICES
Meetings; Sunshine Act, 25899
Options price reporting authority, 25874
Self-regulatory organizations; proposed rule changes:
Philadelphia Stock Exchange, Inc., 25823
Self-regulatory organizations; unlisted trading privileges:
Pacific Stock Exchange, Inc., 25875
Philadelphia Stock Exchange, Inc., 25876
Applications, hearings, determinations, etc.:
Equitable Capital Partners, L.P., et al., 25877
Overland Express Funds, Inc., et al., 25879
Variable Annunity Life Insurance Co. et al., 25881

Small Business Administration
NOTICES
Small business innovation research program policy directive, 25883

State Department
NOTICES
Meetings:
Historical Diplomatic Documentation Advisory Committee, 25896

Transportation Department
See National Highway Traffic Safety Administration

Treasury Department
See Fiscal Service
See Internal Revenue Service

NOTICES
Agency information collection activities under OMB review, 25896, 25897

Separate Parts In This Issue

Part II
Department of Health and Human Services, Food and Drug Administration, 25902

Part III
Department of Health and Human Services, Food and Drug Administration, 25918

Reader Aids
Additional information, including a list of public laws, telephone numbers, and finding aids, appears in the Reader Aids section at the end of this issue.

Electronic Bulletin Board
Free Electronic Bulletin Board service for Public Law numbers, Federal Register finding aids, and a list of Clinton Administration officials is available on 202–275–1538 or 275–0920.

CFR PARTS AFFECTED IN THIS ISSUE

A cumulative list of the parts affected this month can be found in the Reader Aids section at the end of this issue.

4 CFR

Proposed Rules:

27.....25785
28.....25785

7 CFR

Proposed Rules:

1150.....25785
1160.....25900
1788.....25786

9 CFR

Proposed Rules:

112.....25786

17 CFR

200.....25773
240.....25773

18 CFR

365.....25900

21 CFR

312.....25918
314.....25918
320.....25918

Proposed Rules:

876.....25902
1308 (2 documents).....25788, 25790

26 CFR

Proposed Rules:

52.....25791

31 CFR

251.....25774
253.....25774
254.....25775
290.....25775

32 CFR

213.....25776
372a.....25776
390a.....25776

40 CFR

52 (2 documents).....25776, 25777
180 (4 documents).....25779, 25780, 25782, 25783

Proposed Rules:

82.....25793
180.....25792

42 CFR

431.....25784
483.....25784

47 CFR

Proposed Rules:

73.....25794
74.....25794

49 CFR

571.....25900

Rules and Regulations

Federal Register
Vol. 58, No. 80
Wednesday, April 28, 1993

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.

SECURITIES AND EXCHANGE COMMISSION

17 CFR Parts 200 and 240

[Release No. 34-32191]

RIN 3235-AF44

Risk Assessment Rules

AGENCY: Securities and Exchange Commission.

ACTION: Final rule and technical amendments.

SUMMARY: The Securities and Exchange Commission (the "Commission") is amending Rule 30-3 of the Rules of Practice and Investigations to delegate authority to the Director of the Division of Market Regulation to designate Reporting Brokers or Dealers and to grant or deny exemptions from Rules 17h-1T and 17h-2T. The amendments are intended to conserve the resources of the Commission and will expedite the handling of requests by broker-dealers to be designated as Reporting Brokers or Dealers. This document also contains a correction to the risk assessment rules that were published on July 21, 1992 (57 FR 32159).

EFFECTIVE DATE: The amendments become effective on April 28, 1993.

FOR FURTHER INFORMATION CONTACT: Michael A. Macchiaroli, (202) 272-2904 or Roger G. Coffin, (202) 272-7375, Division of Market Regulation, 450 Fifth Street, NW., 20549.

SUPPLEMENTARY INFORMATION:

I. Introduction

On July 16, 1992, the Commission adopted Rules 17h-1T and 17h-2T under the Securities Exchange Act of 1934 (the "Exchange Act"), which together with Form 17-H, establish a risk assessment recordkeeping and reporting system for registered broker-dealers concerning certain of their associated persons.[1] The Rules were adopted pursuant to the authority granted to the Commission by the Market Reform Act of 1990,[2] and are designed to provide the Commission with information concerning the financial and securities activities of those associated persons of the broker-dealer whose business activities are reasonably likely to have a material impact on the registered broker-dealer.

Rule 17h-1T is a recordkeeping rule, which sets forth the records and other information broker-dealers are required to maintain with respect to their Material Associated Persons. Rule 17h-2T is a reporting rule, which requires broker-dealers to file a quarterly summary of the information required to be kept by Rule 17h-1T with the Commission on Form 17-H.

In this release, the Commission is by order designating 58 broker-dealers as Reporting Brokers or Dealers under the risk assessment rules, and conditionally exempting two other broker-dealers.[3]

II. Delegation of Authority to the Director of the Division of Market Regulation

Paragraph (d)(4) of Rule 17h-1T and paragraph (b)(4) of Rule 17h-2T state that the Commission may, upon written application by a Reporting Broker or Dealer, exempt any of its affiliated brokers or dealers, either unconditionally or on specified terms and conditions. The Commission also has the authority, under Section 17(h) of the Exchange Act, to exempt, by rule or by order, broker-dealers from the Rules. In the absence of a delegation of authority, the Commission would be required to issue an order as to each exemptive request.

Therefore, Rule 30-3 of the Rules of Fair Practice and Investigations (17 CFR 200.30-3), will be amended to delegate the authority to perform these functions to the Director of the Division of Market Regulation (the "Director"). A delegation of authority to the Director to grant or deny exemptions and to designate Reporting Brokers or Dealers will conserve the resources of the Commission and will expedite the handling of these requests. Notwithstanding these delegations of authority, the Division will bring any requests for exemptions that raise serious questions to the Commission for consideration.

Therefore, the Commission is amending Rule 30-3 by adding new paragraph (a)(52) to Rule 30-3, which delegates authority under section 17(h) of the Exchange Act to the Director to: (1) Designate broker-dealers as Reporting Brokers or Dealers under paragraph (d)(4) of Rule 17h-1T and paragraph (b)(4) of Rule 17h-2T; (2) grant or deny exemptions from the risk assessment rules pursuant to section 17(h) of the Exchange Act; and (3) determine to withhold information in such exemptive orders from the public pursuant to section 17(h) of the Exchange Act.[4]

The Commission finds, in accordance with section 553(b)(A) of the Administrative Procedure Act,[5] that this amendment relates solely to agency organization, procedure, or practice, and does not relate to a substantive rule. Accordingly, notice and opportunity for public comment are unnecessary, and publication of the amendment 30 days before its effective date is also unnecessary.

III. Technical Amendment

The Commission is adopting one technical amendment to the Rules. A cross-reference in paragraph (a)(1) of Rule 17h-1T to the exemptive provision in Rule 17h-1T is being changed from "paragraph (c)" to "paragraph (d)".

IV. Statutory Analysis

Pursuant to the Securities Exchange Act of 1934 and particularly section 17 thereof, 15 U.S.C. 78q, the Commission is adopting amendments to §§ 240.17h-1T and 240.17h-2T, to title 17 of the Code of Federal Regulations in the manner set forth below.

List of Subjects

17 CFR Part 200

Administrative practice and procedure; Authority delegations

---

[1] Securities Exchange Act Release No. 30929, (July 15, 1992), 57 FR 32159, (July 21, 1992).

[2] Market Reform Act of 1990, Pub. L. 101-432, § 4, 104 Stat. 963, 966-973 (1990).

[3] With respect to the orders being issued herein pursuant to section 17(h) of the Exchange Act, the Commission has determined that the identifying information in the orders should be withheld from the public.

[4] Consistent with the Commission's practice in this regard, the Director would have delegated authority to make similar determinations.

[5] 15 U.S.C. 553(b)(A).

(Government agencies); Organizations and functions.

17 CFR Part 240

Reporting and recordkeeping requirements, Securities.

Text of the Amendments

In accordance with the foregoing, title 17, chapter II of the Code of Federal Regulations is amended as follows:

PART 200—ORGANIZATION; CONDUCT AND ETHICS; AND INFORMATION AND REQUESTS

Subpart A—Organization and Program Management

1. The general authority citation for part 200, subpart A, continues to read, in part, as follows:

Authority: 15 U.S.C. 77s, 78d–1, 78d–2, 78w, 78*ll*(d) , 79t, 77sss, 80a–37, 80b–11, unless otherwise noted.

* * * * *

2. Section 200.30–3 is amended by adding paragraph (a)(52) to read as follows:

§ 200.30–3 Delegation of authority to Director of Division of Market Regulation.

* * * * *

(a) * * *

(52) Pursuant to Rules 17h–1T and 17h–2T of the Act (§§ 240.17h–1T and 240.17h–2T of this chapter):

(i) To designate certain broker-dealers as Reporting Brokers or Dealers; *or and*

(ii) To grant or deny an exemption, conditionally or unconditionally, to a broker or dealer pursuant to section 17(h) of the Act.

* * * * *

PART 240—GENERAL RULES AND REGULATIONS, SECURITY EXCHANGE ACT OF 1934

3. The authority citation for part 240 continues to read, in part as follows:

Authority: 15 U.S.C. 77c, 77d, 77g, 77j, 77s, 77eee, 77ggg, 77nnn, 77sss, 77ttt, 78c, 78d, 78i, 78j, 78*l*, 78m, 78n, 78o, 78p, 78s, 78w, 78x, 78*ll*(d), 79q, 79t, 80a–20, 80a–23, 80a–29, 80a–37, 80b–3 80b–4, and 80b–11, unless otherwise noted.

* * * * *

Section 240.17h–1T also issued under 15 U.S.C. 78q.

§ 240.17h–1T [Amended]

4. In § 240.17h–1T, paragraph (a)(1) is amended by replacing the phrase "paragraph (c)" with the phrase "paragraph (d)".

Dated: April 22, 1993.

By the Commission.

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 93–9923 Filed 4–27–93; 8:45 am]

BILLING CODE 8010–01–M

DEPARTMENT OF THE TREASURY

Fiscal Service

31 CFR Part 251

RIN 1510–AA23

Payment of Unclaimed Interest on Certain Awards of the Mixed Claims Commission, United States and Germany

AGENCY: Financial Management Service, Fiscal Service, Treasury.

ACTION: Final rule.

SUMMARY: This document removes the regulation governing the payment of unclaimed interest on awards of the Mixed Claims Commission. This regulation is obsolete. No applications for payments have been filed against this fund in at least 5 years by the awardholders or their successors in interest. The effect of this document is to remove an unnecessary regulation.

EFFECTIVE DATE: May 28, 1993.

FOR FURTHER INFORMATION CONTACT: Mia Abeya, 202–874–8740.

SUPPLEMENTARY INFORMATION:

Background

This regulation was issued pursuant to the Settlement of War Claims Act of 1928, 45 Stat. 254, as amended, to establish a trust fund for unclaimed interest on awards of the Mixed Claims Commission. No claims have been made against this fund for at least 5 years by awardholders or their successors in interest. Therefore, this regulation is no longer necessary.

The notice of proposed rulemaking was published November 27, 1992 (57 FR 56292). No comments were received during the 30 day comment period. There are no substantive differences between the proposed and final rules.

It has been determined that this document is not a major regulation as defined in E.O. 12291 and a regulatory impact analysis is not required. The removal of this unused regulation will have little or no effect on the economy or consumers. It is hereby certified that removal of this regulation will not have a significant economic impact on a substantial number of small entities. Accordingly, a regulatory flexibility analysis is not required. The removal of this unused regulation will have little or no effect on small entities.

This final rule is issued in accordance with 31 U.S.C. 321(b)(1), which describes the Secretary of Treasury's power to issue regulations.

List of Subjects in 31 CFR Part 251

War claims, Germany.

For the reasons set out in the preamble, 31 CFR part 251 is removed as follows:

PART 251—[REMOVED]

Part 251 is removed.

Russell D. Morris,

Commissioner.

[FR Doc. 93–9862 Filed 4–27–93; 8:45 am]

BILLING CODE 4810–35–M

31 CFR Part 253

RIN 1510–AA24

Payment Under the Act of Congress Approved August 30, 1962, on Unpaid Balances of Awards of Philippine War Damage Commission

AGENCY: Financial Management Service, Fiscal Service, Treasury.

ACTION: Final rule.

SUMMARY: This document removes the regulation governing payment of unpaid balances of awards of the Philippine War Damage Commission. This regulation is obsolete. The time for applying for payment, and making the payment, have passed. The effect of this document is to remove an unnecessary regulation.

EFFECTIVE DATE: May 28, 1993.

FOR FURTHER INFORMATION CONTACT: Mia Abeya, 202–874–8740.

SUPPLEMENTARY INFORMATION:

Background

This regulation was issued pursuant to the Act of August 30, 1962, Public Law 87–616, 76 Stat. 412, as amended, to govern disbursal of payments directed by the Foreign Claims Settlement Commission, which was evaluating unpaid balances of awards made by the Philippine War Damage Commission under Title I of the Philippine Rehabilitation Act of 1946. Under section 2 of Public Law 87–616, applications for payment were to be filed by October 30, 1963, and the Foreign Claims Settlement Commission was to take final action by October 30, 1964. No directions for disbursal are currently outstanding, and none are expected. Therefore, this regulation's guidelines for payment are no longer necessary.

The notice of proposed rulemaking was published November 27, 1992. No

comments were received during the 30 day comment period. There are no substantive differences between the proposed rule and final rule. This action is in accordance with § 253.2, which authorizes the withdrawal or amendment of any or all of the provisions of the regulations in this part.

It has been determined that this document is not a major regulation as defined in Executive Order 12291 and a regulatory impact analysis is not required. The removal of this unused regulation will have little or no effect on the economy or consumers. It is hereby certified that removal of this regulation will not have a significant economic impact on a substantial number of small entities. Accordingly, a regulatory flexibility analysis is not required. The removal of this unused regulation will have little or no effect on small entities.

List of Subjects in 31 CFR Part 253

War claims, Philippines.

For the reasons set out in the preamble, 31 CFR part 253 is removed as follows:

PART 253—[REMOVED]

Part 253 is removed.

Russell D. Morris,

Commissioner.

[FR Doc. 93–9864 Filed 4–27–93; 8:45 am]

BILLING CODE 4810–35–M

---

31 CFR Part 254

RIN 1510–AA25

Payments on Account of Awards and Appraisals in Favor of Nationals of the United States on Claims Against the Government of Mexico

AGENCY: Financial Management Service, Fiscal Service, Treasury.

ACTION: Final rule.

SUMMARY: This document removes this regulation governing payments to United States nationals on their claims against the Government of Mexico. This regulation is obsolete. No claims have been made in more than 5 years and all efforts to contact all awardholders have been exhausted. The effect of this notice is to remove an unnecessary regulation.

EFFECTIVE DATE: May 28, 1993.

FOR FURTHER INFORMATION CONTACT: Mia Abeya, 202–874–8740.

SUPPLEMENTARY INFORMATION:

Background

The regulations governing payments of awards and appraisals due American nationals on their claims against the Mexican government were issued under authority contained in section 161 of the Revised Statutes (5 U.S.C. 22), the act of April 10, 1935 (49 Stat. 149), the Joint Resolution of August 25, 1937 (50 Stat. 783), and the Settlement of Mexican Claims Act of 1942 (56 Stat. 1058; 22 U.S.C. 661–672).

This program has been ongoing since 1943, and all efforts to contact awardholders have been exhausted. Approximately 97 percent of the awardholders have been paid out of the amount that was available for distribution and no payments have been made in more than 5 years. Awards that remain unpaid are to individuals whose whereabouts are unknown. The notice of proposed rulemaking was published November 27, 1992 (57 FR 56293). No comments were received during the 30 day comment period. There are no substantive differences between the proposed rule and final rule. This action is in accordance with § 254.6 which authorizes the revocation or amendment of any part of the current rules at any time.

It has been determined that this document is not a major regulation as defined in E.O. 12291 and a regulatory impact analysis is not required. The removal of this unused regulation will have little or no effect on the economy or consumers. It is hereby certified that removal of this regulation will not have a significant economic impact on a substantial number of small entities. Accordingly, a regulatory flexibility analysis is not required. The removal of this unused regulation will have little or no effect on small entities.

List of Subjects in 31 CFR Part 254

Foreign claims, Mexico.

For the reasons set out in the preamble, 31 CFR part 254 is removed as follows:

PART 254—[REMOVED]

Part 254 is removed.

Russell D. Morris,

Commissioner.

[FR Doc. 93–9861 Filed 4–27–93; 8:45 am]

BILLING CODE 4810–35–M

---

31 CFR Part 290

RIN 1510–AA27

Loans to Public or Private Agencies Under the Refugee Relief Act of 1953

AGENCY: Financial Management Service, Fiscal Service, Treasury.

ACTION: Final rule.

SUMMARY: This document removes the regulation governing loans to public and private agencies of the United States under the Refugee Relief Act of 1953. This regulation is obsolete because the terms of the Act require the loans to mature not later than June 30, 1963. The effect of this notice is to remove an unnecessary regulation.

EFFECTIVE DATE: May 28, 1993.

FOR FURTHER INFORMATION CONTACT: Mia Abeya, 202–874–8740.

SUPPLEMENTARY INFORMATION: This regulation was issued pursuant to section 16 of the Refugee Relief Act of 1953 ("Act"), 67 Stat. 406 (August 7, 1953), and E.O. 10487 (September 22, 1953). The Act authorized issuance of special nonquota immigrant visas. It also authorized the Department of the Treasury to make loans to public and private agencies of the United States for use in paying the immigrants' transportation from ports of entry within the United States to their places of resettlement. The loans were restricted to those immigrants with visas issued under the Act. The loans were to mature not later than June 30, 1963. Therefore, this regulation is no longer necessary.

The notice of proposed rulemaking was published November 27, 1992 (57 FR 56294). No comments were submitted during the 30 day comment period. There are no substantive differences between the proposed and final rule. This action is in accordance with § 290.7(c) which authorizes the withdrawal or amendment of any or all of the provisions of the regulations in this part.

It has been determined that this document is not a major regulation as defined in E.O. 12291 and a regulatory impact analysis is not required. The removal of this unused regulation will have little or no effect on the economy or consumers. It is hereby certified that removal of this regulation will not have a significant economic impact on a substantial number of small entities. Accordingly, a regulatory flexibility analysis is not required. The removal of this unused regulation will have little or no effect on small entities.

List of Subjects in 31 CFR Part 290

Loan programs-social programs, Refugees, Reporting and recordkeeping requirements.

For the reasons set out in the preamble, 31 CFR part 290 is removed as follows:

PART 290—[REMOVED]

Part 290 is removed.

Russell D. Morris,

Commissioner.

[FR Doc. 93–9863 Filed 4–27–93; 8:45 am]

BILLING CODE 4810–35–M

DEPARTMENT OF DEFENSE

Office of the Secretary

32 CFR Parts 213, 372a, and 390a

Removal of Parts

AGENCY: Office of the Secretary, DoD.

ACTION: Final rule.

SUMMARY: The Department of Defense hereby removes 32 CFR part 213 concerning DoD Cooperation with Civilian Law Enforcement Officials, part 372a concerning Armed Forces Radio and Television Service, and part 390a concerning Armed Forces Institute of Pathology. These parts have served the purpose for which they were intended and are no longer valid.

EFFECTIVE DATE: April 28, 1993.

FOR FURTHER INFORMATION CONTACT: L.M. Bynum (703) 697–4111, Correspondence and Directives Directorate, 1155 Defense Pentagon, Washington, DC 20301–1155.

SUPPLEMENTARY INFORMATION: An updated version of DoD Directive 5525.5 (previously part 213), DoD Directive 5120.20 (previously part 372a), and DoD Directive 5154.24 (previously part 390a) is available, from the National Technical Information Service (NTIS), 5285 Port Royal Road, Springfield, VA 22161.

List of Subjects

32 CFR Part 213

Intergovernmental relations, Law enforcement.

32 CFR Parts 372a and 390a

Organization and functions (government agencies).

PARTS 213, 372a and 390a—[REMOVED]

Accordingly, by the authority of 10 U.S.C. 131, 32 CFR parts 213, 372a, and 390a are removed.

Dated: April 22, 1993.

L.M. Bynum,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 93–9770 Filed 4–27–93; 8:45 am]

BILLING CODE 5000–04–M

ENVIRONMENTAL PROTECTION AGENCY

[TN–096–1–5639; FRL–4616–4]

40 CFR Part 52

Approval and Promulgation of Implementation Plans; Knox County: Approval of Revision to Add Prevention of Significant Deterioration (PSD) Regulations

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: EPA approves a revision to the Knox County portion of the Tennessee State Implementation Plan (SIP). The State of Tennessee, through the Tennessee Department of Conservation, submitted revisions to the Knox County portion of the SIP on January 29, 1992, and June 15, 1992. This revision adds a new section, Regulation 45.0—Prevention of Significant Deterioration (PSD), to the Knox County portion of the SIP.

DATES: This action will be effective June 28, 1993, unless notice is received by May 28, 1993, 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: Copies of the material submitted by the State of Tennessee may be examined during normal business hours at the following locations:

Public Information Reference Unit, ATTN: Jerry Kurtzweg (AN 443), Environmental Protection Agency, 401 M Street, SW., Washington, DC 20460.

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

Division of Air Pollution Control, Tennessee Department of Conservation and Environment, L&C Annex, 9th Floor, 401 Church Street, Nashville, Tennessee 37243–1531.

Knox County Department of Air Pollution Control, City/County Building, Suite 459, 400 Main Avenue, Knoxville, Tennessee 37902.

FOR FURTHER INFORMATION CONTACT: Joey LeVasseur, of the EPA Region IV Air Programs Branch at 404–347–2864 and at the above address.

SUPPLEMENTARY INFORMATION: The Clean Air Act Amendments of 1977 required states to include in their SIPs permit regulations for PSD. The Knox County Air Pollution Control Board provided a draft submission of Knox County Air Pollution Control Regulation 45.0, Prevention of Significant Deterioration, on May 31, 1991. This regulation was reviewed and found to have many deficiencies. Comments were made and incorporated before the official submittal by the State. The Tennessee Department of Environment and Conservation submitted this regulation for inclusion in the Knox County portion of the SIP on January 29, 1992. A letter from Douglas Neeley to Harold Hodges on March 13, 1992, identified deficiencies in the proposed Knox County regulation. The Tennessee Department of Conservation resubmitted the revisions on June 15, 1992, that corrected all the deficiencies in the January 29, 1992, submittal.

A brief description of the added regulation follows. This regulation is more fully discussed in the official SIP submittal that is available at the Region IV office listed under the "**ADDRESSES**" section of this notice.

Section 45.0, Prevention of Significant Deterioration, was added to provide permitting requirements for attainment areas where existing air quality is better than the National Ambient Air Quality Standards (NAAQS). This Section meets all of the PSD requirements of 40 CFR part 51.

Final Action

EPA is today approving Section 45.0, Prevention of Significant Deterioration, of the Knox County regulations. 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 June 28, 1993. However, if notice is received by May 28, 1993, 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 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 June 28, 1993. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this rule for purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements. (See 307(b)(2).)

This action has been classified as a Table 2 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 (OMB) waived Table 2 and 3 SIP revisions (54 FR 2222) from the requirements of section 3 of Executive Order 12291 for two years. EPA has submitted a request for a permanent waiver for Table 2 and Table 3 SIP revisions. OMB has agreed to continue the temporary waiver until such time as it rules on EPA's request.

Nothing in this action shall be construed as permitting or allowing or establishing a precedent for any future request for a revision to any State Implementation Plan. Each request for revision to the State Implementation Plan shall be considered separately in light of specific technical, economic and environmental factors and in relation to relevant statutory and regulatory requirements.

Under the Regulatory Flexibility Act, 5 U.S.C. 600 et. seq., EPA must prepare a regulatory flexibility analysis assessing the impact of any proposed or final rule on small entities. 5 U.S.C. 603 and 604. Alternatively, EPA may certify that the rule will not have a significant impact on a substantial number of small entities. Small entities include small businesses, small not for profit enterprises, and government entities with jurisdiction over populations of less than 50,000.

SIP approvals under section 110 and Subchapter I, Part D of the CAA do not create any new requirements, but simply approve requirements that the State is already imposing. Therefore, because the federal SIP-approval does not impose any new requirements, I certify that it does not have a significant impact on any small entities affected. Moreover, due to the nature of the federal-state relationship under the CAA, preparation of a regulatory flexibility analysis would constitute federal inquiry into the economic reasonableness of state action. The CAA forbids EPA to base its actions concerning SIPs on such grounds. *Union Electric Co.* v. *U.S. E.P.A.*, 427 U.S. 246, 256–66 (S.Ct. 1976); 42 U.S.C. 7410(a)(2).

List of Subjects in 40 CFR Part 52

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

Editorial Note: This document was received by the Office of the Federal Register on April 23, 1993.

Dated: February 23, 1993.

Donald Guinyard,

Acting, Regional Administrator.

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

PART 52—[AMENDED]

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

Authority: 42.U.S.C. 7401–7671q.

Subpart—RR

2. Section 52.2220 is amended by adding paragraph (c)(109) to read as follows:

§ 52.2220 Identification of plan.

* * * * *

(c) * * *

(109) Addition of Section 45, Prevention of Significant Deterioration to the Knox County portion of the Tennessee SIP, submitted and revised on January 29, 1992 and June 15, 1992, respectively.

(i) Incorporation by reference.

(A) Amendments to Section 45.0 of the Knox County regulations were adopted on June 10, 1992.

(ii) Other material. None.

[FR Doc. 93–9950 Filed 4–27–93; 8:45 am]

BILLING CODE 6560–50–P

[TN–096–2–5642; FRL–4616–2]

40 CFR Part 52

Approval and Promulgation of Implementation Plans; Knox County: Approval of Revisions to the Volatile Organic Compound (VOC) Regulations

AGENCY: Environmental Protection Agency.

ACTION: Final rule.

SUMMARY: EPA approves revisions to the Knox County portion of the State Implementation Plan (SIP) which corrects the deficiencies identified in the November 1989 SIP call. On January 4, 1991, January 29, 1992, and June 15, 1992, the State of Tennessee submitted revisions to the Knox County portion of the SIP regarding Volatile Organic Compounds (VOCs). The revisions were submitted in response to the November 1989 SIP call to areas in Tennessee which were not achieving the National Ambient Air Quality Standards (NAAQS) for ozone and carbon monoxide.

DATES: This action will be effective on June 28, 1993 unless notice is received by May 28, 1993 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: Copies of the material submitted by the State of Tennessee may be examined during normal business hours at the following locations:

Public Information Reference Unit, ATTN: Jerry Kurtzweg (AN 443), Environmental Protection Agency, 401 M Street SW., Washington, DC 20460.

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

Division of Air Pollution Control, Tennessee Department of Conservation and Environment, L&C Annex, 9th Floor, 401 Church Street, Nashville, Tennessee 37243–1531.

Knox County Department of Air Pollution Control, City/County Building, Suite 459, 400 Main Avenue, Knoxville, Tennessee 37902.

FOR FURTHER INFORMATION CONTACT: Joey LeVasseur, of the EPA Region IV Air Programs Branch at 404–347–2864 and at the above address.

SUPPLEMENTARY INFORMATION: The Clean Air Act Amendments of 1977 provided that states should attain the ozone and carbon monoxide National Ambient Air Quality Standards (NAAQS) by December 31, 1982. However, states could seek an extension of the attainment date to as late as December 31, 1987. When the ambient air quality data was reviewed at the end of 1988 for all areas, it was determined that Knoxville had violated the ozone standard in the summer of 1988. Under the 1977 Act, EPA designated Knoxville as an attainment area. However, Tennessee adopted statewide Reasonably Available Control Technology (RACT) rules applicable to attainment, as well as, nonattainment areas. The Knox County Department of Air Pollution Control then adopted VOC RACT rules applicable to the Knox County attainment area. Subsequently, the Governor of Tennessee was notified by EPA on November 8, 1989, that Knox County was not attaining the standard. A December 5, 1989, letter from Bruce Miller to Terry Harris identified several VOC deficiencies in the Knox County regulations. Three sets of revisions to the Knox County regulations were submitted in response to the SIP call letter. A January 4, 1991, submittal addressed some, but not all of the deficiencies. The agency was notified on September 5, 1991, of the remaining

deficiencies in the Knox County regulations. Together, the January 4, 1991, January 29, 1992, and March 19, 1992, submittals correct all of the deficiencies.

On November 15, 1990, the Clean Air Act Amendments of 1990 (CAAA) were enacted. Pub. L. 101–549, 101 Stat. 2399, codified at 42 U.S.C. 7401–7671q. The amended Act superseded the SIP call and established the RACT requirements for nonattainment areas. Under the amended Act, marginal areas that were pre-enactment nonattainment areas are required to correct their RACT rules to include RACT as required by the pre-amended Act. In addition, areas that were designated nonattainment as of enactment and that were not classified under section 181 are required to adopt RACT rules pursuant to section 172(c)(1) of the amended Act. Knoxville was classified as a new marginal nonattainment area under section 181. EPA believes that the amended Act does not require any additional RACT requirements for areas that are newly designated as marginal ozone nonattainment areas under the amended Act. Therefore no RACT requirements beyond those pursuant to the 1989 SIP call are applicable to Knox County. (See 57 FR 13498, 13503 (April 16, 1992).) Although Knoxville was not subject to the requirements of section 182(a)(2)(A), to correct RACT as it was required under pre-amended section 172(b), these revisions are consistent with pre-enactment guidance.[1]

EPA is approving the following revisions to the Knoxville portion of the Tennessee SIP. These revisions are more fully discussed in the official SIP submittal that is available at the Region IV office listed under the "ADDRESSES" Section of this notice.

Section 26.5–B, Monitoring, Recording, and Reporting of Source Emissions, was amended to require explicitly that sources keep records needed to assess compliance for the time frame specified in the rule. It also gives reporting schedules and reporting formats.

Section 27.2, Source Sampling and Analysis, was amended to incorporate language stating that the Director may specify or approve, in specific cases, the use of a reference method with minor changes in methodology and that only the EPA Administrator can approve equivalent or alternative methods.

Section 13.15, Definitions, and Section 46.4–B.7, Alternate Emission Standard, were amended and added, respectively, to state that VOC emission limit equivalency calculations will be performed on a solids applied basis.

Section 27.2–A, Source Sampling and Analysis, was amended to add Reference Method 23 and Reference Method 26.

Section 28.1–A.4, Variances—General, was amended to state that any cross-line averaging must be submitted as a source specific SIP revision and must meet the provisions of EPA's December 4, 1986, Emissions Trading Policy Statement (ETPS).

Section 46.1–B, Purpose and General Provisions, was added to allow the Director and a source to mutually agree to establish an emission limit more restrictive than otherwise specified in this Section.

Section 46.2–A.7, Definitions, was amended to make it clear that coating lines that do not contain bake ovens are not exempt.

Section 46.2–A.34, Definitions, was amended to revise the definition of VOC to exempt those organic compounds identified by the Administrator as compounds which do not participate in atmospheric photochemical reactions. This Section was also amended to include VOC measuring methods for purposes of determining compliance with emission limits.

Section 46.4–B.8, Alternate Emission Standard, and Section 46.11–B.5, Surface Coating of Miscellaneous Metal Parts and Products, were added to clarify that exempt solvents, as well as water, are excluded from compliance calculations.

Section 46.4–I, Alternate Emission Standard, was added to state that any cross-line averaging must be submitted as a source specific SIP revision and must meet the provisions of EPA's December 4, 1986, Emissions Trading Policy Statement (ETPS).

Section 46.4–B.9, Alternate Emission Standard, Section 46.6–D.8, Petroleum Liquid Storage in External Floating Roof Tanks, and Section 46.8–B.1.d, Bulk Gasoline Terminals, were added to revise Director's Discretion clauses approving alternate control systems to specify that the alternate means of control is comprised solely of hardware.

Section 46.6–D.7, Petroleum Liquid Storage in External Floating Roof Tanks, was amended to state that records were to be maintained as specified in new Section 46.20.

Section 46.11–B.6, Surface Coating of Miscellaneous Metal Parts and Products, was added to specify a compliance time frame associated with the emission limit.

Section 46.17–D, General Provisions for Test Methods and Procedures, was amended to specify that all alternate compliance plans must be submitted to EPA for approval as a source specific SIP revision unless the alternate means of control is comprised solely of hardware.

Section 46.19, Compliance Certification, Recordkeeping, and Reporting Procedures for Coating Sources, and Section 46.20, Compliance Certification, Recordkeeping, and Reporting Procedures for Non-Coating Sources, were added to clarify methods of recordkeeping, reporting, and compliance certification.

Section 46.21, was added to make it clear that any existing controls on VOC sources, required by any section of the Knox County Air Pollution Control Regulations, must be retained unless otherwise approved by EPA.

The Approval of these revisions completes the correction of all identified deficiencies in the Knoxville VOC regulations. The revisions are consistent with Agency policy and guidance.

Final Action: EPA is today approving the aforementioned revisions to the Knoxville VOC regulations. This action is being taken without prior proposal because the changes are noncontroversial and EPA anticipates no adverse comments on them.

The public should be advised that this action will be effective on June 28, 1993. However, if notice is received by May 28, 1993 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 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 June 28, 1993. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this rule for purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements. (See 307(b)(2).)

This action has been classified as a Table 2 action by the Regional Administrator under the procedures

[1] Among other things, the pre-amendment guidance consists of the VOC RACT portions of the Post-87 policy, 52 FR 45044 (Nov. 24, 1987); the Bluebook, "Issues Relating to VOC Regulation Cutpoints, Deficiencies and Deviations, Clarification to Appendix D of November 24, 1987 Federal Register Notice" (of which notice of availability was published in the Federal Register on May 25, 1988); and the existing CTGs.

published in the **Federal Register** on January 19, 1989 (54 FR 2214–2225). On January 6, 1989, the Office of Management and Budget (OMB) waived Table 2 and 3 SIP revisions (54 FR 2222) from the requirements of Section 3 of Executive Order 12291 for two years. EPA has submitted a request for a permanent waiver for Table 2 and Table 3 SIP revisions. OMB has agreed to continue the temporary waiver until such time as it rules on EPA's request.

Nothing in this action shall be construed as permitting or allowing or establishing a precedent for any future request for a revision to any state implementation plan. Each request for revision to the state implementation plan shall be considered separately in light of specific technical economic and environmental factors and in relation to relevant statutory and regulatory requirements.

Under the Regulatory Flexibility Act, 5 U.S.C. 600 *et seq.*, EPA must prepare a regulatory flexibility analysis assessing the impact of any proposed or final rule on small entities. 5 U.S.C. 603 and 604. Alternatively, EPA may certify that the rule will not have a significant impact on a substantial number of small entities. Small entities include small businesses, small not-for-profit enterprises, and government entities with jurisdiction over populations of less than 50,000.

SIP approvals under section 110 and Subchapter I, Part D of the CAA do not create any new requirements, but simply approve requirements that the State is already imposing. Therefore, because the Federal SIP-approval does not impose any new requirements, I certify that it does not have a significant impact on any small entities affected. Moreover, due to the nature of the federal-state relationship under the CAA, preparation of a regulatory flexibility analysis would constitute federal inquiry into the economic reasonableness of state action. The CAA forbids EPA to base its actions concerning SIPs on such grounds. *Union Electric Co.* v. *U.S. E.P.A.*, 427 U.S. 246, 256–66 (S.Ct. 1976); 42 U.S.C. Section 7410(a)(2).

List of Subjects in 40 CFR Part 52

Air pollution control, Hydrocarbons, Incorporation by reference, Intergovernmental relations, Ozone, Particulate matter, Reporting and recordkeeping requirements.

Dated: March 22, 1993.

Patrick M. Tobin,

Acting Regional Administrator.

Part 52 of chapter I, title 40 of the Code of Federal Regulations, is amended as follows:

PART 52—[AMENDED]

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

Authority: 42 U.S.C. 7671q.

Subpart—RR

2. Section 52.2220 is amended by adding paragraph (c)(110) to read as follows:

§ 52.2220 Identification of plan.

* * * * *

(c) * * *

(110) Revisions to the VOC portion of the Knox County portion of the Tennessee SIP to correct deficiencies, which were submitted on January 4, 1991, January 29, 1992, and June 15, 1992, respectively.

(i) Incorporation by reference.

(A) Amendments to the following Sections of the Knox County regulations—13.15, 46.1–B, 46.4–B.7, 46.4–B.8, 46.4–B.9, 46.4–I, 46.6–D.6, 46.8–B.1.d, 46.11–B.5, 46.11–B.6—were adopted on December 13, 1990.

(B) Amendments to the following Sections of the Knox County regulations—27.2–A and 46.2—were adopted on November 13, 1991.

(C) Amendments to the following Sections of the Knox County regulations—26.5–B, 27.2, 28.1–A.4, 46.2–A.7, 46.2–A.34, 46.6–D.7, 46.17–D, 46.19, 46.20, and 46.21—were adopted on June 10, 1992.

(ii) Other material.

(A) Letter of January 4, 1991, from the Tennessee Department of Conservation and Environment.

(B) Letter of January 29, 1992, from the Tennessee Department of Conservation and Environment.

(C) Letter of June 15, 1992, from the Tennessee Department of Conservation and Environment.

[FR Doc. 93–9951 Filed 4–27–93; 8:45 am]

BILLING CODE 6560–50–P

---

40 CFR Part 180

[OPP–300274A; FRL–4576–5]

RIN 2070–AB78

Sodium Bisulfate; Tolerance Exemeption

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This document establishes an exemption from the requirement of a tolerance for residues of sodium bisulfate (CAS Registry No. 7681-38-1) when used as an inert ingredient (acidifying/buffering agent) in pesticide formulations applied to growing crops only. This regulation was requested by the American Cyanamid Co.

EFFECTIVE DATE: This regulation becomes effective April 28, 1993.

ADDRESSES: Written objections, identified by the document control number, [OPP–300274A], may be submitted to: Hearing Clerk (A-110), Environmental Protection Agency, rm. M3708, 401 M St., SW., Washington, DC 20460.

FOR FURTHER INFORMATION CONTACT: By mail: Connie Welch, Registration Support Branch, Registration Division (H7505W), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location and telephone number: 2800 Crystal Drive, North Tower, 6th Floor, Arlington, VA 22202, (703)-308-8320.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of February 17, 1993 (58 FR 8729), a document was issued giving notice that the American Cyanamid Co., Agricultural Research Division, P.O. Box 400, Princeton, NJ 08540, had submitted pesticide petition (PP) 2E4160 to EPA requesting that the Administrator, pursuant to section 408(e) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 346a(e), propose to amend 40 CFR 180.1001(d) by establishing an exemption from the requirement of a tolerance for residues of sodium bisulfate (CAS Reg. No. 7681-38-1) when used as an inert ingredient (acidifying/buffering agent) in pesticide formulations applied to growing crops only.

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

As part of the EPA policy statement on inert ingredients published in the

Federal Register of April 22, 1987 (52 FR 13305), the Agency established data requirements which will be used to evaluate the risks posed by the presence of an inert ingredient in a pesticide formulation. Exemptions from some or all of the requirements may be granted if it can be determined that the inert ingredient will present minimal or no risk.

There were no comments or requests for referral to an advisory committee received in response to the proposed rule.

The data submitted in the petition and other relevant material have been evaluated and discussed in the proposed rule. Based on the data and information considered, the Agency concludes that the tolerance exemption will protect the public health. Therefore, the tolerance exemption is established as set forth below.

Any person adversely affected by this regulation may, within 30 days after publication of this document in the Federal Register, file written objections with the Hearing Clerk, at the address given above (40 CFR 178.20). The objections submitted must specify the provisions of the regulation deemed objectionable and the grounds for the objections (40 CFR 178.25). Each objection must be accompanied by the fee prescribed by 40 CFR 180.33(i). If a hearing is requested, the objections must include a statement of the factual issue(s) on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the objector (40 CFR 178.27). A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is a genuine and substantial issue of fact; there is a reasonable possibility that available evidence identified by the requestor would, if established, resolve one or more of such issues in favor of the requestor, taking into account uncontested claims or facts to the contrary; and resolution of the factual issue(s) in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32).

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

Pursuant to the requirements of the Regulatory Flexibility Act (Pub. L. 96-354, 94 Stat. 1164, 5 U.S.C. 601-612), the Administrator has determined that regulations establishing new tolerances or raising tolerance levels or establishing exemptions from tolerance requirements do not have a significant economic impact on a substantial number of small entities. A certification statement to this effect was published in the Federal Register of May 4, 1981 (46 FR 24950).

List of Subjects in 40 CFR Part 180

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

Dated: April 12, 1993.

Douglas D. Campt,

Director, Office of Pesticide Programs.

Therefore, 40 CFR part 180 is amended as follows:

PART 180—[AMENDED]

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

Authority: 21 U.S.C. 346a and 371.

2. Section 180.1001(d) table is amended by adding and alphabetically inserting the inert ingredients, to read as follows:

§ 180.1001 Exemptions from the requirement of a tolerance.

* * * * *

(d) * * *

Inert ingredients	Limits	Uses
* * * * * * *		
Sodium bisulfate (CAS Registry No. 7681-38-1)		Acidifying/buffering agent
* * * * * * *		

* * * * *

[FR Doc. 93-9817 Filed 4-27-93; 8:45 am]

BILLING CODE 6560-50-F

40 CFR Part 180

[OPP-300271A; FRL-4576-4]

RIN 2070-AB78

Ethoxylated Polyarylalkylphenols; Tolerance Exemeptions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This document establishes exemptions from the requirement of a tolerance for residues of certain ethoxylated polyarylalkylphenols when used as inert ingredients (surfactants) in pesticide formulations applied to growing crops only. This regulation was requested by Rhone-Poulenc, Inc.

EFFECTIVE DATE: This regulation becomes effective April 28, 1993.

ADDRESSES: Written objections, identified by the document control number, [OPP-300271A], may be submitted to: Hearing Clerk (A-110), Environmental Protection Agency, rm. M3708, 401 M St., SW., Washington, DC 20460.

FOR FURTHER INFORMATION CONTACT: By mail: Connie Welch, Registration Support Branch, Registration Division (H7505W), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location and telephone number: 6th Floor, North Tower, 2800 Crystal Drive, Arlington, VA 22202, (703)-308-8320.

SUPPLEMENTARY INFORMATION: In the Federal Register of February 17, 1993 (58 FR 8728), a document was issued giving notice that Rhone-Poulenc, Inc., CN 7500, Cranbury, NJ 08512-7500, had submitted pesticide petition (PP) 1E4003 to EPA requesting that the Administrator, pursuant to section 408(e) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 346a(e), propose to amend 40 CFR 180.1001(d) by establishing an exemption from the requirement of a tolerance for residues of alpha-[2,4,6-tris[1-(phenyl)ethyl]phenyl]-omega-hydroxy poly(oxyethylene); alpha-[2,4,6-tris[1-(phenyl)ethyl]phenyl]omega-hydroxy poly(oxyethylene), mixture of monohydrogen and dihydrogen phosphate esters and the corresponding ammonium, calcium, magnesium, potassium, sodium and zinc salts; alpha-[2,4,6-tris[1-(phenyl)ethyl]phenyl]-omega-hydroxy poly(oxyethylene) sulfate, and the corresponding ammonium, calcium, magnesium, potassium, sodium, and zinc salts; and alpha-[2,4,6-tris[1-(phenyl)ethyl]phenyl]-omega-hydroxy poly(oxyethylene) poly(oxypropylene)

copolymer, when used as inert ingredients (surfactants) in pesticide formulations applied to growing crops only.

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

As part of the EPA policy statement on inert ingredients published in the **Federal Register** of April 22, 1987 (52 FR 13305), the Agency established data requirements which will be used to evaluate the risks posed by the presence of an inert ingredient in a pesticide formulation. Exemptions from some or all of the requirements may be granted if it can be determined that the inert ingredient will present minimal or no risk.

There were no comments or requests for referral to an advisory committee received in response to the proposed rule.

The data submitted in the petition and other relevant material have been evaluated and discussed in the proposed rule. Based on the data and information considered, the Agency concludes that the tolerance exemptions will protect the public health. Therefore, the tolerance exemptions are established as set forth below.

Any person adversely affected by this regulation may, within 30 days after publication of this document in the **Federal Register**, file written objections with the Hearing Clerk, at the address given above (40 CFR 178.20). The objections submitted must specify the provisions of the regulation deemed objectionable and the grounds for the objections (40 CFR 178.25). Each objection must be accompanied by the fee prescribed by 40 CFR 180.33(i). If a hearing is requested, the objections must include a statement of the factual issue(s) on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the objector (40 CFR 178.27). A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is a genuine and substantial issue of fact; there is a reasonable possibility that available evidence identified by the requestor would, if established, resolve one or more of such issues in favor of the requestor, taking into account uncontested claims or facts to the contrary; and resolution of the factual issue(s) in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32).

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

Pursuant to the requirements of the Regulatory Flexibility Act (Pub. L. 96-354, 94 Stat. 1164, 5 U.S.C. 601-612), the Administrator has determined that regulations establishing new tolerances or raising tolerance levels or establishing exemptions from tolerance requirements do not have a significant economic impact on a substantial number of small entities. A certification statement to this effect was published in the **Federal Register** of May 4, 1981 (46 FR 24950).

List of Subjects in 40 CFR Part 180

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

Dated: April 12, 1993.

Douglas D. Campt,

Director, Office of Pesticide Programs.

Therefore, 40 CFR part 180 is amended as follows:

PART 180—[AMENDED]

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

Authority: 21 U.S.C. 346a and 371.

2. Section 180.1001(d) table is amended by adding and alphabetically inserting the inert ingredients, to read as follows:

§ 180.1001 Exemptions from the requirement of a tolerance.

* * * * *

(d) * * *

Inert ingredients	Limits	Uses
* * *	* *	* *
Alpha-[2,4,6-tris[1-(phenyl)ethyl]phenyl]-omega-hydroxy poly(oxyethylene); mixture of monohydrogen and dihydrogen phosphate esters and the corresponding ammonium, calcium, magnesium, potassium, sodium and zinc salts, the poly(oxyethylene) content averages 4-150 moles).	Not more than 15% of the formulation.	Surfactant
Alpha-[2,4,6-tris[1-(phenyl)ethyl]phenyl]-omega-hydroxy poly(oxyethylene) poly(oxypropylene) copolymer, the poly(oxypropylene) content averages 2-8 moles, the poly(oxyethylene) content averages 16-30 moles, and the average molecular weight is 1,500.	Not more than 15% in the pesticide formulation.	Surfactant
Alpha-[2,4,6-tris[1-(phenyl)ethyl]phenyl]-omega-hydroxy poly(oxyethylene) sulfate, and the corresponding ammonium, calcium, magnesium, potassium, sodium, and zinc salts, the poly(oxyethylene content averages 4-150 moles.	Not more than 15% of the pesticide formulation.	Surfactant
Alpha-[2,4,6-tris[1-(phenyl)ethyl]phenyl]-omega-hydroxy poly(oxyethylene), the poly(oxyethylene) content averages 4-150 moles).	Not more than 15% of the formulation.	Surfactant
* * *	* *	* *

* * * * *

[FR Doc. 93–9818 Filed 4–27–93; 8:45 am]
BILLING CODE 6560–50–F

40 CFR Part 180

[OPP–300276A; FRL–4576–6]

RIN 2070–AB78

Acrylic Acid-Sodium Acrylate-Sodium-2-Methylpropanesulfonate Copolymer; Tolerance Exemption

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This document establishes an exemption from the requirement of a tolerance for residues of acrylic acid-sodium acrylate-sodium-2-methylpropanesulfonate copolymer (CAS No. 97953-25-8) when used as an inert ingredient (dispersing agent) in pesticide formulations applied to growing crops only. This regulation was requested by the Petrolite Corp.

EFFECTIVE DATE: This regulation becomes effective April 28, 1993.

ADDRESSES: Written objections, identified by the document control number, [OPP-300276A], may be submitted to: Hearing Clerk (A-110), Environmental Protection Agency, Rm. M3708, 401 M St., SW., Washington, DC 20460.

FOR FURTHER INFORMATION CONTACT: By mail: Connie Welch, Registration Support Branch, Registration Division (H7505W), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location and telephone number: 6th Floor, North Tower, 2800 Crystal Drive, Arlington, VA 22202, (703)-308-8320.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of March 3, 1993 (58 FR 12199), a document was issued giving notice that the Petrolite Corp., 369 Marshall Ave., St. Louis, MO 63119-1897, had submitted a request that the Administrator, pursuant to section 408(e) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 346a(e), propose to amend 40 CFR 180.1001(d) by establishing an exemption from the requirement of a tolerance for residues of acrylic acid-sodium acrylate-sodium-2-methylpropanesulfonate copolymer when used as an inert ingredient (dispersing agent) in pesticide formulations applied to growing crops only.

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

As part of the EPA policy statement on inert ingredients published in the **Federal Register** of April 22, 1987 (52 FR 13305), the Agency established data requirements which will be used to evaluate the risks posed by the presence of an inert ingredient in a pesticide formulation. Exemptions from some or all of the requirements may be granted if it can be determined that the inert ingredient will present minimal or no risk.

There were no comments or requests for referral to an advisory committee received in response to the proposed rule.

The data submitted in the petition and other relevant material have been evaluated and discussed in the proposed rule. Based on the data and information considered, the Agency concludes that the tolerance exemption will protect the public health. Therefore, the tolerance exemption is established as set forth below.

Any person adversely affected by this regulation may, within 30 days after publication of this document in the **Federal Register**, file written objections with the Hearing Clerk, at the address given above (40 CFR 178.20). The objections submitted must specify the provisions of the regulation deemed objectionable and the grounds for the objections (40 CFR 178.25). Each objection must be accompanied by the fee prescribed by 40 CFR 180.33(i). If a hearing is requested, the objections must include a statement of the factual issue(s) on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the objector (40 CFR 178.27). A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is a genuine and substantial issue of fact; there is a reasonable possibility that available evidence identified by the requestor would, if established, resolve one or more of such issues in favor of the requestor, taking into account uncontested claims or facts to the contrary; and resolution of the factual issue(s) in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32).

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

Pursuant to the requirements of the Regulatory Flexibility Act (Pub. L. 96-354, 94 Stat. 1164, 5 U.S.C. 601-612), the Administrator has determined that regulations establishing new tolerances or raising tolerance levels or establishing exemptions from tolerance requirements do not have a significant economic impact on a substantial number of small entities. A certification statement to this effect was published in the **Federal Register** of May 4, 1981 (46 FR 24950).

List of Subjects in 40 CFR Part 180

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

Dated: April 12, 1993.

Douglas D. Campt,
Director, Office of Pesticide Programs.

Therefore, 40 CFR part 180 is amended as follows:

PART 180—[AMENDED]

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

Authority: 21 U.S.C. 346a and 371.

2. Section 180.1001(d) table is amended by adding and alphabetically inserting the inert ingredients, to read as follows:

§ 180.1001 Exemptions from the requirement of a tolerance.

* * * * *

(d) * * *

Inert ingredients	Limits	Uses
* * * * * * *		
Acrylic acid-sodium acrylate-sodium-2-methylpropanesulfonate copolymer (minimum average molecular weight 4,500); CAS No. 97953-25-8.		Dispersing agent
* * * * * * *		

* * * * *

[FR Doc. 93-9816 Filed 4-27-93; 8:45 am]
BILLING CODE 6560-50-F

40 CFR Part 180

[PP 2F4040/R1178; FRL-4165-2]
RIN 2070-AB78

Spod-X Bioinsecticide; Tolerance Exemption

AGENCY: Environmental Protection Agency (EPA).
ACTION: Final rule.

SUMMARY: This document establishes an exemption from the requirement of a tolerance for residues of the microbial pest control agent *Spodoptera exigua* nuclear polyhedrosis virus in or on all raw agricultural commodities. The product Spod-X is an insecticidal virus product containing the polyhedral inclusion bodies of *Spodoptera exigua* nuclear polyhedrosis virus (Family: Baculoviridae). This exemption was requested by Crop Genetics International. This rule eliminates the need to establish a maximum permissible level for residues of *Spodoptera exigua* nuclear polyhedrosis virus.

EFFECTIVE DATE: Effective on April 28, 1993.

ADDRESSES: Written objections, identified by the document control number [PP 2F4040/R1178], may be submitted to the Hearing Clerk (A-110), Environmental Protection Agency, Rm. 3708M, 401 M St., SW., Washington, DC 20460.

FOR FURTHER INFORMATION CONTACT: Philip O. Hutton, Product Manager (PM) 18, Registration Division (H7505C), Office of Pesticide Programs, Environmental Protection Agency, Rm. 213, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA 22202, (703)-305-7690.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of March 11, 1992 (57 FR 8658), EPA issued a notice that announced Espro, Inc., (subsequently acquired by Crop Genetics International, 7170 Standard Drive, Hanover, MD 21076), had submitted pesticide petition (PP) 2F4040 to EPA under section 408(d) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 346a(d), proposing that 40 CFR part 180 be amended by establishing an exemption from the requirement of a tolerance for residues of the insecticide Spod-X containing the polyhedral inclusion bodies of *S. exigua* nuclear polyhedrosis virus in or on all raw agricultural commodities when used to control the beet armyworm.

There were no comments or requests for referral to an advisory committee received in response to the notice of filing.

Residue Chemistry Data and Toxicology Data

Although Spod-X bioinsecticide will be applied on a variety of vegetable and floriculture crops at rates varying from 2 to 50 grams per acre, residue chemistry data were not required. Such data were determined to be necessary only if the submitted toxicology studies indicated that additional Tier II or III toxicology data would be required as specified in 40 CFR 158.165(e). The submitted toxicology data for this use indicated that the product is of low mammalian toxicity; therefore, Tier II or III data were not required.

The toxicological data considered in support of this exemption from the requirements of a tolerance included an acute oral toxicity/pathogenicity study in the rat, an acute pulmonary toxicity/pathogenicity study in the rat, an acute intraperitoneal toxicity/pathogenicity study in the rat, and a primary eye irritation study in the rabbit. A dermal toxicty study was submitted and considered supplemental data. The results of the toxicity/pathogenicity studies showed no toxic, pathogenic, or adverse effects.

Reference Dose (RfD) and maximum permissible intake (MPI) considerations are not relevant to this petition because of the low toxicity and lack of pathogenicity or infectivity observed in the submitted studies.

Based on the information cited above, the Agency has determined that the potential acute toxicity/pathogenicity of *Spodoptera exigua* nuclear polyhedrosis virus is sufficiently low to support the proposed exemption from the requirements of a tolerance on all raw agricultural commodities. Thus, a tolerance for the active ingredient *Spodoptera exigua* nuclear polyhedrosis virus is not necessary to protect the public health. Therefore, 40 CFR part 180 is amended as set forth below.

Any person adversely affected by this regulation may, within 30 days after the date of publication of this document in the **Federal Register**, file written objections and/or a request for a hearing with the Hearing Clerk at the address given above. 40 CFR 178.20. The objections submitted must specify the provisions of the regulation deemed objectionable and the grounds for the objections. 40 CFR 178.25. Each objection must be accompanied by the fee prescribed by 40 CFR 180.33(i). If a hearing is requested, the objections must include a statement of the factual issue(s) on which a hearing is requested, the requestor's contentions on each such issue, and a summary of any evidence relied upon by the objector. 40 CFR 178.27. A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: there is a genuine and substantial issue of fact; there is a reasonable possibility that available evidence identified by the requestor would, if established, resolve one or more of such issues in favor of the requestor, taking into account uncontested claims or facts to the contrary; and resolution of the factual issue(s) in the manner sought by the requestor would be adequate to justify the action requested. 40 CFR 178.32.

The Office of Management and Budget has exempted this rule from the requirements of section 3 of Executive Order 12291. Pursuant to the requirements of the Regulatory Flexibility Act (Pub. L. 96-354, 94 Stat. 1164, 5 U.S.C. 601-612), the Administrator has determined that regulations establishing new tolerances or food additive regulations or raising tolerance levels or food additive regulations or establishing exemptions from tolerance requirements do not have a significant economic impact on a substantial number of small entities. A certification statement to this effect was published in the **Federal Register** of May 4, 1981 (46 FR 24950).

List of Subjects in 40 CFR Part 180

Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Recording and recordkeeping requirements.

Dated: April 8, 1993.

Douglas D. Campt,

Director, Office of Pesticide Programs.

Therefore, 40 CFR part 180 is amended as follows:

PART 180—[AMENDED]

1. In part 180:

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

Authority: 21 U.S.C. 346a and 371.

b. In subpart D, by adding new § 180.1118, to read as follows:

§ 180.1118 Spodoptera exigua nuclear polyhedrosis virus; exemption from the requirement of a tolerance.

An exemption from the requirement of a tolerance is established for the microbial pest control agent *Spodoptera exigua* nuclear polyhedrosis virus when used as a pesticide control agent on all raw agricultural commodities.

[FR Doc. 93–9810 Filed 4–27–93; 8:45 am]

BILLING CODE 6560–50–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

42 CFR Parts 431, 483

[BPD–661–CN]

RIN 0938–AE49

Medicare and Medicaid Programs; Preadmission Screening and Annual Resident Review

AGENCY: Health Care Financing Administration (HCFA), HHS.

ACTION: Final rule; correction.

SUMMARY: In the November 30, 1992 issue of the **Federal Register**, we established requirements for preadmission and annual review of individuals with mental illness or mental retardation who are applicants to or residents of nursing facilities that are certified for Medicaid. We also established an appeals system for individuals who may be transferred or discharged from facilities or who wish to dispute a determination made in the preadmission screening and annual review process. This notice corrects typographical errors made in that document.

EFFECTIVE DATE: This correction notice is effective on January 29, 1993.

FOR FURTHER INFORMATION CONTACT: Jan Earle, (410) 966–0103.

SUPPLEMENTARY INFORMATION: The final rule, Preadmission Screening and Annual Resident Review, published in the **Federal Register** on November 30, 1992 at 57 FR 56450, contained several typographical errors, as indicated below:

§ 431.206 [Corrected]

1. On page 56505, in column two, § 431.206(c)(2), line three, "his" is corrected to read "his or her".

§ 431.213 [Corrected]

2. On page 56505, in column three, § 431.213(h), line three, the cross-reference to "§ 483.12(a)(4)(ii)" is revised to read "§ 483.12(a)(5)(ii)", and the cross-reference to "§ 483.12(a)(4)(i)." in line five is corrected to read "§ 483.12(a)(5)(i)."

§ 431.621 [Corrected]

3. On page 56506, in column two, § 431.621(c)(4), the cross-reference to "§§ 431.112(c) and 483.114(c)" in the fourth line of the subparagraph is corrected to read, "§§ 483.112(c) and 483.114(c)".

§ 483.102 [Corrected]

4. We make the following corrections to § 483.102:

a. On page 56507, in column one, § 483.102(a) is corrected by removing the phrase "and regardless of the source of payment for the NF services," in lines seven and eight of that paragraph.

b. On page 56507, in column two, § 483.102(b)(2), line five, "Revised" is corrected to read "revised".

§ 483.106 [Corrected]

5. We make the following corrections to § 483.106:

a. On page 56508, in column one, § 483.106(d) introductory text, line four, "requires," is corrected to read "requires".

b. On page 56508, in column two, § 483.106(e)(3), line two, "MR" is corrected to read "MI".

c. On page 56508, in column two, § 483,106(e)(3), line twelve, a period is added at the end of the sentence.

§ 483.110 [Corrected]

6. On page 56508, in column three, § 483.110(a), line eight, the cross-reference to "§ 431.52(b)(1)." is corrected to read "§ 431.52(b)."

§ 483.128 [Corrected]

7. On page 56510, in column three, § 483.128(i)(3), line five, the cross-reference to "paragraph (g)(4)" is corrected to read "paragraph (i)(5)".

§ 483.130 [Corrected]

8. We make the following corrections to § 483.130:

a. On page 56511, in column two, § 483.130(d)(3), line eleven, "active treatment;" is corrected to read "specialized services;".

b. On page 56511, in column three, § 483.130(f), line seven, the cross-reference to "§ 483.120(d)(4)–(6)." is corrected to read "§ 483.130(d)(4)–(6)."

§ 483.136 [Corrected]

9. On page 56513, in column three, § 483.136(c)(2) introductory text, lines ten and eleven, "State mental health authority" is corrected to read "State mental retardation authority".

§ 483.204 [Corrected]

10. On page 56514, column two, § 483.204(b), line four, "subchapter." is corrected to read "chapter."

Authority: Sections 1819(e) and 1919(e) of the Social Security Act (42 U.S.C. 1395i–3(e) and 1396r(e))

(Catalog of Federal Domestic Assistance Program No. 13.714, Medical Assistance Program; Medicare—Supplementary Medical Insurance Program)

Dated: April 20, 1993.

Neil J. Stillman,

Deputy Assistant Secretary for Information Resources Management.

[FR Doc. 93–9858 Filed 4–27–93; 8:45 am]

BILLING CODE 4120–01–P

Proposed Rules

Federal Register
Vol. 58, No. 80
Wednesday, April 28, 1993

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.

GENERAL ACCOUNTING OFFICE

Personnel Appeals Board

4 CFR Parts 27 and 28

Procedural Regulations

AGENCY: General Accounting Office Personnel Appeals Board.

ACTION: Notice of proposed rulemaking.

SUMMARY: The General Accounting Office Personnel Appeals Board is proposing to revise its procedural regulations. The changes are intended to clarify the meaning of some sections, to fine-tune certain procedures, to correct a few errors in the prior regulations and to bring the regulations into conformity with the Civil Rights Act of 1991.

DATES: Comments must be submitted on or before June 30, 1993.

ADDRESSES: All comments concerning these regulations should be addressed to Dora Patton, Clerk of the Board, Personnel Appeals Board, U.S. General Accounting Office, Union Center Plaza II, suite 830, 441 G St., NW., Washington, DC 20548.

FOR FURTHER INFORMATION CONTACT: Dora Patton, Clerk of the Board, 202–512–6137.

SUPPLEMENTARY INFORMATION: The General Accounting Office Personnel Appeals Board hears and decides cases brought by GAO employees concerning various personnel matters including adverse or performance-based actions, claims of discrimination, alleged prohibited personnel practices and labor-management relations. The Board's current procedural regulations appear at 4 CFR parts 27 and 28. The Board is proposing to revise and reissue these regulations. The changes are intended to clarify the meaning of some sections, to fine-tune certain procedures, to correct a few errors in the prior regulations and to bring the regulations into conformity with the Civil Rights Act of 1991. Since the Board's jurisdiction is confined to personnel practices at the General Accounting Office (GAO), the Board is distributing copies of its proposed regulations, along with an explanation of the proposed changes, directly to employee groups and management officials within GAO. The text of the proposed regulations is not being published in the **Federal Register** because it is not likely to be of interest outside of the GAO community. However, any individual or group interested in receiving a copy of the Board's proposed regulations, along with an explanation of the proposed changes, may do so by contacting the Clerk of the Board at the address and telephone number listed above. All comments on the proposed regulations must be received by the Clerk of the Board (address above) on or before June 30, 1993. The full text of the final revised regulations will be published in the **Federal Register** prior to the effective date of the new regulations.

List of Subjects

4 CFR Part 27

Government employees, organization and functions (government agencies).

4 CFR Part 28

Administrative practice and procedure, equal employment opportunity, government employees, labor-management relations.

Authority: 31 U.S.C. 753(d).

Alan S. Rosenthal,

Chairman, Personnel Appeals Board, U.S. General Accounting Office.

[FR Doc. 93–9872 Filed 4–27–93; 8:45 am]

BILLING CODE 1610–01–M

DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

7 CFR Part 1150

[DA–93–09]

Dairy Promotion Program; Notice of Referendum

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Notice of referendum.

SUMMARY: This document announces that a referendum will be held to determine whether milk producers favor the continuation of the National Dairy Promotion Program, which was established by the Dairy and Tobacco Adjustment Act of 1983. This action is in response to a request by a large number of producers for the opportunity to vote on the producer-funded program. In order for it to be continued, the Promotion Program must be approved by a majority of the producers who vote in the referendum.

DATES: The referendum will be held during August 1993.

FOR FURTHER INFORMATION CONTACT: Eugene Krueger, Referendum Agent, USDA/AMS/Dairy Division, room 2968 South Building, P.O. Box 96456, Washington, DC 20090–6456, (202) 690–4128.

SUPPLEMENTARY INFORMATION: This document announces that a referendum will be conducted among producers for the purpose of determining whether the Dairy Promotion and Research Order should be continued. Pursuant to section 116(b) of the Dairy and Tobacco Adjustment Act of 1983, such order shall remain in effect if the Secretary determines that continuance of the order is favored by a majority of the producers voting in a referendum who during a representative period (as determined by the Secretary) were engaged in the production of milk for commercial use.

The month of April 1993 is hereby determined to be the representative period for the conduct of such referendum.

Eugene Krueger is hereby designated as the agent of the Secretary to conduct such referendum in accordance with the procedure for the conduct of referenda in connection with the Dairy Promotion and Research Order (7 CFR 1150.200 *et seq.*).

Such referendum shall be held during the month of August 1993.

List of Subjects in 7 CFR Part 1150

Dairy products, Reporting and recordkeeping requirements, Research.

(Pub. L. 98–180, 97 Stat. 1128)

Dated: April 22, 1993.

L.P. Massaro,

Acting Administrator.

FR Doc. 93–9866 Filed 4–27–93; 8:45 am]

BILLING CODE 3410–02–M

Rural Electrification Administration

7 CFR Part 1788

REA Fidelity and Insurance Requirements for Electric and Telephone Borrowers

AGENCY: Rural Electrification Administration, USDA.

ACTION: Advance notice of proposed rulemaking.

SUMMARY: As part of its ongoing program of updating and streamlining its regulations, the Rural Electrification Administration (REA) is considering revising its regulation concerning the fidelity and insurance requirements for electric and telephone borrowers. To assist the Agency in this endeavor, comments are requested concerning any aspect covered by the regulation.

DATES: Written comments and recommendations must be received by REA by June 28, 1993.

ADDRESSES: Written comments should be addressed to F. Lamont Heppe, Jr., Deputy Director, Program Support Staff, Rural Electrification Administration, room 2234, 14th and Independence Avenue, SW., Washington, DC 20250–1500. REA requires a signed original and three copies of all comments (7 CFR 1700.30(e)). All comments received will be made available for public inspection at room 2234-S (address as above) during regular business hours (7 CFR 1.27(b)).

FOR FURTHER INFORMATION CONTACT: F. Lamont Heppe, Jr., Deputy Director, Program Support Staff, room 2234-S, at the above address. Telephone: (202) 720–0736.

SUPPLEMENTARY INFORMATION: Advance notice is given that REA is considering the revision of 7 CFR part 1788, REA Fidelity And Insurance Requirements For Electric And Telephone Borrowers. Interested parties are invited to submit written comments concerning this advance notice. The submittal of comments from other lenders which have made loans to REA borrowers is particularly desired.

Background

Part 1788 was published in 1986 and has never been amended or revised. REA is interested in ensuring that the regulation remains current and compatible with industry practice. Consequently, comments will be considered on any issue covered by the regulation. REA is particularly interested in information on the insurance requirements of other lenders serving electric and telephone utilities.

Authority: 7 U.S.C. 901 *et seq.*, 7 U.S.C. 1921 *et seq.*

Dated: April 22, 1993.

Robert Peters,

Acting Under Secretary, Small Community and Rural Development.

[FR Doc 93–9943 Filed 4–27–93; 8:45 am]

BILLING CODE 3410–15–F

Animal and Plant Health Inspection Service

9 CFR Part 112

[Docket No. 92–098–1]

Viruses, Serums, and Toxins and Analogous Products; Packaging and Labeling

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Proposed rule.

SUMMARY: This proposed rule would amend the regulations pertaining to packaging and labeling of veterinary biological products by prohibiting final containers of product packaged at licensed establishments in cartons or other containers from being repackaged for sale or distribution. The proposed rule also clarifies that, unless otherwise authorized, labeling may only be performed at a licensed establishment and amends the "Applicability" statement to clarify its intent.

The proposed action is necessary in order to assure that, because of incomplete, unclear, misleading, or inappropriate labeling, veterinary biological products are not rendered worthless, contaminated, dangerous, or harmful. The effect of the proposed rule would be to prohibit the repackaging, for sale or distribution, of final containers of veterinary biological products that are packaged in multiple container cartons or other containers.

DATES: Consideration will be given only to comments received on or before June 28, 1993.

ADDRESSES: Please send an original and three copies of your comments to Chief, Regulatory Analysis and Development Staff, PPD, APHIS, USDA, room 804, Federal Building, 6505 Belcrest Road, Hyattsville, MD 20782. Please state that your comments refer to Docket No. 92–098–1. Comments received may be inspected at USDA, room 1141, South Building, 14th Street and Independence Avenue, SW., Washington, DC, between 8 a.m. and 4:30 p.m., Monday through Friday, except holidays.

FOR FURTHER INFORMATION CONTACT: Dr. David A. Espeseth, Deputy Director, Veterinary Biologics, BBEP, APHIS, USDA, room 838, Federal Building, 6505 Belcrest Road, Hyattsville, MD 20782, telephone number (301)–436–8245.

SUPPLEMENTARY INFORMATION:

Background

The Virus-Serum-Toxin Act (21 U.S.C. 151–159; hereinafter the Act), as amended by 1985 Food Security Act, prohibits the shipment of veterinary biological products anywhere in or from the United States that are worthless, contaminated, dangerous or harmful. It also prohibits such shipment of products unless they are prepared pursuant to USDA regulations in an establishment licensed by USDA. The term "preparation", as it is defined in the regulations, includes packaging and labeling. The 1985 amendments granted additional rulemaking authority to implement the requirements of the Act. Under the Act and regulations, the Animal and Plant Health Inspection Service (APHIS) of the U.S. Department of Agriculture grants licenses for veterinary biological products which are pure, safe, potent, and efficacious when used according to label instructions. Complete labeling (either on the product or accompanying the product) must be reviewed and approved by APHIS in accordance with 9 CFR 112.5 prior to their use.

Recently, it has come to APHIS' attention that certain licensed veterinary biological products have been repackaged and sold after they had been removed from the licensed establishment where they were produced. This repackaging has resulted in products being sold without accompanying USDA approved labeling which was applied or included as part of product preparation. Such repackaging raises the issue of the safety and efficacy of the licensed product and of its use. It is also contrary to the statutory requirement that veterinary biological products must be "prepared" in a USDA licensed establishment.

There has been at least one recent case of the death and injury of dogs as a result of the use of such repackaged veterinary biological products.

Recent examples of repackaging which has resulted in false and misleading labeling which rendered the licensed product worthless and harmful are (1) the use of product labels for a product that were intended or approved for another licensed product; (2) the deletion or omission of approved directions for use, indications, warnings, or cautions from repackaged labels; (3) the alteration of directions for use on repackaged labels which

rendered vaccination ineffective; and (4) the preparation of an unlicensed combination product resulting from the unauthorized repackaging of two licensed products from different manufacturers.

Part 112 of the regulations prohibits labeling which is false or misleading in any particular (see 9 CFR 112.1(a)). Section 112.1(c) states that biological products shall be withheld from the market if such labels have been altered, mutilated, destroyed, obliterated, or removed. Section 112.2(a)(5) requires full label instructions for the proper use of the product, including vaccination schedules, warnings, cautions, and the like. Section 112.4 further requires that labels used by distributors comply with requirements for review, approval, and filing of labels used for licensed biological products distributed and sold by licensees.

The current regulations, however, do not address directly the issue of repackaging of licensed veterinary biologics, except for poultry products in § 112.6(c)(1–4). The rationale for prohibiting repackaging of poultry products was to ensure that 1,000 dose packages of poultry product remained intact with the appropriate amount of diluent for use with automatic vaccinating systems which dispense large numbers of doses over a relatively short period of time. Prohibiting the repackaging of such a product assures that the proper amount of diluent is supplied with the multiple dose product for use with automatic dispensers and minimizes the loss of potency that would occur with time after reconstitution with diluent were the product to be administered manually as individual doses. These regulations, however, do not directly address the current safety and efficacy issues posed by the repackaging of multiple container cartons of other veterinary biological products.

In order to assure the safety and efficacy of biological products after they have been shipped from a licensed establishment, APHIS is proposing to amend its regulations by adding § 112.6 (e) and (f) which would prohibit the repackaging of final containers of product which had been packed in multiple container cartons or other containers by the licensee unless each final container of product has affixed thereto, or is accompanied by, complete approved labeling applied or included by the producer during preparation of the product. Repackaging after a product has been shipped from a licensed establishment has led, in many cases, to removal and alteration of approved label instructions. Such actions can render the product worthless, contaminated, dangerous, or harmful and result in product preparation that is in violation of the Act and regulations (see 21 U.S.C. 151). APHIS thus proposes to prohibit the repackaging of final containers of product (either single or multiple dose containers) packed in multiple container cartons if the carton label or enclosure is required to complete the labeling for the container.

Proposed paragraphs (a) through (d) of § 112.1 of the regulations would clarify that preparation, which includes labeling, of veterinary biological products shall only be done in a licensed establishment (see proposed § 112.1(a)), and that labeling which is altered, mutilated, destroyed, obliterated, or removed at any time prior to marketing of the product would render the veterinary biological product in violation of the regulations (see proposed § 112.1(c)). The regulations under proposed paragraphs (a) through (d) of § 112.1 would be applicable generally to any person and would not be restricted to licensees.

Proposed § 112.4 (introductory paragraph) would be revised to indicate that labeling used by subsidiaries, divisions, distributors, and permittees shall be prepared only in a licensed establishment and affixed by the licensee.

Executive Order 12291 and Regulatory Flexibility Act

We are issuing this proposed rule in conformance with Executive Order 12291, and we have determined that it is not a "major rule." Based on information compiled by the Department, it has been determined that this proposed rule would have an effect on the economy of less than $100 million; would not cause a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions, and would not have a significant adverse effect 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 proposed rule would prohibit the repackaging of multiple container cartons of veterinary biological products which would result in (1) preparation, including labeling, of a veterinary biological product in violation of the Act and regulations; and (2) the removal or alteration of approved labeling, thereby compromising the safety and efficacy of the biological product. In the absence of approved labeling, the safe and effective use of the veterinary biological product cannot be assured. The proposed action would benefit users in that it would assure that users are provided with a product that is properly labeled with approved directions, indications, and cautions for use.

The intent of the action is to provide greater assurance to consumers that licensed veterinary biological products are prepared only with approved labeling with adequate directions for use. The prohibition against repackaging outside of licensed facilities would ensure that cases involving unapproved labeling of biological products such as those which resulted in the recent death and injury of dogs are avoided in the future. Given limited resources, APHIS believes that safety to animal health can best be assured by restricting to licensed facilities the preparation, which includes packaging and labeling, of veterinary biological products.

Distributors who are currently in the business of breaking apart multiple container cartons and repackaging them for sale as individual final containers of product would be provided notice that their actions are in violation of the Act and regulations. Distributors would still be able to purchase from licensed manufacturers products that are already individually packaged and labeled in accordance with part 112 rather than purchasing multiple container cartons that must be broken apart and repackaged to provide a single dose final container package for distribution. This action would not prohibit the distribution of "private label" products as long as the product was produced in a licensed establishment under an approved Outline of Production with approved labeling. Thus persons currently repackaging and distributing a licensed product could seek to have a licensee produce the product for distribution under a distributor label.

Under these circumstances, the Administrator of the Animal and Plant Health Inspection Service has determined that this action will not have a significant economic impact on a substantial number of small entities.

Executive Order 12778

This proposed rule has been reviewed under Executive Order 12778, Civil Justice Reform. It is not intended to have retroactive effect. This rule will not preempt State or local laws, regulations, or policies, unless they present an irreconcilable conflict with this rule. There are no administrative proceedings which must be exhausted prior to any judicial challenge to the provisions of this rule.

Paperwork Reduction Act

The proposed rule contains no information collection or recordkeeping requirements under the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 *et seq.*).

Executive Order 12372

This program/activity is listed in the Catalog of Federal Domestic Assistance under No. 10.025 and is subject to Executive Order 12372, which requires intergovernmental consultation with State and local officials (see 7 CFR part 3015, subpart V).

List of Subjects in 9 CFR Part 112

Animal biologics.

Accordingly, 9 CFR part 112 is amended as follows:

PART 112—PACKAGING AND LABELING

1. The authority citation for 9 CFR part 112 continues to read as follows:

Authority: 21 U.S.C. 151–159; 7 CFR 2.17, 2.51, and 371.2(d).

2. Section 112.1 would be revised to read as follows:

§ 112.1 General.

(a) Unless otherwise authorized or directed by the Administrator, each biological product prepared at a licensed establishment or imported shall be packaged and labeled as prescribed in this part before it is removed from the licensed establishment or presented for importation: *Provided,* That biological products to be imported for research and evaluation shall be subject to packaging and labeling requirements in § 112.9. *Provided further,* That unless otherwise exempted, all preparation, including packaging and labeling, of biological products shall only be done in a licensed establishment under an approved Outline of Production.

(b) No person shall apply or affix to or include with, or cause to be applied or affixed to or included with, any carton or final container of a biological product, any label, stamp, mark or statement that is false or misleading in any particular, is not in compliance with the regulations, or is not approved by APHIS.

(c) No person shall alter, mark or remove any approved labeling affixed to or included with any biological product prior to selling or otherwise distributing such product. In addition, no person shall mark any carton, other container, or final container of a biological product so as to falsify the labeling, make it misleading, or cause it to be illegible.

(d) Labels that are stamped, printed or glued directly on cartons, other containers, or final containers shall be legible throughout the dating period. Biological products bearing labels, which have been altered, mutilated, destroyed, obliterated or removed, shall be withheld from the market.

3. In § 112.4, the introductory paragraph is revised to read as follows:

§ 112.4 Subsidiaries, divisions, distributors, and permittees.

Labels used by subsidiaries, divisions, distributors, and permittees shall be affixed by the licensee in a licensed establishment where the product is produced. Such labels shall comply with requirements for their review, approval, and filing as provided in this section.

* * * * *

4. In § 112.6, new paragraphs (e) and (f) are added to read as follows:

§ 112.6 Packaging biological products.

* * * * *

(e) Final containers of biological product packaged at a licensed establishment in cartons or other containers shall not be removed from such cartons or containers and repackaged for sale or distribution unless each final container bears or is accompanied by complete and approved labeling which is affixed to or included with each container by the licensed establishment producing the product.

(f) Labels which are affixed to or included with a biological product shall not be removed or altered in any manner.

Done in Washington, DC, this 21st day of April 1993.

Kenneth C. Clayton,

Acting Assistant Secretary, Marketing and Inspection Services.

[FR Doc. 93–9889 Filed 4–27–93; 8:45 am]

BILLING CODE 3410–34–M

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

Schedules of Controlled Substances; Proposed Placement of Methcathinone into Schedule I

AGENCY: Drug Enforcement Administration, Justice.

ACTION: Notice of proposed rulemaking.

SUMMARY: This notice of proposed rulemaking is issued by the Administrator of the Drug Enforcement Administration (DEA) to place methcathinone into Schedule I of the Controlled Substances Act (CSA). This proposed action by the DEA Administrator is based on data gathered and reviewed by the DEA. If finalized, this proposed action would impose the regulatory control mechanisms and criminal sanctions of Schedule I on the manufacture, distribution and possession of methcathinone.

DATES: Comments must be submitted on or before May 28, 1993.

ADDRESSES: Comments and objections should be submitted to the Administrator, Drug Enforcement Administration, Washington, DC 20537, Attention: DEA Federal Register Representative.

FOR FURTHER INFORMATION CONTACT: Howard McClain, Jr., Chief, Drug and Chemical Evaluation Section, Drug Enforcement Administration, Washington, DC 20537. Telephone: (202) 307–7183.

SUPPLEMENTARY INFORMATION: On May 1, 1992, the Administrator of the DEA published a final rule in the **Federal Register** (57 FR 18824) temporarily placing methcathinone into Schedule I of the CSA using the temporary scheduling provisions of the CSA (21 U.S.C. 811(h)). This final rule, which became effective on the date of publication, was based on a finding by the Administrator that the temporary scheduling of methcathinone was necessary to avoid an imminent hazard to the public safety. Section 201(h)(2) of the CSA (21 U.S.C. 811(h)(2)) requires that the temporary scheduling of a substance expires at the end of one year from the effective date of the order. However, if proceedings to schedule a substance pursuant to 21 U.S.C. 811(a)(1) have been initiated and are pending, the temporary scheduling of a substance may be extended for up to six months. Under this provision, the temporary scheduling of methcathinone which would expire on May 1, 1993, may be extended to November 1, 1993. This extension is being ordered by the DEA Administrator in a separate action.

The DEA has gathered and reviewed the available information regarding the actual base and relative potential for abuse for methcathinone. The DEA, in conjunction with the National Institute on Drug Abuse (NIDA), has provided for the synthesis and biological testing of methcathinone. By letter, the Administrator has submitted data which the DEA has gathered regarding methcathinone to the Assistant Secretary for Health, Department of Health and Human Services. In accordance with 21 U.S.C. 811(b), the DEA Administrator also requested a

scientific and medical evaluation and a scheduling recommendation for methcathinone from the Assistant Secretary for Health.

Methcathinone has a chemical structure and pharmacological profile similar to that of methamphetamine and cathinone. All forms of methamphetamine have been controlled in Schedule II of the CSA since 1971. As a result of prior control of cathinone in Schedule I of the 1971 Convention on Psychotropic Substances and in response to a recommendation received by the Administrator from the Assistant Secretary for Health and Human Services, cathinone was placed into Schedule I of the CSA on February 14, 1993.

In preclinical studies, methcathinone hydrochloride produces pharmacological effects and appears to have an abuse potential similar to that of psychomotor stimulants such as the amphetamines. In a manner similar to that of other amphetamines, methcathinone hydrochloride increases spontaneous rodent locomotor activity, potentiates the release of radiolabelled dopamine from dopaminergic nerve terminals in the brain and causes appetite suppression. In drug discrimination studies, methcathinone hydrochloride evokes either (+)-amphetamine or cocaine induced appropriate responding. When examined in particular pharmacological assays for psychomotor stimulant-like activity, both the d and the l enantiomeric forms of methcathinone hydrochloride have been found to be pharmacologically active. In these assays, the l-form of methcathinone is more active than either d-methcathinone or (+)-amphetamine. Racemic methcathinone hydrochloride is intravenously self-addressed by baboons, thus indicating that methcathinone produces reinforcing effects in this laboratory animal and suggesting that this drug has a potential for abuse in the human population.

To date, the distribution and abuse of methcathinone has been documented in Michigan and Wisconsin. Abuse of methcathinone has been known since at least January 1991. Since that time, the abuse of methcathinone has increased substantially in the upper peninsula of Michigan and, more recently, in Wisconsin. The principal form of methcathinone distributed and abused is the hydrochloride salt of the 1-enantiomer, which exists as a white to off-white, chunky powdered material. It is usually sold as itself under such street names as "Cat" and "Goob". Less often it is passed off as methamphetamine under such names as "Crank" or "Speed". The most common route of administration is via nasal insufflation. Other routes of administration include oral ingestion, intravenous injection and smoking. Methcathinone is abused in binges lasting two to six days. During this time, methcathinone is repeatedly administered, resulting in the daily administration of amounts surpassing one or two grams. The methcathinone binge resembles amphetamine binges in that the abuser does not sleep or eat and takes in little in the way of liquids. The methcathinone binge is followed by a "crash" characterized by long periods of sleep, excess eating and possibly depression.

Methcathinone is abused for its psychomotor stimulant effects. It is reported by abusers to produce such effects as a "burst of energy", "headrush", "bodyrush", a "speeding of the mind", an "increased feeling of self-confidence" and "euphoria". Abusers have also reported that methcathinone produces unpleasant effects such as paranoia, hallucinations, anxiety, tremor, insomnia, malnutrition, weight loss, dehydration, sweating, stomach pains, noise bleeding and body aches. Following the crash, some individuals have experienced depression with or without thoughts of suicide.

Methcathinone hydrochloride is produced for street distribution in clandestine laboratories. Between June, 1991 and February, 1993, 19 active or clandestine methcathinone laboratories were seized by Federal, state and local law enforcement officials in Michigan. In August 1991 a clandestine methcathinone laboratory was seized in Seattle, Washington. Since January , 1993, at least two clandestine methcathinone laboratories have been encountered in Wisconsin.

Methcathinone has been encountered by law enforcement officials in Michigan and Wisconsin. Michigan State Police obtained the first street sample of methcathinone in February 1991. Since that time there have been over 50 encounters of methcathinone by Federal, state and law enforcement officials in Michigan. Methcathinone was first encountered in Wisconsin in March 1992. Since October 1992, there have been more than twenty Federal, state or local law enforcement encounters of methcathinone in Wisconsin. With the exception of the seizure of a single clandestine methcathinone laboratory in Washington, the DEA is not aware of any other law enforcement encounters of methcathinone within the United States, other than those in Michigan and Wisconsin.

Health officials in Michigan and Wisconsin have encountered abusers of methcathinone. There have been a number of documented emergency room cases involving the purported abuse of methcathinone. Drug abuse treatment centers in Marquette and Iron Mountain, Michigan, as well as several psychiatric treatment centers in Wisconsin have reported encounters with methcathinone abusers.

Sigma Chemical Company is the only known commercial manufacturer and supplier of methcathinone in the United States. The Food and Drug Administration (FDA) has notified the DEA that there are no exemptions or approvals in effect under section 505 of the Federal Food, Drug and Cosmetic Act for methcathinone. A search of the scientific and medical literature revealed no indications of current medical use of methcathinone in the United States.

The DEA Administrator, based on the information gathered and reviewed by his staff and after consideration of the factors in 21 U.S.C. 811(c), believes that sufficient data exists to propose and to support that methcathinone be placed into Schedule I of the CSA pursuant to 21 U.S.C. 811(a). The specific findings required pursuant to 21 U.S.C. 811 and 812 for a substance to be placed into Schedule I are as follows:

(1) The drug or other substance has a high potential for abuse.

(2) The drug or other substance has no currently accepted medical use in treatment in the United States.

(3) There is a lack of accepted safety for use of the drug or other substance under medical supervision.

Before issuing a final rule in this matter, the DEA Administrator will take into consideration the scientific and medical evaluation and scheduling recommendation of the Secretary of the Department of Health and Human Services in accordance with 21 U.S.C. 811(b). The recommendations of the Secretary regarding scientific and medical matters are binding on the Administrator and if the Secretary recommends that a substance should not be controlled, the DEA Administrator will not control it. The Administrator will also consider relevant comments from other concerned parties.

Interested persons are invited to submit their comments, objections or requests for a hearing in writing with regard to this proposal. Requests for a hearing should state with particularity the issues concerning which the person desires to be heard. All correspondence regarding this matter should be submitted to the Administrator, Drug

Enforcement Administration, Washington, DC 20537, Attention: DEA Federal Register Representative. In the event that comments, objections or requests for a hearing raise one or more issues which the Administrator finds warrant a hearing, the Administrator shall order a public hearing by notice of the **Federal Register**, summarizing the issues to be heard and setting the time for hearing.

The Administrator of the DEA hereby certifies that the proposed placement of methcathinone into Schedule I of the CSA will have no significant impact upon entities whose interests must be considered under the Regulatory Flexibility Act, 5 U.S.C. 601 *et seq.* This action involves the control of a substance with no currently approved medical use or manufacture in the United States.

This proposed rulemaking is not a major rule for the purposes of Executive Order 12291 (46 FR 13193) of February 17, 1981. It has been determined that drug scheduling matters are not subject to review by the Office of Management and Budget (OMB) pursuant to the provisions of Executive Order 12291. Accordingly, this drug scheduling action is not subject to the provisions of Executive Order 12778 which are contingent upon review by OMB.

This action has been analyzed in accordance with the principles and criteria in Executive Order 12612, and it has been determined that this proposed rulemaking does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

List of Subjects in 21 CFR Part 1308

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

Under the authority vested in the Attorney General by section 201(a) of the CSA (21 U.S.C. 811(a)), and delegated to the Administrator of the DEA by Department of Justice regulations (28 CFR 0.100), the Administrator hereby proposes that 21 CFR part 1308 be amended as follows:

PART 1308—[AMENDED]

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

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

2. Section 1308.11 is amended by adding paragraph (f)(6) to read as follows:

§ 1308.11 Schedule I.

* * * * *

(f) * * *

(6) Methcathinone (Some other names: 2-(methylamino)-propiophenone, alpha (methylamino)-propiophenone, 2-(methylamino)-1-phenylpropan-1-one, alpha-N-methylaminopropiophenone, monomethylpropion, ephedrone, N-methylcathinone, methycathinone, AL–464, AL–422, AL–463 and UR1431) its salts, optical isomers and salts of optical isomers . . . 1237.

3. § 1308.11 is further amended by removing and reserving paragraph (g)(3).

Dated: April 22, 1993.

Robert C. Bonner,

Administrator of Drug Enforcement.

[FR Doc. 93–9945 Filed 4–27–93; 8:45 am]

BILLING CODE 4410–09–M

---

21 CFR Part 1308

Schedules of Controlled Substances Proposed Transfer of Levo-alphacetylmethadol From Schedule I into Schedule II

AGENCY: Drug Enforcement Administration, Justice.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Administrator of the Drug Enforcement Administration (DEA) is issuing this notice of proposed rulemaking to transfer the Schedule I narcotic, levo-alphacetylmethadol (LAAM), to Schedule II of the Controlled Substances Act (CSA) in accordance with 21 U.S.C. 801 *et seq.* This action is initiated upon receipt of a letter from the Acting Assistant Secretary for Health, Department of Health and Human Services (DHHS), recommending that LAAM be transferred from Schedule I to Schedule II upon approval of a New Drug Application (NDA) for LAAM. As a result of this proposed rule, if finalized, the regulatory controls and criminal sanctions of Schedule II will be applicable to the manufacture, distribution, importation and exportation of LAAM. Additionally, the use of LAAM for the treatment of narcotic addiction will be subject to compliance with the requirements of the Narcotic Addict Treatment Act of 1974 and regulations concerning narcotic treatment programs.

DATES: Comments must be submitted on or before May 28, 1993.

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

FOR FURTHER INFORMATION CONTACT: Howard McClain, Jr., Chief, Drug and Chemical Evaluation Section, Drug Enforcement Administration, Washington, DC 20537, Telephone: (202) 307–7183.

SUPPLEMENTARY INFORMATION: On March 12, 1993, the Acting Assistant Secretary for Health, on behalf of the Secretary of the DHHS, sent the Administrator of the DEA a letter recommending that levo-alphacetylmethadol be transferred to Schedule II of the CSA once it is approved for marketing. Enclosed with the letter was a document prepared by the Food and Drug Administration (FDA) entitled "Basis for the Recommendation for Transferring of Levo-alpha-acetylmethadol (LAAM) from Schedule I to II of the Controlled Substances Act." The document contained a review of the factors which the CSA requires the Secretary to consider (21 U.S.C. 811(b) and 811(c)) and the summarized recommendations regarding the transfer of LAAM. The factors considered by the Acting Assistant Secretary for Health with respect to LAAM are:

(1) Its actual or relative potential for abuse;

(2) Scientific evidence of its pharmacological effects, if known;

(3) The state of the current scientific knowledge regarding the drug or other substance;

(4) Its history and current pattern of abuse;

(5) The scope, duration, and significance of abuse;

(6) What, if any, risk there is to the public health;

(7) Its psychic or physiological dependence liability; and

(8) Whether the substance is an immediate precursor of a substance already controlled under this title.

The FDA has received and reviewed substantial evidence on the effectiveness and safety of LAAM. The FDA's scientific and medical evaluation shows that LAAM has a potential for abuse and physical and psychological dependence liability similar to other μ-opioid agonists which are in Schedule II of the CSA. Upon approval of the NDA for treatment of narcotic addiction, LAAM will have met DEA's criteria for currently accepted medical use in treatment in the United States. These criteria were discussed at length in the matter of the Marijuana Rescheduling Petition, 57 FR 10499, 10503–10507 (1992). This transfer will apply to the *levo* isomer of alphacetylmethadol while all other isomers of alphacetylmethadol will remain in Schedule I.

Interested persons are invited to submit their comments or objections in writing regarding this proposal. If a

person believes that one or more issues warrant a hearing, the reasons for such belief should be stated and summarized. If the Administrator finds that the written responses to this proposal warrant a hearing, the Administrator will order a public hearing. A notice of the hearing will be published in the **Federal Register** summarizing the issues to be heard and setting a time for the hearing that will be at least 30 days after the publication of the notice. If no objections presenting grounds for a hearing on this proposal are received within the time limitation or if interested parties waive or are deemed to have waived their opportunity for a hearing or to participate in a hearing, the Administrator, after giving consideration to written comments and objections, will issue his final order pursuant to 21 CFR 1308.48 without a hearing. DEA's final decision concerning the relative abuse potential of LAAM will take into account the Acting Assistant Secretary's recommendation and any information received in response to this proposal.

Pursuant to 5 U.S.C. 605(b), the Administrator certifies that the transfer of LAAM, as proposed herein, will have no significant impact upon small businesses or other entities whose interests must be considered under the Regulatory Flexibility Act (Pub. L. 96–354). Many of the regulatory requirements imposed on Schedule II substances are similar to those imposed on Schedule I substances. Additionally, substances in Schedule II may be used in medical treatment in the United States.

This action has been analyzed in accordance with the principles and criteria contained in Executive Order 12612, and it has been determined that this matter does not have sufficient federalism implications to require the preparation of a Federalism Assessment.

In accordance with the provisions of 21 U.S.C. 811(a), this proposal to transfer LAAM from Schedule I to Schedule II is a formal rulemaking "on the record after opportunity for hearing." Such proceedings are conducted pursuant to the provisions of 5 U.S.C. 556 and 557 and as such have been exempted from the consultation requirements for Executive Order 12291 (46 FR 13193).

List of Subjects in 21 CFR Part 1308

Administrative practice and procedure, Drug traffic control, Narcotics, Prescription drugs, Reporting and Record keeping requirements.

Based on the scientific and medical evaluation and the recommendation of the Acting Assistant Secretary for Health, the Administrator of the DEA, pursuant to 21 U.S.C. 811(a) and 811(b), finds that:

(1) Based on all available information, LAAM has a high potential for abuse.

(2) LAAM, upon final approval of a NDA by the FDA, will meet the criteria for currently accepted medical use in treatment in the United States.

(3) Abuse of this substance may lead to severe psychological or physical dependence.

Therefore, under the authority vested in the Attorney General (21 U.S.C. 811(a)) and delegated to the Administrator of the DEA by the Department of Justice regulations (28 CFR 0.100), the Administrator hereby proposes that 21 CFR Part 1308 be amended as follows:

PART 1308—SCHEDULES OF CONTROLLED SUBSTANCES

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

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

2. Section 1308.11 is proposed to be amended by revising paragraph (b)(4) to read as follows:

§ 1308.11 Schedule I.

* * * * *

(b) * * *

(4) Alphacetylmethadol (except Levo-alphacetylmethadol (LAAM))—9603

* * * * *

3. Section 1308.12 is proposed to be amended by redesignating the existing paragraphs (c)(11) through (c)(25) as (c)(12) through (c)(26) respectively and adding a new paragraph (c)(11) to read as follows:

§ 1308.12 Schedule II.

* * * * *

(c) * * *

(11) Levo-alphacetylmethadol (LAAM)—9648

* * * * *

Dated: April 22, 1993.

Robert C. Bonner,

Administrator of Drug Enforcement.

[FR Doc. 93–9946 Filed 4–27–93; 8:45 am]

BILLING CODE 4410–09–M

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 52

[PS–89–91]

RIN 1545–AQ23

Exports of Chemicals That Deplete the Ozone Layer; Special Rules for Certain Medical Uses of Chemicals That Deplete the Ozone Layer; Hearing Cancellation

AGENCY: Internal Revenue Service, Treasury.

ACTION: Cancellation of notice of public hearing on proposed regulations.

SUMMARY: This document provides notice of cancellation of a public hearing on proposed regulations relating to taxes imposed on exports of chemicals that deplete the ozone layer, taxes imposed on ozone-depleting chemicals used as medical sterilants or propellants in metered-dose inhalers, and floor stocks taxes on ozone-depleting chemicals.

DATES: The public hearing originally scheduled for Thursday, May 27, 1993, beginning at 10 a.m. is cancelled.

FOR FURTHER INFORMATION CONTACT: Carol Savage of the Regulations Unit, Assistant Chief Counsel (Corporate), (202) 622–8452 or (202) 622–7180 (not toll-free numbers).

SUPPLEMENTARY INFORMATION: The subject of the public hearing is proposed regulations under sections 4681 and 4682 of the Internal Revenue Code. A notice of proposed rulemaking and public hearing appearing in the **Federal Register** for Friday, January 15, 1993, (58 FR 4625), announced that the public hearing on the proposed regulations would be held on Thursday, May 27, 1993, beginning at 10 a.m., in the Commissioner's Conference Room, room 3313, Internal Revenue Service Building, 1111 Constitution Avenue, NW., Washington, DC.

The public hearing scheduled for Thursday, May 27, 1993, has been cancelled.

Dale D. Goode,

Federal Register Liaison Officer, Assistant Chief Counsel (Corporate).

[FR Doc. 93–9854 Filed 4–27–93; 8:45 am]

BILLING CODE 4830–01–U

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–300281; FRL–4576–2]

RIN No. 2070–AC18

Cross-Linked Polyurea-Type Encapsulating Polymer; Tolerance Exemption

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: This document proposes that an exemption from the requirement of a tolerance be established for residues of cross-linked polyurea-type encapsulating polymer when used as an inert ingredient (encapsulating agent) in pesticide formulations applied to growing crops only. This regulation replaces the current exemption for cross-linked polyurea-type encapsulating polymer when used as an encapsulating material in pesticide formulations applied prior to planting under 40 CFR 180.1039. This proposed regulation was requested by ICI Americas, Inc.

DATES: Comments, identified by the document control number [OPP-300281], must be received on or before May 28, 1993.

ADDRESSES: By mail, submit written comments to: Public Response and Program Resources Branch, Field Operations Division (H7506C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person, deliver comments to: Rm. 1132, Crystal Mall Bldg. #2, 1921 Jefferson Davis Highway Arlington, VA 22202. Information submitted as a comment concerning this document may be claimed confidential by marking any part of all of that information as "Confidential Business Information" (CBI).

Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the comment that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential will be included in the public docket by EPA without prior notice. The public docket is available for public inspection in Rm. 1132 at the address given above, from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays.

FOR FURTHER INFORMATION CONTACT: By mail: Connie Welch, Registration Support Branch, Registration Division (H7505W), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location and telephone number: 2800 Crystal Drive, North Tower, Arlington, VA 22202, (703)-308-8320.

SUPPLEMENTARY INFORMATION: ICI Americas, Inc., Wilmington, DE 19897, has submitted pesticide petition (PP) 2E4146 to EPA requesting that the Administrator, pursuant to section 408(e) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 346a(e), propose to amend 40 CFR 180.1001(d) by establishing an exemption from the requirement of a tolerance for residues of cross-linked polyurea-type encapsulating polymer when used as an inert ingredient (encapsulating agent) in pesticide formulations applied to growing crops only. This regulation replaces the current exemption from the requirement of a tolerance for this chemical under 40 CFR 180.1039. Because neither the amount nor the use in the formulation has any bearing on the exemption, reference to a specific amount has been dropped.

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

The data submitted in support of the current exemption and also the data submitted in this petition have been evaluated. As part of the EPA policy statement on inert ingredients published in the **Federal Register** of April 22, 1987 (52 FR 13305), the Agency established data requirements which will be used to evaluate the risks posed by the presence of an inert ingredient in a pesticide formulation. Exemptions from some or all of the requirements may be granted if it can be determined that the inert ingredient will present minimal or no risk. The Agency has decided that any additional data normally required to support the proposed tolerance exemption for cross-linked polyurea-type encapsulating polymer will not need to be submitted. The rationale for this decision is described below:

In the case of certain chemical substances which are defined as "polymers," the Agency has established a set of criteria which identify categories of polymers that present low risk. These criteria (described in 40 CFR 723.250) identify polymers that are relatively unreactive and stable compared to other chemical substances as well as polymers that typically are not readily absorbed. These properties generally limit a polymer's ability to cause adverse effects. In addition, these criteria exclude polymers about which little is known. The Agency believes that polymers meeting the criteria noted above will present minimal or no risk. Cross-linked polyurea-type encapsulating polymer conforms to the definition of a polymer given in 40 CFR 723.250(b)(11) and meets the following criteria which are used to identify low-risk polymers:

1. The minimum average molecular weight of the above-mentioned polymer is 5×10^{13}. Substances with molecular weights greater than 400 are generally not readily absorbed through the intact skin and substances with molecular weights greater than 1,000 are generally not absorbed through the intact gastrointestinal (GI) tract. Chemicals not absorbed through the skin or GI tract are generally incapable of eliciting a toxic response.

2. The above-mentioned polymer is not a cationic polymer, nor is it reasonably anticipated to become a cationic polymer in a natural aquatic environment.

3. The above-mentioned polymer does not contain less than 32.0 percent by weight of the atomic element carbon.

4. The above-mentioned polymer contains as an integral part of its composition the atomic elements carbon, hydrogen, nitrogen, and oxygen.

5. The above-mentioned polymer does not contain as an integral part of its composition, except as impurities, any elements other than those listed in 40 CFR 723.250(d)(3)(ii).

6. The above-mentioned polymer is not a biopolymer, a synthetic equivalent of a biopolymer, or a derivative or modification of a biopolymer that is substantially intact.

7. The above-mentioned polymer is not manufactured from reactants containing, other than as impurities, halogen atoms or cyano groups.

8. The above-mentioned polymer does not contain reactive functional groups that are intended or reasonably anticipated to undergo further reaction.

9. The above-mentioned polymer is not designed or reasonably anticipated to substantially degrade, decompose, or depolymerize. Based upon the above information and review of its use, EPA has found that, when used in

accordance with good agricultural practice, this ingredient is useful and a tolerance is not necessary to protect the public health.

Therefore, EPA proposes that the exemption from the requirement of a tolerance be established as set forth below.

Any person who has registered or submitted an application for registration of a pesticide, under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) as amended, which contains any of the ingredients listed herein, may request within 30 days after publication of this document in the **Federal Register** that this rulemaking proposal be referred to an Advisory Committee in accordance with section 408(e) of the Federal Food, Drug, and Cosmetic Act.

Interested persons are invited to submit written comments on the proposed regulation. Comments must bear a notation indicating the document control number, [OPP–300281]. All written comments filed in response to this petition will be available in the Public Response and Program Resources Branch, at the address given above from 8 a.m. to 4 p.m., Monday through Friday, except legal holidays.

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

Pursuant to the requirements of the Regulatory Flexibility Act (Pub. L. 96-354, 94 Stat. 1164, 5 U.S.C. 601-612), the Administrator has determined that regulations establishing new tolerances or raising tolerance levels or establishing exemptions from tolerance requirements do not have a significant economic effect on a substantial number of small entities. A certification statement to this effect was published in the **Federal Register** of May 4, 1981 (46 FR 24950).

List of Subjects in 40 CFR Part 180

Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Recording and recordkeeping requirements.

Dated: April 8, 1993.

Lawrence E. Culleen,

Acting Director, Registration Division, Office of Pesticide Programs.

Therefore, it is proposed that 40 CFR part 180 be amended as follows:

Part 180—[AMENDED]

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

Authority: 21 U.S.C. 346a and 371.

2. Section 180.1001(d) table is amended by adding and alphabetically inserting the inert ingredient, to read as follows:

§ 180.1001 Exemptions from the requirement of a tolerance.

* * * * *

(d) * * *

Inert ingredients	Limits	Uses
• • • • •		
Cross-linked polyurea-type encapsulating polymer		Encapsulating agent
• • • • •		

* * * * *

§ 180.1039 [Removed]

3. By removing § 180.1039 *Cross-linked polyurea-type encapsulating polymer; exemption from the requirement of a tolerance.*

[FR Doc. 93–9819 Filed 4–27–93; 8:45 am]

BILLING CODE 6560–50–F

40 CFR Part 82

[FRL–4618–9]

Extension of the Deadline for Submission of Comments on the Amended Schedule for the Phaseout of Ozone-Depleting Substances and Request for Comment on the Allowance Level for 1995 of Class I, Group I Substances

AGENCY: Environmental Protection Agency.

ACTION: Proposed rule; extension of comment period and request for comment.

SUMMARY: Through this action, EPA is extending the deadline for the submission of comments on the proposed regulation on the amended schedule on the phaseout of ozone-depleting substances. Further, EPA is specifically seeking comment on the 1995 reduction level in allowable production and consumption of class I, group I substances proposed on March 18, 1993.

DATES: This action extends the deadline for the submission of comments on the proposed rule published on March 18, 1993 at (58 FR 15014) to May 18, 1993. Comments on this proposed rule should be submitted to EPA no later than May 18, 1993.

ADDRESSES: Comments on the notice of proposed rulemaking and on this notice should be submitted in duplicate to the attention of Air Docket No. A–92–13 at: U.S. Environmental Protection Agency, 401 M Street, SW., Washington, DC, 20460. A copy should also be sent to Peter Voigt at the address indicated below. The Docket is located in room M–1500, First Floor Waterside Mall.

FOR FURTHER INFORMATION CONTACT: Peter Voigt, U.S. EPA, Stratospheric Protection Division, Office of Atmospheric Programs, Office of Air and Radiation, 6205J, 401 M Street SW., Washington, DC, 20460, (202) 233–9185.

SUPPLEMENTARY INFORMATION:

Background

On March 18, 1993, EPA issued a proposed rule affecting the phaseout of a number of ozone-depleting substances (58 FR 15014). Specifically, the notice proposes to amend the phaseout schedule for specified ozone-depleting substances under section 606 of the Clean Air Act Amendments, responds to several petitions submitted to EPA under section 602, and proposes to implement amendments and adjustments to the Montreal Protocol agreed to by the Parties at their November 1992 meeting. EPA held a public hearing on the proposal on April 2, 1993. At that hearing, the Methyl Bromide Working Group (MBWG) requested that EPA extend the public comment period and provide for a second public hearing after ninety days from the date of the proposal. This would effectively extend the public comment period to 120 days, since the comment period must remain open for thirty days following a public hearing

under the Clean Air Act section 307(d)(5). The MBWG confirmed this request in a letter to the docket dated April 6, 1993, and referred to the reasons for the request provided at the public hearing. At the public hearing, the MBWG explained that it needs the additional time to assemble and evaluate pertinent scientific and economic information and to prepare its written comments; that 45 days is an inadequate period of time for these tasks; that a public meeting to be held after submission of the written comments; that 45 days is an inadequate period of time for these tasks; that a public meeting to be held after submission of these written comments will allow interested parties to address issues others have raised; and that there is no compelling reasons for the Agency to promulgate a final rule listing methyl bromide at the expense of informed public review and comment.

In response to the MBWG's request, EPA has decided to allow an additional fifteen days for public comment. The comment period for this proposed rule will now close on May 18, 1993. EPA believes that this comment period of 60 days is adequate time for interested parties to prepare comments on this proposed rule. EPA notes that the MBWG has been aware of the petition filed with EPA to list methyl bromide for more than a year prior to the proposal. Further, EPA believes that the interested parties had sufficient opportunity at the April 2 public hearing or in their own written comments to address the issues others have raised in written comments. Therefore, EPA does not believe that a second public hearing is warranted.

As a part of the proposal on the phaseout of ozone-depleting substances, EPA had specified an interim reduction of 85 percent of the allowable baseline of production and consumption for class I, group I substances (CFCs) for the control period beginning on January 1, 1995. Comments received by EPA have raised concerns regarding the viability of the 85 percent interim reduction and EPA is specifically seeking comment on the advantages and disadvantages of changing this reduction to 75 percent of the allowable baseline. This would allow greater availability prior to the complete phaseout. Comments on this issue should also be submitted to the Agency prior to the close of the comment period on May 18, 1993.

Dated: April 22, 1993.

Michael H. Shapiro,

Acting Assistant Administrator, Office of Air and Radiation.

[FR Doc. 93–10056 Filed 4–27–93; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Parts 73 and 74

[MM Docket No. 93–114, FCC 93–187]

Radio Broadcast Services; Low Power Television Service; Application Acceptance Standard; Definition of Major Changes; Four-letter Call Signs

AGENCY: Federal Communications Commission.

ACTION: Proposed rule.

SUMMARY: The Commission, by this Notice of Proposed Rulemaking (Notice) seeks comments on proposals to amend the rules governing the low power television (LPTV) service in three respects. The Notice first solicits comment on proposals to relax the strict acceptance standard for new and major change applications including the expansion of the waiver policy regarding terrain shielding. Second, the Notice solicits comment on a proposal to narrow the definition of a major change. Last, in response to a Petition for Rulemaking filed by the Community Broadcasters Association, the Notice seeks comment on two proposals for making licensed low power television stations eligible to apply for conventional four-letter call signs.

DATES: Comments are due by June 18, 1993, and reply comments are due by July 16, 1993.

ADDRESSES: Federal Communications Commission, 1919 M Street NW., Washington, DC 20554.

FOR FURTHER INFORMATION CONTACT: Keith A. Larson, Mass Media Bureau, Video Services Division, Low Power Television Branch, (202) 632–3894.

SUPPLEMENTAL INFORMATION: This is a synopsis of the Commission's Notice of Proposed Rulemaking in MM Docket. No. 93–114, adopted on April 9, 1993, and released on April 22, 1993. The complete text of this Notice of Proposed Rulemaking is available for inspection and copying during normal business hours in the FCC Reference Center, room 239, at the Federal Communications Commission, 1919 M Street, NW., Washington, DC, 20554, and may also be purchased from the Commission's copy contractor, International Transcription Service, at (202) 857–3800, 2100 M Street, NW., suite 140, Washington, DC 20037.

Synopsis of the Notice of Proposed Rulemaking

1. Since the inception of the LPTV service in 1982, the Commission has employed a strict approach known as the "complete and sufficient" acceptance standard for new and major change LPTV and TV translator applications. See 47 CFR 73.3564(a). Under this approach applications must be letter perfect at the time they are filed and are subject to dismissal for minor defects and omissions. The Commission adopted a strict standard at the time in order to process an extremely large number of pending applications on file. However, the backlog of pending LPTV applications has since decreased; at the same time the quality of the applications received has increased. Therefore, the Commission believes it may now be possible to relax the application acceptance standard without causing an undue delay in processing applications or in authorizing service to the public.

2. Accordingly, the Commission proposes to employ the "substantially complete" acceptance standard, used in full service television, for new and major change applications filed in the LPTV service. Under this proposed standard, an application would be dismissed with no opportunity for reinstatement only if it were patently defective. A determination of substantially incomplete is made when an application, viewed as a whole, cannot be processed. Under this proposed approach, applications found to be substantially complete, but containing minor defects or omissions other than those related to fee matters or the timeliness of an application, would not be returned. Rather, applicants would be sent a deficiency letter and afforded a 30-day opportunity to cure all defects specified in the letter.[1] Corrective amendments would have to be minor amendments and otherwise acceptable in all respects.

3. The Notice also proposes an alternative mid-level acceptance standard which, while not as lenient as substantially complete, would be less strict than the present complete and sufficient standard. Under this hybrid approach, not only would applications be returned for deficiencies which would fail the substantial completeness test, but applications would also be subject to dismissal, without an

[1] Consistent with this approach, applicants could submit corrective amendments to eliminate predicted interference.

opportunity for a corrective amendment, for certain specified defects. Adoption of this approach would require specification of the defects which would be considered so serious or time-consuming that correction should not be allowed.

4. The Commission seeks comment on its proposals to modify its LPTV acceptance standards. Further, the Notice also solicits comment on the practicality of permitting corrective amendments for applications that are defective due to predicted interference and whether there are alternatives to the approaches outlined therein that would be consistent with the twin goals of application quality and processing efficiency.

5. Further, for the same reasons which permit consideration of relaxing the application acceptance standard, the Commission proposes removing the current restrictions regarding the acceptance of waiver requests based on terrain shielding. Pursuant to Commission Policy Regarding Terrain Shielding ("Policy Statement"), 53 FR 15557, May 2, 1988, *recon. granted in part*, 54 FR 1174, January 12, 1989, the Commission waives its interference protection rules when it is apparent that, due to intervening terrain, interference to another facility would not be caused by an applicant's proposed operation. However, under the present policy, the Commission limits consideration of terrain shielding waivers to applications that are not mutually exclusive with any other application submitted during the same filing window.[2] The Notice proposes to no longer limit consideration of applications with terrain shielding waivers to those which are not mutually exclusive.

6. Under the Commission's proposal, applicants whose proposed operations are predicted to cause interference to another application filed during the same filing window could submit detailed terrain profiles prepared in the manner specified in the Policy Statement demonstrating that terrain shielding would prevent actual interference. Further, the proposal also provides that, in accordance with the Policy Statement permitting applicants to submit letters of assent from potentially affected stations stating that interference would not occur due to terrain shielding, applicants could resolve mutual exclusivity among themselves by agreement. In addition, the Notice proposes to consider terrain shielding when raised for the first time by applicants in amendments responding to deficiency letters issued under the proposed new acceptance standard. The Notice seeks comments on the Commission's proposal to extend its terrain shielding waiver policy.

7. Next, the Commission's rules define certain modifications to authorized facilities as major changes. See 47 CFR 73.3572(a). In the case of LPTV and TV translator stations, major changes generally include changes in frequency (output channel), operating power, transmitting antenna system, antenna height and antenna location exceeding 200 meters. However, such changes are not considered major if the resulting signal range of the station would not increase in any horizontal direction. In other words, changes in facilities are considered to be "minor", provided that the station's protected service contour, as modified, lies completely within its unmodified service contour. Major changes were defined in a broad manner when the service was established. The Commission's experience, however, leads it to believe that a more precise definition of the rule can be devised which could enhance the ability of LPTV and TV translator operators to make necessary modifications to their facilities without causing an undue burden upon the staff. The Commission believes that the modifications it is proposing to allow are minor with respect to the rights of other operators and the public.

8. Accordingly, the Commission proposes that any modification to an existing authorization, other than a change in channel be considered a minor change, provided that three conditions are met. First, the proposal must be in compliance with the low power television interference protection rules. Second, the application must not be mutually exclusive with any previously filed application. Third, the protected contour resulting from the modification must be entirely enclosed by a circle, centered at the previously authorized site coordinates, and of radius equal to the largest distance between those coordinates and the protected contour resulting from the existing authorization. The Notice proposes to limit this proposal to authorized facilities and, therefore, not to extend it to pending applications.

9. Under this proposal, stations using directional antennas would be permitted to increase the extent of their footprints in particular directions. In these cases, the LPTV interference protection standards would subsequently be applied to the larger service contour due to the minor change; the bounding circle itself would not be protected against interference. As a result, situations could arise where minor change applications, which may be filed outside of filing windows, might become entangled in interference conflicts with later-filed applications; for example, "new and major change" applications tendered in a filing window. In order to continue authorizing minor changes relatively quickly, the Commission wishes to prevent such applications from being mutually exclusive and involved in the lottery process. Therefore, the Notice proposes to consider minor change applications cutoff on the date filed.

10. The Commission recognizes that this policy could adversely affect some prospective applicants whose later-filed application proposals might conflict with, and be considered untimely filed to, a minor change application having cut off status. Moreover, prospective applicants for new facilities might design a proposed operation to avoid prohibited signal contour overlap within the existing protected contour overlap of another facility, but would not anticipate such overlap with the latter facility's slightly larger protected contour resulting from its pending minor change application. However, the Commission believes that the relatively few instances in which these situations are likely to occur could be resolved through minor amendments. Nevertheless, the Notice proposes to delay implementation of the broader allowance for minor changes until after the close of the first LPTV filing window following adoption of these proposals. Additionally, the Notice proposes to permit minor change applications to be filed during filing windows. However, those applications which increase a station's protected contour in a horizontal direction and are found to be mutually exclusive with other applications in that window would be reclassified as major change applications and processed accordingly.

11. The Commission seeks comment on whether the present distinction between major and minor changes should be modified, including our suggested approach, and whether there are alternatives that could accomplish the Commission's objective. Further, the Notice asks for comment on the proposal to cut off minor change applications on the date filed, as well as whether the proposal to broaden the definition of a minor change should be limited to authorized facilities.

12. Finally, in its Petition for rulemaking (RM–7772), the Community Broadcasters Association (CBA) stated

[2] The Commission accepts new and major change applications only during designated filing windows.

that the difficulty low power television stations already face in making ADI-wide ratings report due to their smaller coverage area, is exacerbated by the fact that ratings services generally have difficulty determining the audience levels that view these stations.[3] Accordingly the Commission believes that the assignment of four-letter call signs to low power television stations may benefit an industry struggling to reach sufficient audience share levels to be economically viable, by more readily enabling viewers to recognize the low power stations as television stations.

13. Therefore, the Commission proposes to allow licensed low power television stations to apply for four-letter call signs. The Notice sets forth two options for implementing this proposal. Under the first option, as suggested by the CBA, only low power television stations which operate a minimum number of hours, provide a certain amount of locally originated programming and abide by the nonengineering rules for conventional television stations would be eligible to receive four-letter call signs. Under the second option, which the Commission tentatively favors, all licensed low power television stations would be entitled to apply for four-letter call signs, irrespective of the nature or extent of their programming.

14. The Notice seeks comment on these two proposals, and whether low power television licensees, in general, should be eligible to apply for four-letter call signs. Further, the Commission is interested in what effect, if any, this proposal would have on full service television broadcasters and any other suggestions which might assist it in implementing this proposal.

Administrative Matters

Initial Regulatory Flexibility Analysis

Pursuant to the Regulatory Flexibility Act of 1980, the Commission finds:

15. *Reason for the Action:* The Commission is initiating this rulemaking to consider whether to make its low power television and television translator rules more lenient with respect to: The acceptance and amendment of defective applications; the definition of major change applications; and the assignment of four-letter call signs. Consideration of these changes is prompted by recent favorable changes in the quality and quantity of these applications and in response to a petition for rulemaking by the Community Broadcasters Association.

16. *Objective of the Action:* The Commission seeks public comment on its tentative conclusions that the strict complete and sufficient processing procedures are no longer necessary; that a relaxes definition of major changes will allow operators increased flexibility to make facilities changes without having to await a filing window, and thereby expedite service to the public; and that four-letter call signs will be beneficial to the LPTV industry by enhancing viewer recognition.

17. *Legal Basis:* Authority for the actions proposed in the Notice may be found in sections 4, 301 and 303 of the Communications Act of 1934, as amended, 47 CFR 154, 301 and 303.

18. *Reporting, Recordkeeping, and Other Compliance Requirements:* The Notice proposes no new requirements.

19. *Federal Rules Which Overlap Duplicate or Conflict With the Proposed Rule:* None.

20. *Description, Potential Impact and Number of Small Entities Involved:* The Commission believes that the adoption of the proposals set forth in this Notice would benefit small entities interested in acquiring new low power television and television translator licenses and small entities already licensed for low power television and television translator facilities who wish to modify their current authorizations. This proposal would also allow such applicants a limited opportunity to amend defective applications to correct errors.

21. *Any Significant Alternatives Minimizing the Impact on Small Entities and Consistent With the Stated Objectives:* The purpose of the Notice is to seek comment on issues including alternatives that would minimize the impact on small entities.

22. As required by section 603 of the Regulatory Flexibility Act, the Commission has prepared an initial regulatory flexibility analysis (IFRA) of the expected impact of these proposed policies and rules on small entities. Written public comments are requested on the IFRA. These comments must be filed in accordance with the same filing deadlines as comments on the rest of the Notice, but they must have a separate and distinct heading designating them as responses to the regulatory flexibility analysis. The Secretary shall cause a copy of the Notice, including the initial regulatory flexibility analysis, to be sent to the Chief Counsel for Advocacy of the Small Business Administration in accordance with Section 603(a) of the Regulatory Flexibility Act, Pub. L. No. 96–354, 94 Stat. 1164, 5 U.S.C. Section 601 *et seq.* (1981).

Ex Parte

23. This is a non-restricted notice and comment rulemaking proceeding. *Ex parte* presentations are permitted, except during the Sunshine Agenda period, provided they are disclosed as provided in the Commission's rules. See generally 47 CFR 1.1202, 1.1203 and 1.1206(a).

Comments

24. Pursuant to applicable procedures set forth in §§ 1.415 and 1.419 of the Commission's Rules, 47 CFR 1.415 and 1.419, interested parties may file comments on or before June 18, 1993, and reply comments on or before July 16, 1993. To file formally in this proceeding, you must file an original plus four copies of all comments, reply comments, and supporting comments. If you want each Commissioner to receive a personal copy of your comments, you must file an original plus nine copies. You should send comment and reply comments to the Office of the Secretary, Federal Communications Commission, Washington, DC 20554. Comments and reply comments will be available for public inspection during regular business hours in the FCC Reference Center, room 239, Federal Communications Commission, 1919 M. Street, NW., Washington, DC 20554.

List of Subjects

47 CFR Part 73

[Television broadcasting]

47 CFR Part 74

Television broadcasting.

Federal Communications Commission.

Donna R. Search,

Secretary.

[FR Doc. 93–9857 Filed 4–27–93; 8:45 am]

BILLING CODE 6712–01–M

[3] Presently, LPTV stations are awarded a five alpha-numeric character call sign consisting of the initial letter K or W followed by the channel number assigned to the station and two additional letters. *See* 47 CFR Section 74.783(d).

Notices

Federal Register
Vol. 58, No. 80
Wednesday, April 28, 1993

This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

DEPARTMENT OF AGRICULTURE

Forest Service

Newspapers To Be Used for Publication of Legal Notice of Appealable Decisions for Southern Region; Alabama, Kentucky, Georgia, Tennessee, Florida, Louisiana, Mississippi, Virginia, West Virginia, Arkansas, Oklahoma, North Carolina, South Carolina, Texas, Puerto Rico

AGENCY: Forest Service, USDA.

ACTION: Notice.

SUMMARY: Deciding Officers in the Southern Region will publish notice of decisions subject to administrative appeal under 36 CFR part 217 in the legal notice section of the newspapers listed in the **SUPPLEMENTARY INFORMATION** section of this notice. As provided in 36 CFR 217.5(d), the public shall be advised, through **Federal Register** notice, of the principal newspaper to be utilized for publishing legal notices of decisions. Newspaper publication of notices of decisions is in addition to direct notice of decisions to those who have requested notice in writing and to those known to be interested in or affected by a specific decision.

DATES: Use of these newspapers for purpose of publishing legal notices of decisions subject to appeal under 36 CFR part 217 shall begin on or after the date of this publication.

FOR FURTHER INFORMATION CONTACT: Jean Paul Kruglewicz, Regional Appeals Coordinator, Southern Region, Planning and Budget, 1720 Peachtree Road, NW., Atlanta, Georgia 30367–9102, Phone: 404–347–4867.

SUPPLEMENTARY INFORMATION: Deciding Officers in the Southern Region will give legal notice of decisions subject to appeal under 36 CFR part 217 in the following newspapers which are listed by Forest Service administrative unit. Where more than one newspaper is listed for any unit, the first newspaper listed is the principal newspaper that will be utilized for publishing the legal notices of decisions. Additional newspapers listed for a particular unit are those newspapers the Deciding Officer expects to use for purposes of providing additional notice. The timeframe for appeal shall be based on the date of publication of the legal notice of the decision in the principal newspaper.

Southern Regional Forester Decisions affecting National Forest System lands in more than one state of the 13 states of the Southern Region and the Commonwealth of Puerto Rico.

Atlanta Journal, published daily in Atlanta, GA

Southern Regional Forester Decision affecting National Forest System lands in only one state of the 13 states of the Southern Region and the Commonwealth of Puerto Rico will appear in the principal paper elected by the National Forest(s) of that state.

National Forests in Alabama, Alabama

Forest Supervisor Decisions

Montgomery Advertiser, published daily in Montgomery, AL

District Rangers Decisions

Bankhead Ranger District: Northwest Alabamian, published weekly (Monday & Thursday) in Haleyville, AL

Conecuh Ranger District: The Andalusia Star, published daily (Tuesday through Saturday) in Andalusia, AL

Brewton Standard, published daily in Brewton, AL

Oakmulgee Ranger District: The Tuscaloosa News, published daily in Tuscaloosa, AL

Shoal Creek Ranger District: The Anniston Star, published daily in Anniston, AL

Talladega Ranger District: The Daily Home, published daily in Talladega, AL

Tuskegee Ranger District: Tuskegee News, published weekly (Thursday) in Tuskegee, AL

Caribbean National Forest, Puerto Rico

Forest Supervisor Decisions

El Nuevo Dia, published daily in Spanish in San Juan, PR

San Juan Star, published daily in San Juan, PR

District Ranger Decisions

El Horizonte, published Weekly (Wednesday) in Fajardo, PR

Chattahoochee-Oconee National Forest, Georgia

Forest Supervisor Decisions

The Times, published daily in Gainesville, GA

District Ranger Decisions

Armuchee Ranger District: Walker County Messenger, published bi-weekly (Wednesday & Friday) in LaFayette, GA

Toccoa Ranger District: The News Observer published weekly (Wednesday) in Blue Ridge, GA

Chestatee Ranger District: Dahlonega Nugget, published weekly (Thursday) in Dahlonega, GA

Brasstown Ranger District: North Georgia News, published weekly (Tuesday) in Blairsville GA

Towns County Herald, published weekly (Tuesday) in Hiawesse, GA

Tallulah Ranger District: Clayton. Tribune, published weekly (Wednesday) in Clayton, GA

Chattooga Ranger District: Northeast Georgian, published weekly (Wednesday) in Clarksville, GA

Toccoa Record, published weekly (Thursday) in Toccoa, GA

The Telegraph, published weekly (Wednesday) in Cleveland, GA

Cohutta Ranger District: Chatsworth Times, published weekly (Tuesday) in Chatsworth, GA

Oconee Ranger District: Monticello News, published weekly (Thursday) in Monticello, GA

Cherokee National Forest, Tennessee

Forest Supervisor Decisions

Knoxville News Sentinel, published daily in Knoxville, TN (covering McMinn, Monroe, and Polk Counties)

Johnson City Press, published daily in Johnson City, TN (covering Carter, Cocke, Greene, Johnson, Sullivan, Unicoi and Washington Counties)

District Rangers Decisions

Ocoee Ranger District: Polk County News, published weekly (Wednesday) in Benton, TN

Hiwassee Ranger District: Daily Post-Athenian, published daily (Monday–Friday) in Athens, TN

Tellico Ranger District: Monroe County Advocate, published weekly (Thursday) in Sweetwater, TN
Nolichucky Ranger District: Greeneville Sun, published daily (Monday–Saturday) in Greeneville, TN
Unaka Ranger District: Johnson City Press, published daily in Johnson City, TN
Watauga Ranger District: Elizabethton Star, published daily (Sunday–Friday) in Elizabethton, TN

Daniel Boone National Forest, Kentucky

Forest Supervisor Decisions

Lexington Herald-Leader, published daily in Lexington, KY

District Rangers Decisions

Morehead Ranger District: Morehead News, published bi-weekly (Tuesday and Friday) in Morehead, KY
Stanton Ranger District: The Clay City Times, published weekly (Thursday) in Clay City, KY
Berea Ranger District: Jackson County Sun, published weekly (Thursday) in McKee, KY
London Ranger District: The Sentinel-Echo, published tri-weekly (Monday, Wednesday, and Friday) in London, KY
Somerset Ranger District: Commonwealth-Journal, published daily (Sunday through Friday) in Somerset, KY
Stearns Ranger District: McCreary County Record, published weekly (Tuesday) in Whitley City, KY
Redbird Ranger District: Manchester Enterprise, published weekly (Thursday) in Manchester, KY

National Forests in Florida, Florida

Forest Supervisor Decisions

The Tallahassee Democrat, published daily in Tallahassee, FL

District Rangers Decisions

Apalachicola Ranger District: The Weekly Journal, published weekly (Wednesday) in Bristol, FL
Lake George Ranger District: The Ocala Star Banner, published daily in Ocala, FL
Osceola Ranger District: The Lake City Reporter, published daily (Monday–Saturday) in Lake City, FL
Seminole Ranger District: The Daily Commercial, published daily in Leesburg, FL
Wakulla Ranger District: The Tallahassee Democrat, published daily in Tallahassee, FL

Francis Marion & Sumter National Forest, South Carolina

Forest Supervisor Decisions

The State, published daily in Columbia, SC

District Rangers Decisions

Enoree Ranger District: Newberry Observer, published tri-weekly (Monday, Wednesday and Friday) Newberry, SC
Andrew Pickens Ranger District: Seneca Journal and Tribune, published bi-weekly (Wednesday and Friday) in Seneca, SC
Long Cane Ranger District: Index-Journal, published daily (Sunday through Friday) in Greenwood, SC
Wambaw Ranger District: News and Courier, published daily in Charleston, SC
Witherbee Ranger District: News and Courier, published daily in Charleston, SC
Tyger Ranger District: The State, published daily in Columbia, SC
Edgefield Ranger District: Augusta Herald, published daily in Augusta, GA

George Washington National Forest, Virginia

Forest Supervisor Decisions

Daily News Record, published daily in Harrisonburg, VA

District Rangers Decisions

Lee Ranger District: Shenandoah Valley Herald, published weekly (Wednesday) in Woodstock, VA
Warm Springs Ranger District: The Recorder, published weekly (Thursday) in Monterey, VA
Pedlar Ranger District: News-Gazette, published weekly (Wednesday) in Lexington, VA
James River Ranger District: Virginian Review, published daily in Covington, VA
Deerfield Ranger District: Daily News Leader, published daily in Staunton, VA
Dry River Ranger District: Daily News Record, published daily in Harrisonburg, VA

Jefferson National Forest, Virginia

Forest Supervisor Decisions

Roanoke Times & World-News, published daily in Roanoke, VA

District Rangers Decisions

Blacksburg Ranger District: Roanoke Times & World-News, published daily in Roanoke, VA
Monroe Watchman, published weekly (Thursday) in Union, WV (only for those decisions in West VA—notice will be published in the Roanoke Times and Monroe Watchman.)
Glenwood Ranger District: Roanoke Times & World-News, published daily in Roanoke, VA
New Castle Ranger District: Roanoke Times & World-News, published daily in Roanoke, VA
Monroe Watchman, published weekly (Thursday) in Union, WV (only for those decisions in West VA—notice will be published in the Roanoke Times and Monroe Watchman.)
Mount Rogers National Recreation Area: Bristol Herald Courier, published daily in Bristol, VA
Clinch Ranger District: Kingsport-Times News, published daily in Kingsport, TN
Wythe Ranger District: Southwest Virginia Enterprise, published bi-weekly (Wednesday and Saturday) in Wytheville, VA

Kisatchie National Forest, Louisiana

Forest Supervisor Decisions

Alexandria Daily Town Talk, published daily in Alexandria, LA

District Ranger Decisions

Caney Ranger District: Minden Press Herald, published daily in Minden, LA
Homer Guardian Journal, published weekly (Wednesday) in Homer, LA
Catahoula Ranger District: Alexandria Daily Town Talk, published daily in Alexandria, LA
Colfax Chronicle, published weekly (Wednesday) in Colfax, LA
Evangeline Ranger District: Alexandria Daily Town Talk, published daily in Alexandria, LA
Kisatchie Ranger District: Natchitoches Times, published bi-weekly (Sunday and Wednesday) in Natchitoches, LA
Vernon Ranger District: Leesville Leader, published daily in Leesville, LA
Winn Ranger District: Winn Parish Enterprise, published weekly (Wednesday) in Winnfield, LA

National Forests in Mississippi, Mississippi

Forest Supervisor Decisions

Clarion-Ledger, published daily in Jackson, MS

District Ranger Decisions

Bienville Ranger District: Clarion-Ledger, published daily in Jackson, MS
Biloxi Ranger District: Clarion-Ledger, published daily in Jackson, MS
Black Creek Ranger District: Clarion-Ledger, published daily in Jackson, MS

Bude Ranger District: Clarion-Ledger, published daily in Jackson, MS
Chickasawhey Ranger District: Clarion-Ledger, published daily in Jackson, MS
Delta Ranger District: Clarion-Ledger, published daily in Jackson, MS
Holly Springs Ranger District: Clarion-Ledger, published daily in Jackson, MS
Homochitto Ranger District: Clarion-Ledger, published daily in Jackson, MS
Strong River Ranger District: Clarion-Ledger, published daily in Jackson, MS
Tombigbee Ranger District: Clarion-Ledger, published daily in Jackson, MS
Ashe-Erambert Project: Clarion-Ledger, published daily in Jackson, MS

National Forests in North Carolina, North Carolina

Forest Supervisor Decisions

The Asheville Citizen-Times, published daily in Asheville, NC

District Ranger Decisions

Cheoah Ranger District: Graham Star, published weekly (Thursday) in Robbinsville, NC
Croatan Ranger District: The Sun Journal, published weekly (Sunday through Friday) in New Bern, NC
French Broad District: The Ashville Citizen-Times, published daily in Asheville, NC
Grandfather District: McDowell News, published daily in Marion, NC
Highlands Ranger District: The Highlander, published weekly (May-Oct Tues & Fri; Oct-April Tues only) in Highlands, NC
Pisgah Ranger District: The Asheville Citizen-Times, published daily in Asheville, NC
Toecane Ranger District: The Asheville Citizen-Times, published daily in Asheville, NC
Tusquitee Ranger District: Cherokee Scout, published weekly (Wednesday) in Murphy, NC
Uwharrie Ranger District: Montgomery Herald, published weekly (Wednesday) in Troy, NC
Wayah Ranger District: The Franklin Press, published tri-weekly (Monday, Wednesday, and Friday) in Franklin, NC

Ouachita National Forest, Arkansas, Oklahoma

Forest Supervisor Decisions

Arkansas Democrat-Gazette, published daily in Little Rock, AR

District Ranger Decisions

Caddo Ranger District: Arkansas Democrat-Gazette, published daily in Little Rock, AR
Cold Springs Ranger District: Arkansas Democrat-Gazette, published daily in Little Rock, AR
Fourche Ranger District: Arkansas Democrat-Gazette, published daily in Little Rock, AR
Jessieville Ranger District: Arkansas Democrat-Gazette, published daily in Little Rock, AR
Mena Ranger District: Arkansas Democrat-Gazette, published daily in Little Rock, AR
Oden Ranger District: Arkansas Democrat-Gazette, published daily in Little Rock, AR
Poteau Ranger District: Arkansas Democrat-Gazette, published daily in Little Rock, AR
Winona Ranger District: Arkansas Democrat-Gazette, published daily in Little Rock, AR
Womble Ranger District: Arkansas Democrat-Gazette, published daily in Little Rock, AR
Choctaw Ranger District: Tulsa World, published daily in Tulsa, OK
Kiamichi Ranger District: Tulsa World, published daily in Tulsa, OK
Tiak Ranger District: Tulsa World, published daily in Tulsa, OK

Ozark-St. Francis National Forest: Arkansas

Forest Supervisor Decisions

Courier-Democrat, published daily (Sunday through Friday) in Russellville, AR

District Ranger Decisions

Sylamore Ranger District: Stone County Leader, published weekly (Tuesday) in Mountain View, AR
Buffalo Ranger District: Newton County Times, published weekly (Wednesday) in Jasper, AR
Bayou Ranger District: Courier-Democrat, published daily (Sunday through Friday) in Russellville, AR
Pleasant Hill Ranger District: Johnson County Graphic, published weekly (Wednesday) in Clarksville, AR
Boston Mountain Ranger District: Southwest Times Record, published daily in Fort Smith, AR
Magazine Ranger District: Southwest Times Record, published daily in Fort Smith, AR
St. Francis Ranger District: The Daily World, published daily (Sunday through Friday) in Helena, AR

National Forests in Texas, Texas

Forest Supervisor Decisions:

The Lufkin Daily News, published daily in Lufkin, TX

District Rangers Decisions:

Angelina Ranger District: The Lufkin Daily News, published daily in Lufkin, TX
San Jacinto Ranger District: The Houston Post, published daily in Houston, TX
Neches Ranger District: The Lufkin Daily News, published daily in Lufkin, TX
Raven Ranger District: The Courier, published daily in Conroe, TX
Tenaha Ranger District: The Lufkin Daily News, published daily in Lufkin, TX
Trinity Ranger District: The Lufkin Daily News, published daily in Lufkin, TX
Yellowpine Ranger District: The Beaumont Enterprise, published daily in Beaumont, TX
Caddo-LBJ Ranger District—Caddo-LBJ National Grassland: Denton Record-Chronicle, published daily in Denton, TX

Dated: April 20, 1993.

Ralph F. Mumme,

Acting Deputy Regional Forester.

[FR Doc. 93-9900 Filed 4-27-93; 8:45 am]

BILLING CODE 3410-11-M

Suitability Study for Nine Streams and Rivers Being Considered for National Wild and Scenic River Status, Tahoe National Forest, Placer, Yuba, Eldorado, Sierra, and Nevada Counties, CA

AGENCY: Forest Service, USDA.

ACTION: Notice of intent to prepare an environmental impact statement.

SUMMARY: The Forest Service, USDA, will prepare a legislative environmental impact statement (EIS) and wild and scenic river study report to determine the suitability or non-suitability of the approximately 70 miles of nine eligible streams and rivers on the Tahoe National Forest and the Lake Tahoe Basin Management Unit for inclusion in the National Wild and Scenic Rivers System. In addition, the agency gives notice of the environmental analysis and decisionmaking process that will occur on the proposal so that interested and affected people are aware of how they may participate and contribute to the final decision.

DATES: Comments concerning the suitability of these rivers must be received by May 31, 1993.

ADDRESSES: Submit written comments and suggestions to Terry B. Randolph, Planning Team Leader, P.O. Box 640, Carson City, Nevada 89701.

FOR FURTHER INFORMATION CONTACT:

Terry Randolph, Planning Team Leader, P.O. Box 640, Carson City, Nevada 89701 or telephone (702) 882–3436.

SUPPLEMENTARY INFORMATION: The Tahoe National Forest Plan and the Lake Tahoe Basin Management Unit Forest Plan determined the eligibility of the approximately 70 miles of the rivers located within the Tahoe Basin and the Truckee River drainage. The eligible rivers are:

1. Upper Truckee River from its headwaters below Carson Pass to Christmas Valley near the south shore of Lake Tahoe
2. Truckee River from Tahoe City to Truckee
3. Martis Creek
4. Cold Stream
5. Alder Creek
6. Sagehen Creek
7. Perazzo Creek
8. Little Truckee River
9. Upper Independence Creek

The planned EIS completes considering these streams and rivers for inclusion in the wild and scenic rivers system.

The suitability study and EIS will consider approximately 70 miles of the nine eligible rivers. The area of consideration for each river is a minimum of ¼ mile from each bank for the entire length of the eligible portion of the river within the Tahoe National Forest and Lake Tahoe Basin Management Unit boundaries.

Public participation will be especially important at several points during the analysis. The first point is the scoping process (40 CFR 1501.7). The Forest Service has and is seeking information, comments, and assistance from Federal, State, and local agencies and other individuals or organizations who may be interested in or affected by the proposed action. This input will be used in preparation of the draft environmental impact statement.

Informal open houses will be held at Truckee, Tahoe City, and South Lake Tahoe, California in the early stages of the analysis to inform the public of the analysis process and to provide for public participation and involvement. Federal, State, and local agencies, user groups, and other organizations who would be interested in the study will be invited to participate in scoping the issues that should be considered.

The comment period on this draft environmental impact statement will be 90 days from the date the Environmental Protection Agency's notice of availability appears in the **Federal Register**. It is very important that those interested in the suitability of the streams for inclusion in the National Wild and Scenic Rivers system participate at this time.

The Forest Service believes, at this early stage, it is important to give reviewers notice of several court rulings related to public participation in the environmental review process. First, reviewers of draft environmental impact statements must structure their participation in the environmental review of the proposal so that it is meaningful and alerts an agency to the reviewer's position and contentions. *Vermont Yankee Nuclear Power Corp* v. *NRDC*, 435 U.S. 519, 533 (1978). Also, environmental objections that could be raised at the draft environmental impact statement stage but that are not raised until after completion of the final environmental impact statement may be waived or dismissed by the courts. *City of Angoon* v. *Hodel*, 803 F.2d 1016, 1022 (9th Cir. 1986) and *Wisconsin Heritages, Inc.* v. *Harris*, 490 F. Suppl. 1334, 1338 (E.D. Wis. 1980). Because of these court rulings, it is very important that those interested in this proposed action participate by the close of the 90-day comment period so that substantive comments and objections are made available to the Forest Service at a time when it can meaningfully consider them and respond to them in the final environmental impact statement.

To assist the Forest Service in identifying and considering issues and concerns on the proposed action, comments on the draft environmental impact statement should be as specific as possible. It is also helpful if comments refer to specific pages or chapters of the draft statement. Comments may also address the adequacy of the draft environmental impact statement or the merits of the alternatives formulated and discussed in the statement. Reviewers may wish to refer to the Council on Environmental Quality Regulations for implementing the procedural provisions of the National Environmental Policy Act at 40 CFR 1503.3 in addressing these points. After the comment period ends on the draft EIS, the comments will be analyzed and considered by the Forest Service in preparing the final environmental impact statement.

John Skinner, Forest Supervisor, Tahoe National Forest, P.O. Box 6003, Nevada City, California 95959–6003, and Robert Harris, Forest Supervisor, Lake Tahoe Basin Management Unit, 870 Emerald Bay Road, Suite 1, South Lake Tahoe, California 96150 are the responsible officials for the suitability study. Michael Epsy, Secretary of Agriculture, U.S. Department of Agriculture, room 200–A, Adm. Bldg., Washington, DC 20250, is the responsible official for recommendations for wild and scenic river designation.

The draft environmental impact statement is expected to be filed with the Environmental Protection Agency (EPA) and to be available for public review by December 31, 1993. At that time the EPA will publish a notice of availability of the draft EIS in the **Federal Register**.

Dated: April 20, 1993.

Thomas J. Mills,

Associate Deputy Chief.

[FR Doc. 93–9959 Filed 4–27–93; 8:45 am]

BILLING CODE 3410–11–M

DEPARTMENT OF COMMERCE

Bureau of Export Administration

Action Affecting Export Privileges

In the Matter of: Reza Zandian, also known as Golamreza Zandianjazi, with addresses at—

5 Hillsborough, Newport Beach, California 92660

and

c/o Iran Business Machines, USA, 600 Anton Boulevard, Costa Mesa, California 92626

Charles Robert Reger, 9582 Erskine Drive, Huntington Beach, California 92646

Iran Business Machines, No. 50 Molla Sadra Avenue, 14357 Tehran, Iran

Iran Business Machines, USA, 600 Anton Boulevard, Costa Mesa, California 92626

Lucach Corporation, and its division, Computerworld North America, also known as Computer World, 17526–B Von Karman, Irvine, California 92714

and

Computerworld Europe, also known as Computer World and C.E.P.A.T., Rue Jean-Grandel, BP 12–95102 Argenteuil, France,

Respondents.

Order Modifying Temporary Denial Order

On April 16, 1993, pursuant to the provisions of § 788.19 of the Export Administration Regulations (currently codified at 15 CFR parts 768–799 (1992)) (the Regulations), issued pursuant to the Export Administration Act of 1979, as amended (currently codified at 50 U.S.C.A. app. §§ 2401–2420 (1991, Supp. 1992, and Pub. L. No. 103–10)) (the Act), I issued an order temporarily denying all United States export privileges of Reza Zandian, also known as Golamreza Zandianjazi (Zandian); Charles Robert Reger (Reger); Iran Business Machines; Iran Business Machines, USA; Lucach Corporation and its division, Computerworld North America, also known as Computer World (Lucach); and Computerworld Europe, also known as Computer World

and C.E.P.A.T. (Computerworld Europe) (hereinafter collectively referred to as respondents). In addition to denying respondents' U.S. export privileges for a period of 180 days from the date of issuance,[1] the Order also named several companies, including Optima Technology Corporation, 17526 Von Karman, Irvine, California 92714 (Optima), as persons related to one or more of the respondents. Accordingly, Optima and the other named related persons were made subject to the provisions of the Order as related persons.

The Office of Export Enforcement, Bureau of Export Administration, U.S. Department of Commerce (Department), and Optima have jointly moved, based on evidence presented to the Department by Optima, to modify the temporary denial order by deleting Optima as a person related to one or more of the respondents.

Based on the submission by the Department and Optima, I hereby grant the motion to modify the temporary denial order. Accordingly, the temporary denial order entered against respondents on April 16, 1993, is modified to read as follows:

Accordingly, *it is hereby Ordered:*

I. All outstanding individual validated licenses in which any of the respondents appears or participates, in any manner or capacity, are hereby revoked and shall be returned forthwith to the Office of Export Licensing for cancellation. Further, all of respondents' privileges of participating, in any manner or capacity, in any special licensing procedures, including, but not limited to, distribution licenses, are hereby revoked.

II. For a period of 180 days from the date of entry of this order, Reza Zandian, also known as Golamreza Zandianjazi, with addresses at 5 Hillsborough, Newport Beach, California 92660 and c/o Iran Business Machines, USA, 600 Anton Boulevard, Costa Mesa, California 92626; Charles Robert Reger, 9582 Erskine Drive, Huntington Beach, California 92646; Iran Business Machines, No. 50 Molla Sadra Avenue, 14357 Tehran, Iran; Iran Business Machines, USA, 600 Anton Boulevard, Costa Mesa, California 92626; Lucach Corporation, and its division, Computerworld North America, also known as Computer World, 17526–B Von Karman, Irvine, California 92714; and Computerworld Europe, also known as Computer World and C.E.P.A.T., Rue Jean-Grandel, BP 12–95102 Argenteuil, France, and all their successors, assignees, officers, partners, representatives, agents, and employees, hereby are denied all privileges of participating, directly or indirectly, in any manner or capacity, in any transaction in the United States or abroad involving any commodity or technical data exported or to be exported from the United States, in whole or in part, and subject to the Regulations. Without limiting the generality of the foregoing, participation, either in the United States or abroad, shall include participation, directly or indirectly, in any manner or capacity: (i) As a party or as a representative of a party to any export license application submitted to the Department; (ii) in preparing or filing with the Department any export license application or request for reexport authorization, or any document to be submitted therewith; (iii) in obtaining from the Department or using any validated or general export license, reexport authorization, or other export control document; (iv) in carrying on negotiations with respect to, or in receiving, ordering, buying, selling, delivering, storing, using, or disposing of, in whole or in part, any commodities or technical data exported or to be exported from the United States, in whole or in part, and subject to the Regulations; and (v) in financing, forwarding, transporting, or other servicing of such commodities or technical data.

III. After notice and opportunity for comment as provided in § 788.3(c), any person, firm, corporation, or business organization related to respondents by affiliation, ownership, control, or position of responsibility in the conduct of trade or related services may also be subject to the provisions of this Order. Based on the showing made by the Department, I have determined that the following companies are related to one or more of the respondents by affiliation, ownership, or control in the conduct of trade and related services and, accordingly, are hereby made subject to this Order:

Optima Technology Europe, also known as O.T.E., Rue Jean-Grandel, BP 12–95102 Argenteuil, France

Optima Technology Middle East, also known as O.T.M.E., 132 Felestin Avenue, Tehran, Iran

Computerworld Middle East, No. 50 Molla Sandra Avenue, 14357 Tehran, Iran

AS/TEQ Corporation, 17526 Von Karman, Irvine, California 92714

U.S. Business Machines Corporation, 17526 Von Karman, Irvine, California 92714

RISQ Technology Corporation, 17526 Von Karman, Irvine, California 92714

and

ICSAA Trade Company with addresses at—7502 Mar Avenue, La Jolla, California 92037

and

P.O. Box 27082, 1395 Marine Drive, West Vancouver, British Columbia, V7T2X8 Canada

IV. As provided by § 787.12(a) of the Regulations, without prior disclosure of the facts to and specific authorization of the Office of Export Licensing, in consultation with the Office of Export Enforcement, no person may directly or indirectly, in any manner or capacity: (i) Apply for, obtain, or use any license, Shipper's Export Declaration, bill of lading, or other export control document relating to an export or reexport of commodities or technical data by, to, or for another person then subject to an order revoking or denying his export privileges or then excluded from practice before the Bureau of Export Administration; or (ii) order, buy, receive, use, sell, deliver, store, dispose of, forward, transport, finance, or otherwise service or participate: (a) In any transaction which may involve any commodity or technical data exported or to be exported from the United States; (b) in any reexport thereof; or (c) in any other transaction which is subject to the Export Administration Regulations, if the person denied export privileges may obtain any benefit or have any interest in, directly or indirectly, any of these transactions.

V. In accordance with the provisions of § 788.19(e) of the Regulations, any respondent may, at any time, appeal this temporary denial order by filing with the Office of the Administrative Law Judge, U.S. Department of Commerce/Export Control, room H–4017, 14th Street and Constitution Avenue, NW., Washington, DC 20230, a full written statement in support of the appeal. Any related person may appeal the finding that it is related to one or more of the denied parties, but may not appeal the underlying issuance of the temporary denial order.

VI. This amended order is effective immediately and shall remain in effect until October 13, 1993.

VII. In accordance with the provisions of § 788.19(d) of the Regulations, the Department may seek renewal of this temporary denial order by filing a written request not later than 20 days before the expiration date. Any respondent may oppose a request to renew this temporary denial order by filing a written submission with the Assistant Secretary for Export Enforcement, which must be received not later than seven days before the expiration date of this order.

[1] The temporary denial order is effective until October 13, 1993, which is 180 days from April 16, 1993.

A copy of this order shall be served on each respondent and each named related person. This order shall be published in the **Federal Register**.

Dated: April 23, 1993.

Douglas E. Lavin,

Acting Assistant Secretary for Export Enforcement.

[FR Doc. 93–10057 Filed 4–27–93; 8:45 am]

BILLING CODE 3510–DT–M

International Trade Administration

Antidumping or Countervailing Duty Order, Finding, or Suspended Investigation; Opportunity To Request Administrative Review

AGENCY: International Trade Administration/Import Administration, Department of Commerce.

ACTION: Notice of Opportunity to Request Administrative Review of Antidumping or Countervailing Duty Order, Finding, or Suspended Investigation.

Background: Each year during the anniversary month of the publication of an antidumping or countervailing duty order, finding, or suspension of investigation, an interested party as defined in section 771(9) of the Tariff Act of 1930, as amended, may request, in accordance with section 353.22 or 355.22 of the Commerce Regulations, that the Department of Commerce ("the Department") conduct an administrative review of that antidumping or countervailing duty order, finding, or suspended investigation.

Opportunity to Request a Review: Not later than May 31, 1993, interested parties may request administrative review of the following orders, findings, or suspended investigations, with anniversary dates in May for the following periods:

	Period
Antidumping Duty Proceedings	
Argentina: Light-Wall Welded Rectangular Carbon Steel Tubing (A–357–802)	05/01/92–04/30/93
Brazil: Certain Carbon Steel Butt-Weld Pipe Fittings (A–351–602)	05/01/92–04/30/93
Brazil: Certain Iron Construction Castings (A–351–503)	05/01/92–04/30/93
Brazil: Frozen Concentrated Orange Juice (A–351–605)	05/01/92–04/30/93
Dominican Republic: Portland Cement, Other Than White, Nonstaining Portland Cement (A–247–003)	05/01/92–04/30/93
France: Ball Bearings, Cylindrical Roller Bearings, Spherical Plain Bearings, and Parts Thereof (A–427–801)	05/01/92–04/30/93
Germany: Ball Bearings, Cylindrical Roller Bearings, Spherical Plain Bearings, and Parts Thereof (A–428–801)	05/01/92–04/30/93
India: Certain Welded Carbon Steel Standard Pipes and Tubes (A–533–502)	05/01/92–04/30/93
Italy: Ball Bearings, Cylindrical Roller Bearings, and Parts Thereof (A–475–801)	05/01/92–04/30/93
Japan: Ball Bearings, Cylindrical Roller Bearings, Spherical Plain Bearings, and Parts Thereof (A–588–804)	05/01/92–04/30/93
Japan: Impression Fabric (A–588–066)	05/01/92–04/30/93
Japan: Portable Electric Typewriters (A–588–087)	05/01/92–04/30/93
Japan: Gray Portland Cement and Clinker (A–588–815)	05/01/92–04/30/93
Romania: Ball Bearings and Parts Thereof (A–485–801)	05/01/92–04/30/93
Singapore: Ball Bearings and Parts Thereof (A–559–801)	05/01/92–04/30/93
Sweden: Ball Bearings, Cylindrical Roller Bearings, and Parts Thereof (A–401–801)	05/01/92–04/30/93
Taiwan: Certain Circular Welded Carbon Steel Pipes and Tubes (A–583–008)	05/01/92–04/30/93
Taiwan: Malleable Cast-Iron Pipe Fittings, Other Than Grooved (A–583–507)	05/01/92–04/30/93
Thailand: Ball Bearings and Parts Thereof (A–549–801)	05/01/92–04/30/93
The People's Republic of China: Certain Iron Construction Castings (A–570–502)	05/01/92–04/30/93
The Republic of Korea: Malleable Cast Iron Pipe Fittings, Other Than Grooved (A–580–507)	05/01/92–04/30/93
The United Kingdom: Ball Bearings, Cylindrical Roller Bearings, and Parts Thereof (A–412–801)	05/01/92–04/30/93
Turkey: Welded Carbon Steel Standard Pipe and Tube Products (A–489–501)	05/01/92–04/30/93
Countervailing Duty Proceedings	
Brazil: Certain Heavy Iron Construction Castings (C–351–504)	01/01/92–12/31/92
Mexico: Ceramic Tile (C–201–003)	01/01/92–12/31/92
Singapore: Antifriction Bearings (Other Than Tapered Rollered Bearings) and Parts Thereof (C–559–802)	01/01/92–12/31/92
Sweden: Viscose Rayon Staple Fiber (C–401–056)	01/01/92–12/31/92
Thailand: Ball Bearings and Parts Thereof (C–549–802)	01/01/92–12/31/92

In accordance with sections 353.22(a) and 355.22(a) of the Commerce regulations, an interested party may request in writing that the Secretary conduct an administrative review of specified individual producers or resellers covered by an order, if the requesting person states why the person desires the Secretary to review those particular producers or resellers. If the interested party intends for the Secretary to review sales of merchandise by a reseller (or a producer if that producer also resells merchandise from other suppliers) which was produced in more than one country of origin, and each country of origin is subject to a separate order, then the interested party must state specifically which reseller(s) and which countries of origin for each reseller the request is intended to cover.

Seven copies of the request should be submitted to the Assistant Secretary for Import Administration, International

Trade Administration, room B–099, U.S. Department of Commerce, Washington, DC 20230. The Department also asks parties to serve a copy of their requests to the Office of Antidumping Compliance, Attention: Thomas Futtner, in room 3069–A of the main Commerce Building. Further, in accordance with section 353.31(g) or 355.31(g) of the Commerce Regulations, a copy of each request must be served on every party on the Department's service list.

The Department will publish in the **Federal Register** a notice of "Initiation of Antidumping (Countervailing) Duty Administrative Review", for requests received by May 31, 1993.

If the Department does not receive, by May 31, 1993, a request for review of entries covered by an order or finding listed in this notice and for the period identified above, the Department will instruct the Customs Service to assess antidumping or countervailing duties on those entries at a rate equal to the cash deposit of (or bond for) estimated antidumping or countervailing duties required on those entries at the time of entry, or withdrawal from warehouse, for consumption and to continue to collect the cash deposit previously ordered.

This notice is not required by statute, but is published as a service to the international trading community.

Dated: April 21, 1993.

Joseph A. Spetrini,

Deputy Assistant Secretary for Compliance.

[FR Doc. 93–9954 Filed 4–27–93; 8:45 am]

BILLING CODE 3510–DS–M

[A–201–802]

Gray Portland Cement and Clinker From Mexico; Final Results of Antidumping Duty Administrative Review

AGENCY: International Trade Administration/Import Administration, Department of Commerce.

ACTION: Notice of final results of antidumping duty administrative review.

SUMMARY: On January 26, 1993, the Department of Commerce published the preliminary results of its administrative review of the antidumping duty order on gray portland cement and clinker from Mexico. The review covers two manufacturers/exporters of the subject merchandise to the United States and the review period April 12, 1990, through August 31, 1991.

We gave interested parties an opportunity to comment on our preliminary results. Based on our analysis of the comments received and the correction of certain clerical errors, we have revised the preliminary rates. The final dumping margins range from 30.44 percent to 53.26 percent.

EFFECTIVE DATE: April 28, 1993.

FOR FURTHER INFORMATION CONTACT: Marina McClelland, Office of Antidumping Compliance, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue NW., Washington, DC 20230; telephone (202) 482–4852.

SUPPLEMENTARY INFORMATION:

Background

On January 26, 1993, the Department of Commerce (the Department) published in the **Federal Register** (58 FR 6113) the preliminary results of its administrative review of the antidumping duty order on gray portland cement and clinker from Mexico (August 19, 1990, 58 FR 6113). The Department has now completed that review in accordance with section 751 of the Tariff Act of 1930, as amended (the Act).

Scope of Review

The products covered by this review are gray portland cement and clinker. Gray portland cement is a hydraulic cement and the primary component of concrete. Clinker, an intermediate material product produced when manufacturing cement, has no use other than of being ground into finished cement.

Gray portland cement is currently classifiable under the Harmonized Tariff Schedule (HTS) item number 2523.29, and cement clinker is currently classifiable under number 2523.10. Gray portland cement has also been entered under number 2523.90 as "other hydraulic cements." The HTS subheadings are provided for convenience and U.S. Customs Service purposes only. The written description remains dispositive as to the scope of the product coverage.

The review covers two manufacturers/exporters of the subject merchandise to the United States and the period April 12, 1990 through August 31, 1991. One manufacturer/exporter, Apasco, S.A. de C.V. (Apasco), made no shipments during the period of review (POR). As a result, the Department has retained as the cash deposit for Apasco the margin percentage calculated for Apasco in the final determination of sales at less than fair value.

Analysis of Comments Received

We invited interested parties to comment on the preliminary results. We received written comments from the Ad Hoc Committee of AZ–NM–TX–FL Producers of Gray Portland Cement and the National Cement Company of California (the petitioners), and one respondent, CEMEX, S.A. (CEMEX). On March 19, 1993, we held a public hearing.

Comment 1: Relying on section 773(a)(5) of the Act of 1930, as amended, petitioners allege that through different movements in the prices of Types I and II cement in the home market, CEMEX created a fictitious market in order to reduce or eliminate the dumping margin on Type II cement. Petitioners state that the foreign market value (FMV) of Type II cement decreased while the FMV of Type I increased slightly after the issuance of the antidumping duty order on Mexican cement. Petitioners add that although Type I and Type II cement are interchangeable for most purposes, the relative quantities of Type I and Type II cement sold changed little during the period of the pricing movements.

In making this allegation, petitioners insist that the price movements relevant to a fictitious market are the movements of net, ex-factory price or FMV, rather than movements in gross price or delivered price. Moreover, petitioners argue that the statute does not require that the sales evidencing a fictitious market be non-bona fide sales.

Petitioners explain that because CEMEX sells primarily Type I cement and relatively little Type II cement in the home market, the lowering of FMV of Type II cement does not measurably affect home market revenue, while it does decrease CEMEX's financial burden of exporting goods which are assessed a large antidumping duty. Consequently, petitioners argue, the Department should reject CEMEX's home market sales of Type II cement as the basis for FMV and should instead use home market sales of Type I cement to calculate FMV. Petitioners add that under the statute, CEMEX's "plausible business reasons" are no defense against an allegation of a fictitious market.

CEMEX asserts that petitioners erroneously base their fictitious market allegation on net prices (*i.e.*, FMV). CEMEX argues that the petitioners must prove their claim of fictitious market by showing the existence of non-bona fide Type II cement sales in the home market. CEMEX also insists that the statute requires the Department to examine only the price paid by the customer, minus discounts and rebates.

CEMEX states that these principles are clearly stated in the statute and its legislative history and are reflected in the Department's approach to previous fictitious market allegations.

CEMEX argues that there is no evidence in the record of any non-bona fide sales. In addition, CEMEX maintains that any conceivable anomaly in price movements vanishes when the price paid by the customer is examined.

CEMEX further argues that petitioners have not made any realistic challenge to CEMEX's claim that its pricing behavior resulted from good faith decision-making both before and after the antidumping duty order was issued. According to CEMEX, following the relocation of production of Type II cement to northern Mexico and an increase in rail freight rates, CEMEX made a business decision to assume responsibility for, rather than pass on, much of the resulting additional freight costs in order to retain its Type II cement customers. In addition, CEMEX decided to lower its prices of Type II cement near Chihuahua, Mexico, due to new U.S. cement competition resulting from the Mexican Government's elimination of duties on cement imported into Mexico from the United States. Therefore, CEMEX claims that any theoretical anomaly in Type II cement FMV resulted from CEMEX's legitimate business decisions to retain Type II cement customers in Mexico.

Department's Position: We disagree with petitioners' contention that the Department should disregard Type II cement sales as the basis for FMV under section 773(a)(5) of the Tariff Act. In our preliminary results of review, we found that the evidence in the record was not sufficient to establish that CEMEX had created a fictitious market (see Gray Portland Cement and Clinker from Mexico; Preliminary Results of Antidumping Duty Administrative Review, 58 FR 6113 (January 26, 1993)). After reviewing the case and rebuttal briefs, the Department continues to hold that the evidence does not warrant the finding of a fictitious market.

In reaching this conclusion, the Department does not accept CEMEX's argument that petitioners must show non-bona fide Type II cement sales. Prior to 1988, section 773(a)(1) of the Act was the only provision in the statute addressing fictitious markets. Under that provision, the analysis the Department was to undertake arguably focused only on the existence of non-bona fide sales, as the required examination addressed only the existence of pretended sales or offers for sale, or sales or offers for sale intended to establish a fictitious market. See *Monsanto* v. *United States*, 698 F. Supp. 275, 279 (CIT 1988); H.R. Conf. Rep. No. 79, 67th Cong., 1st Sess. at 11 (1921). However, with the addition of section 773(a)(5) to the statute in 1988, language was added to the statute expressly allowing for examination of the price movements of different forms of the subject merchandise when assessing the existence of a fictitious market. As a result, the Department clearly need not require the existence of non-bona fide sales in establishing the existence of a fictitious market. Rather, accepting all sales as legitimate, the Department can look at the price movements of the multiple forms of the subject merchandise and, depending on the nature of those price movements, find that a respondent has established a fictitious market (see Tubeless Steel Disc Wheels from Brazil; Final Results of Antidumping Duty Administrative Review, 56 FR 14083, 14085 (April 5, 1991) (Steel Wheels from Brazil); Cyanuric Acid and its Chlorinated Derivatives from Japan; Final Results of Antidumping Duty Administrative Review, 55 FR 1690, 1691 (January 18, 1990) (Cyanuric Acid from Japan); S. Rep. No. 71, 100th Cong., 1st Sess. at 126 (1987)).

In fact, section 773(a)(5) of the Act states that in determining the existence of a fictitious market, the Department may consider evidence of movements in the prices at which different forms of the subject merchandise are sold after the issuance of an antidumping duty order. The Department examines the prices paid by the customers and determines what effect the movements of those prices have on the FMV of the subject merchandise. If the price movements appear to reduce the amount by which the FMV of the merchandise exceeds the United States price (USP) of the merchandise, the Department may consider the price movements to be evidence of a fictitious market. As the legislative history of section 773(a)(5) explains:

> It has come to the Committee's attention that fictitious markets may be created relatively easily when merchandise is produced and sold in multiple forms. If a foreign manufacturer or producer exports only one of such forms to the United States and has been found to be dumping that form, he may artificially set his home market prices of the different forms to reduce the amount by which the foreign market value of the identical merchandise exceeds the U.S. price of such merchandise. If only sales of the identical merchandise are used in determining the foreign market value, the net effect of such artificial pricing may be to eliminate any finding of dumping even though the average home market price of the different forms of the merchandise may still exceed the U.S. price of the imported merchandise.
>
> For example, a chemical product may be produced and sold in powder and granular forms, both of which have similar uses and production costs. If a foreign manufacturer who produces and sells both products in his home market is found to be dumping the powder product in the United States, the only form that the manufacturer exports, he can minimize any antidumping duties finally assessed, and avoid a finding of sales at less than fair value during any review under section 751, by lowering his home market price for the powder product while maintaining or raising his home market price for the granular product.

See S. Rep. No. 71, 100th Cong., 1st Sess. at 126 (1987). See also Steel Wheels from Brazil and Cyanuric Acid from Japan.

However, contrary to petitioners' assertions, the existence of a fictitious market is not necessarily established merely on the basis of price movements without regard to the reasons that may have caused those price movements. The presence of commercial factors other than the existence of an antidumping duty order is relevant in determining whether a fictitious market exists. Thus, we have found it appropriate to consider the business justifications offered by the respondent in determining whether a fictitious home market exists. In Cyanuric Acid from Japan, the Department considered the respondent's "plausible reasons" for the price movements at issue and rejected the petitioner's fictitious market allegation.

In this case, the POR is April 12, 1990 through August 31, 1991. The Department published the antidumping duty order on August 19, 1990. After issuance of the order, and until the end of the POR, the price to the customer of CEMEX's Type I and Type II cement followed similar patterns, increasing only with the rate of inflation. However, while the FMV of Type I cement meanwhile remained steady, increasing only with the rate of inflation, the FMV of Type II cement decreased twice after issuance of the order. The net effect of the decrease in the FMV for Type II cement was a reduction in the amount by which the FMV of the merchandise exceeded the USP of this merchandise.

The decrease of the FMV of Type II cement resulted in large part from a business decision made by CEMEX not to pass on to its Type II customers certain transportation expenses that CEMEX incurred upon consolidating its Type II production. The changes in the FMV of Type II cement coincided generally with the relocation of CEMEX's production of Type II cement to a single plant in northern Mexico and

a general increase in rail cargo rates. Before the issuance of the antidumping duty order, CEMEX planned to consolidate its production of Type II cement to a plant in northern Mexico. This plant is not only more efficient, but it also better facilitates sales to the United States, CEMEX's largest Type II cement market. In the spring of 1990, CEMEX began to move production of Type II cement to its northern Mexico plant. The freight charges associated with sales to most Type II customers in Mexico rose because the physical distances between plant and customer increased. In addition, in October of 1990, there was a fifteen percent increase in rail cargo rates which increased further the freight expenses for Type II cement sales.

The price of Type I cement was less affected by the general rail freight increase because CEMEX continued to produce Type I cement in all regions of the country. With many production sites, CEMEX does not depend as heavily on rail transportation of its Type I cement sales as it does for its Type II cement sales. As a result, the FMV of Type I cement was not significantly affected by the general increase in rail freight rates.

Rather than risk losing its Type II customers, CEMEX decided to assume responsibility for much of the increased freight costs resulting from the relocation of the production of Type II cement to northern Mexico and the increase in rail rates. CEMEX therefore increased only slightly the price paid by its Type II cement customers.

In addition, the FMV of Type II cement decreased as a result of CEMEX's efforts to meet the added competition in Chihuahua from U.S. exporters of Type II cement. This increase in U.S. competition resulted from the Mexican government elimination of duties on cement imported into Mexico from producers on the U.S. side of the frontier zone.

Given these facts, and in the absence of information to rebut them, the Department accepts the business reasons offered by CEMEX in this case as an explanation of the different movements of prices, unrelated to establishing a fictitious market. We do not find that CEMEX's pricing of Type I and II cement has resulted in a fictitious market.

Comment 2: Addressing the Department's cost of production (COP) calculation, petitioners contend that only the interest income specifically recorded in CEMEX's short-term interest income account should be allowed as an offset to CEMEX's interest expense; other financial income should not be allowed as an offset since it cannot be tied to short-term investments.

CEMEX contends that because of the fungibility of interest income, such income should be treated symmetrically (i.e., netted) with interest expense. Accordingly, the Department should not disregard any financial income. If, however, the Department decides to disregard CEMEX's long-term interest income, CEMEX argues that the Department should continue to disregard the monetary losses associated with that income.

Department's Position: We agree with petitioners. The Department has a well-established practice of disallowing long-term interest income offsets to interest expense because such activities are generally considered by the Department to be income-producing activities unrelated to the product under review (See Department's Position to Comment 9, Television Receivers, Monochrome and Color, from Japan; Final Results of Antidumping Duty Administrative Review, 56 FR 56189, 56192 (November 1, 1991)); see also Final Determination of Sales at Less Than Fair Value; Steel Wire Rope from Korea, 58 FR 11029, 11035 (February 23, 1993)). However, the Department typically allows short-term interest income offsets to interest expense if that income can be attributed to the production of the product under review. Because CEMEX's sub-account 6421 was the only portion of interest income that we verified to be short-term, we disallowed all of CEMEX's other interest income. Given that the disallowance of long-term interest income affected the monetary correction adjustment to CEMEX's corporate financial expense, we made a corresponding adjustment to CEMEX's reported monetary correction (see our response to Comment 4 for explanation of monetary correction).

Comment 3: Petitioners contend that in calculating the cost of production, it is the Department's established practice to adjust corporate financial expense only for foreign exchange gains and losses specifically related to the cost of manufacturing the subject merchandise. Petitioners argue that because foreign exchange gains realized by certain CEMEX subsidiaries are not related to the manufacture of the subject merchandise, such gains should not be permitted to offset CEMEX's foreign exchange losses.

CEMEX contends that the Department correctly offset CEMEX's interest expense with all of CEMEX's foreign exchange gains.

Department's Position: We agree with petitioners and have made the appropriate changes in our final results. The Department has long upheld the position that foreign exchange gains and losses not specifically incurred as a cost of producing the subject merchandise should not be allowed as an offset to cost of manufacture (see Certain Stainless Steel Cooking Ware from the Republic of Korea, 58 FR 9560, 9561 (February 22, 1993)); see also Final Results of Antidumping Duty Administrative Review; Color Television Receivers, Except for Video Monitors, from Taiwan, 56 FR 31378, 31385 (July 10, 1991) and Final Determination of Sales at Less Than Fair Value: Certain Small Business Telephone Systems and Subassemblies Thereof from Korea, 54 FR 53141, 53149 (December 27, 1989)).

CEMEX's foreign exchange gains and losses largely resulted from foreign-held monetary assets and liabilities. Although many of these assets and liabilities were held by CEMEX to finance the company's general cement-producing operations, the gains and losses were not attributable to production inputs of products under review and, as such, have been disallowed in our final results. Given that the disallowance of foreign exchange gains and losses affected the monetary correction adjustment to CEMEX's corporate financial expense, we made a corresponding adjustment to CEMEX's reported monetary correction (see Comment 4 below for explanation of monetary correction.)

Comment 4: Citing Steel Wheels from Brazil, 52 FR 8947 (March 20, 1989), Paint Filters and Strainers from Brazil, 52 FR 19181, 19183 (May 21, 1987), and Frozen Concentrated Orange Juice from Brazil, 52 FR 8324, 8329 (March 17, 1987), petitioners contend that a monetary correction adjustment due to inflation should not be made to CEMEX's reported corporate financial expense because such an adjustment is contrary to Departmental precedent, would distort CEMEX's actual cost of production during the period of review, and largely results from related party transactions.

Petitioners also argue that an adjustment for monetary correction should be rejected because such an adjustment violates both Mexican and United States generally accepted accounting principles (GAAP). For example, petitioners contend that an adjustment for monetary correction violates the "matching principle" in which costs incurred during a particular period are matched with their associated revenues. Although petitioners concede that Bulletin B–10 of Mexican GAAP requires Mexican companies to report the effects of

inflation on their monetary assets and liabilities, petitioners contend that Bulletin B–10's monetary correction provision should not be applied in this review since its purpose is to facilitate year-to-year comparisons of financial statements, not to calculate production costs. Likewise, petitioners contend that Financial Accounting Standards Board Statement of Financial Accounting Standard 89 (FASB–89), promulgated under U.S. GAAP, excludes purchasing power gains and losses from income from continuing operations.

Alternatively, petitioners argue that if the Department departs from its past practice and allows an adjustment for monetary correction to interest expense, only the portion of monetary position gain attributable to the cost of producing the subject merchandise should be allowed to offset interest expense.

CEMEX contends that the Department correctly included monetary gains and losses in the calculation of net financing expenses. CEMEX contends that the Department's adjustment for monetary position gains and losses due to inflation (*i.e.*, monetary correction) is consistent with Departmental policy and accurately reflects CEMEX's actual cost of financing in a non-distortive manner. CEMEX also contends that CEMEX's adjustment for monetary correction is consistent with the cost/revenue matching principle and is not a result of related-party transactions.

Department's Position: We disagree with petitioners and agree with respondent. The Department has a well-established practice of recognizing the effects of inflation on companies' reported costs. In Brazil, for example, a country the Department considers to be hyperinflationary, Brazilian GAAP recognizes the effects of inflation by requiring companies to index their debt principal. We also reflect the effects of inflation by calculating monthly costs of production. Our use of monthly current costs, however renders further monetary correction unnecessary.

This is not the case with Mexico. Because we do not consider Mexico to have been hyperinflationary during the period of review, we have not used monthly current costs of production in our final results. Nonetheless, Mexico did experience significant inflation during the period of review. Given that monetary correction under Mexican GAAP pertains solely to the holding of monetary assets and liabilities, not accounting for the effects of inflation, which are recognized by CEMEX's adjustment for monetary correction, would distort CEMEX's corporate financial expense and income.

Petitioners have cited the first administrative review of Porcelain-on-Steel Cookware from Mexico (Cookware), 55 FR 39186 (September 25, 1990), as precedent for disallowing adjustments for monetary correction. While the Department denied the respondent an adjustment for monetary correction in the first administrative review of Cookware, the Department accepted the adjustment in the second and third reviews. An adjustment for monetary correction was also a factor in our decision to initiate the sales-below-cost investigation of CEMEX in this review.

Citing New Minivans from Japan; Final Determination of Sales at Less Than Fair Value, 57 FR 21937 (May 26, 1992), petitioners contend that the Department does not always rely on the respondent country's GAAP when calculating cost of production. Although we agree with petitioners that the Department sometimes deviates from another country's GAAP, such deviations are usually made when adherence to that country's GAAP materially distorts a respondent's actual production costs. Given the significant inflation experienced by Mexico during the period of review, we believe that deviating from Mexican GAAP by not allowing for the monetary correction would lead to distortions in CEMEX's costs of production.

We disagree with petitioners' contention that an adjustment for monetary correction violates the "matching" of CEMEX's costs and revenues. Contrary to petitioners' assertion, the monetary correction is not simply a year-end adjustment to CEMEX's corporate financial expense. Rather, it is the sum of all corrections to financial expenses made throughout the year. Accordingly, it is an integral component of CEMEX's corporate financial expense which, if not reflected in CEMEX's corporate financial expense, would lead to distortions in CEMEX's reported cost of production.

We also disagree with petitioners' alternative assertion that monetary position gains should be limited to the portion that can be specifically tied to the cost of producing the subject merchandise. The Department has long upheld the position that financing expenses are fungible. Accordingly, consistent with past Departmental practice, we do not distinguish whether interest expense is related or unrelated to the merchandise under review (see Final Determination of Sales at Less Than Fair Value; Steel Wire Rope from Korea, 58 FR 11035 (February 23, 1993)). Therefore, we have adjusted CEMEX's interest expense for monetary correction and allocated the adjustment amount over the cost of goods sold for all products.

Petitioners' assertion that CEMEX's monetary gains result largely from related party transactions is incorrect. The financial statement footnotes to which petitioners refer apply to CEMEX's unconsolidated corporate financial statements. In accordance with Department practice, we used CEMEX's consolidated corporate financial statements in determining corporate financial expense. As stated in the footnotes to CEMEX's consolidated financial statements, all intercompany related party transactions have been eliminated.

Comment 5: CEMEX argues that the Department incorrectly adjusted the home market price for sales that CEMEX termed "anticipated" sales by adding an imputed credit revenue. These sales included a minimal number of home market sales for which CEMEX was paid in advance of shipment. CEMEX argues that the Department has had a practice of not recognizing "opportunity benefits" in USP and FMV calculations and should, therefore, reject this additional imputed credit revenue. CEMEX cites Carbon Steel Wire Rod from Brazil; Final Determination of Sales at Less than Fair Value, 48 FR 43202, 43204 (September 22, 1983), and Certain Steel Pipes and Tubes from Japan; Preliminary Determination of Sales at Less than Fair Value, 47 FR 37263, 37265 (August 25, 1982).

Petitioners claim that CEMEX financially benefitted, at the annual rate of short-term investments, from these advance payments. Therefore, petitioners argue, the Department correctly determined the number of days between receipt of payment and shipment of the cement, and then multiplied this number by CEMEX's reported home market interest rate, in order to derive an imputed credit revenue.

Department's Position: We disagree with the respondent. The Department's current practice is to recognize "opportunity benefits" in FMV calculations (see, *e.g.*, Fuel Ethanol from Brazil; Final Results of Sales at Less than Fair Value, 51 FR 5,572, 5,576 (February 14, 1986)). In Large Power Transformers from Italy; Final Results of Antidumping Duty Administrative Review, 52 FR 46806 (December 10, 1987), for example, the Department determined that if a respondent manufacturer receives payment before shipping the merchandise, the credit calculation should reflect a credit income because the respondent had use of the money prior to shipment.

Similarly, in this case, CEMEX had use of the pre-paid money prior to shipment. Therefore, the Department determines that it correctly adjusted FMV for credit revenue on pre-paid sales.

Comment 6: Petitioners argue that the Department should not deduct CEMEX's pre-sale freight expenses from its plant to its terminals in calculating FMV. Petitioners disagree with the Department's policy of deducting pre-sale freight costs from FMV. Petitioners explain that while the statute requires the Department to deduct pre-sale freight expenses from USP in both purchase price (PP) and exporter's sales price (ESP) sales, the statute contains no similar provision authorizing such deductions in the calculation of FMV.

CEMEX argues that the Department correctly followed its policy of deducting pre-sale freight expenses. CEMEX points out that this policy recently was approved by the Court of International Trade (CIT) in *Ad Hoc Committee of AZ-NM-TX-FL Producers of Gray Portland Cement* v. *United States*, 787 F. Supp. 208, 213 (CIT 1992), which concerned the Department's final determination in the investigation of this case.

Department's Position: We disagree with petitioners. Since the final determination in the investigation in this case, we have followed a policy of deducting home market pre-sale freight expenses when calculating FMV for PP sales or ESP sales. This ensures an apples-to-apples comparison. See Gray Portland Cement and Clinker from Mexico; Final Determination of Sales at Less than Fair Value, 55 FR 29244 (July 18, 1990), Tapered Roller Bearings, Four Inches or Less in Outside Diameter, and Certain Components Thereof, from Japan; Final Results of Antidumping Duty Administrative Review, 56 FR 26054 (June 6, 1991); Red Raspberries from Canada; Final Results and Termination in Part of Antidumping Duty Administrative Reviews, 56 FR 677 (January 8, 1991). Further, as CEMEX notes, in the appeal of the final determination of the investigation in this case, the CIT approved the Department's policy of deducting pre-sale freight expenses when calculating FMV for PP sales.

Comment 7: Petitioners contend that it was appropriate for the Department to calculate cost of production on a monthly basis. However, because of aberrations in CEMEX's December 1990 costs of manufacture for Type II cement, best information available should be used for that month's costs.

CEMEX contends that, as verified by the Department, its December 1990 costs of manufacture for Type II cement are accurate. However, CEMEX contends that the Department should calculate CEMEX's cost of production on an annual basis rather than a monthly basis.

Department's Position: We agree with respondent. During our verification of CEMEX, we determined that the "aberrations" referred to by petitioners were the result of normal year-end adjustments recorded in CEMEX's December accounting records. Our use of monthly costs of production in our preliminary results caused the December 1990 costs for some of CEMEX's facilities to appear aberrational. We have calculated and used annual 1990 and 1991 cost of production figures in our final results.

Comment 9: Petitioners argue that the Department should apply the "arm's length test" described in Certain Cold-Rolled Carbon Steel Flat-Rolled Products from Argentina; Preliminary Determination of Sales at Less Than Fair Value (Steel Flat-Rolled Products from Argentina), 58 FR 7066, 7069 (Appendix II, Section A) (February 4, 1993), in determining whether to accept related party sales for purposes of calculating FMV. According to petitioners, when that test is applied in this case, some sales made by CEMEX to related parties must be disregarded. Petitioners apply the test by disregarding sales where the weighted-average net price for an individual related party for a particular month is not equal to or greater than all unrelated customer weighted-average net prices for that month.

CEMEX disagrees with the petitioners' proposed treatment of related party transactions in the calculation of FMV. CEMEX argues that petitioners' comparison of a specific net prices of sales to a related party to an average net prices of sales to all unrelated parties from all terminals is not a valid comparison. Further, CEMEX argues that there is no legal basis for selective exclusion of related-party transactions when the sales to a particular related party are excluded in one month and then included in the next month. CEMEX asserts that the established practice by the Department is either to find all sales to a particular related party to be unreliable and exclude them all from FMV calculations, or to accept the arms-length nature of the sales to that party and include them all in the calculations. CEMEX argues finally that if petitioners had compared net prices on a terminal-specific basis and had not analyzed the sales on a monthly basis, petitioners would have discovered that net prices of sales to related customers are, on the whole, equal to or greater than the unrelated customer net prices.

Department's Position: We disagree with petitioners. The Department is currently accepting comments from interested parties on the application of the "arm's length" test described in the preliminary determination of Steel Flat-Rolled Products from Argentina. Due to the preliminary nature of the "arm's length" test used in Steel Flat-Rolled Products from Argentina, the Department used a test based on our past practice. See Antifriction Bearings (Other Than Tapered Roller Bearings) and Parts thereof from France; Final Results of Antidumping Duty Administrative Reviews, 57 FR 28393 (June 24, 1992). Upon examination, we used sales to related customers only where we determined such sales were made at arm's length, *i.e.*, at prices comparable to prices at which the firm sold identical merchandise to unrelated customers.

Comment 10: Petitioners argue that best information available (BIA) should be used to account for invoice No. CA–1528 because CEMEX incorrectly instructed the Department prior to verification to delete this invoice from the U.S. sales data base. Petitioners contend that this sale should have been included in the U.S. sales data base because the record shows that it is an ESP sale and that this sale occurred during the POR.

CEMEX argues that BIA should not be used because CEMEX reported all requested data and merely pointed out to the Department that the sale at issue should not legally be included in the antidumping calculation. CEMEX further explains that liquidation of the entry for this sale had not been suspended by the U.S. Customs Service. CEMEX states that the statute makes it clear that entries whose liquidation had not been suspended are not subject to an administrative review.

Department's Position: The Department has examined the information pertaining to the entry which was prematurely liquidated. Although the entry was liquidated, we have decided that inclusion of the sale in our analysis is appropriate in order to determine the estimated antidumping duty (cash deposit) for CEMEX. Therefore, we have included this transaction in our calculations, using the information CEMEX provided to determine the appropriate classification and adjustments.

Comment 11: Petitioners assert that certain sales reported as purchase price sales should be treated as ESP sales, because there is no evidence that these sales were made prior to the date of

importation. According to the statute, a purchase price sale is identified as a sale that occurs prior to importation. An ESP sale may occur either before or after importation into the United States depending on certain factors. Petitioners claim that because the cement was shipped from Mexico well in advance of the reported dates of sale and CEMEX did not report the date of importation, importation likely occurred prior to the reported dates of sale and the sales, therefore, must be considered ESP sales.

CEMEX argues that the sales were correctly classified as PP sales, and that petitioners' argument is evidentiary in nature. According to CEMEX, petitioners can, at most, establish that the sales were made after exportation, but that, in itself, provides no evidence of whether a sale is ESP. CEMEX asserts that petitioners would have to show that the sales were made after importation. Without that evidence, CEMEX insists that the Department should accept CEMEX's representation, through CEMEX's classification of these sales as PP sales, that these sales were made prior to importation. CEMEX adds that petitioners' argument is based on an assumption rather than factual evidence.

Department's Position: We agree in part with petitioners. In order for the Department to determine the classification of the sales in question, the Department requested that CEMEX provide the entry documents for those sales. CEMEX provided the requested information. Upon evaluation of this and other information in the record, the Department determines that some of the sales recorded as PP sales are ESP sales because the date of importation occurred before the date of sale. Consequently, for those sales misclassified as PP sales, the Department has treated them as ESP sales. Further, because the Department does not have adequate information on which to determine the correct adjustments for these ESP sales, we have used BIA as the basis for the deductions. Treating CEMEX essentially as a cooperative respondent, the Department used a weighted-average of the ESP expenses reported in the original ESP response as BIA for these ESP sales. We purposely did not attempt to alter these expenses when analyzing the re-classified ESP sales.

Comment 12: CEMEX states that the "roller chain" principle should be applied to sales where less than 1% of the value of the product sold in the United States is of the imported merchandise.

Petitioners state that the "roller chain" principle is not applicable to any U.S. sales of cement during the period of review. Further, petitioners argue that the principle should not extend to any U.S. sales for which the Department uses BIA to calculate U.S. price.

Department's Position: We agree with petitioners. Under the so-called "roller chain" principle, the Department eliminates the assessment of duties on a product if the imported product forms less than 1 percent of the value of the further manufactured product sold in the United States. The Department articulated this approach in Antifriction Bearings (Other Than Tapered Roller Bearings) and Parts thereof from France, 57 FR 28360 (June 24, 1992), and Roller Chain, Other than Bicycle, from Japan, 48 FR 51801 (November 14, 1983). In this case, the value of the product imported in both BIA and non-BIA further manufactured sales exceeds 1 percent. Accordingly, the Department will not apply the "roller chain" principle in this case.

Comment 13: CEMEX argues that the Department incorrectly added the adjustment for uncollected taxes to the U.S. net price in calculating the profit on U.S. further manufactured sales. According to CEMEX, the home market value added tax, real or imputed, bears no relationship to CEMEX's profit on sales of concrete in the United States, and the Department's further manufacturing methodology does not make use of the adjustment for uncollected home market taxes. CEMEX cites to the methodology used by the Department in New Minivans from Japan; Final Determination of Sales at Less than Fair Value (57 FR 21937, 21939, May 26, 1992), as an example to calculate profit on further manufactured sales in the United States.

Department's Position: We agree with CEMEX. In New Minivans from Japan, in calculating the profit on U.S. further manufactured sales, the Department deducted all value added to the minivan after importation, pursuant to section 772(e)(3) of the Act. The value added consisted of the portion of the minivan further manufactured in the United States as well as a proportional amount of profit attributable to the value added. Profit was calculated by deducting from the sales price of the minivan all production and selling costs which the company incurred with respect to the minivan. The resulting profit (or loss) amount was then allocated proportionally to all components of cost, and then only the profit (or loss) attributable to the value added was deducted in arriving at the profit (or loss) on the U.S. further manufactured sales. Consistent with this methodology, the Department does not increase the profit on a further manufactured transaction by the amount of uncollected taxes because those taxes do not contribute to the increased value resulting from further processing in the United States. Accordingly, we made the appropriate changes for our final results.

Comment 14: Petitioners contend that inventory carrying costs should not be added to home market prices when determining sales below cost.

Department's Position: We agree with petitioners and have made the appropriate change in our final results.

Comment 15: Petitioners contend that, as a result of CEMEX's refusal to provide profit data on pozzolanic cement, the Department should use BIA in calculating the profit to be used in constructed value.

CEMEX contends that the Department did not require the company to report home market sales of pozzolanic cement, that pozzolanic cement was specifically excluded from the scope of petitioners' antidumping petition, and that including profit from pozzolanic cement is irrelevant since the Department does not have to resort to constructed value in determining its final results.

Department's Position: Because we never resorted to constructive value (CV) for model match purposes, this issue is not relevant to this case.

Comment 16: Petitioners contend that the Department should use a more adverse BIA for the 1991 concrete materials costs at Sunward Materials's Tucson Division. Petitioners maintain that CEMEX misled the Department in failing to notify it that it did not calculate product-specific costs for its 1991 Tucson Division concrete materials costs. Petitioners contend that the appropriate BIA to be used for such costs should be based on the highest calculated materials cost from Sunward's Phoenix Division.

CEMEX contends that the Department's application of BIA for added material cost was unnecessary, erroneous, and excessive. CEMEX also contends that the adverse BIA proposed by petitioners is inappropriate because it is based on the costs of another division. CEMEX also contends that the approach taken by the Department in the preliminary results whereby the Tucson Division's 1990 concrete materials costs were used as BIA for 1991 Tucson Division concrete materials is already sufficiently adverse.

Department's Position: We disagree with both petitioners and respondent. CEMEX's U.S. subsidiary, Sunward Materials, did not calculate product-specific costs for any products

manufactured at Sunward's Tucson Division during 1991. Instead, respondent applied a single adjustment factor to the 1990 Tucson Division product-specific costs to reflect changes in cost from 1990 to 1991.

Respondent also did not calculate product-specific materials costs for certain types of concrete at Sunward's Tucson and Phoenix Divisions. Rather, Sunward calculated product-specific materials costs for the majority of concrete products manufactured at those two divisions and used an average cost for the remaining products at each division, respectively.

As in our preliminary results, we have had to use BIA for all products for which Sunward did not report product-specific materials costs. For the Phoenix Division, BIA was based on the highest individually calculated materials costs from the Phoenix Division. The same approach was applied to those costs not specifically calculated at the Tucson Division (*i.e.*, the Tucson Division's highest calculated cost was used). Petitioners' contention that we should apply the highest calculated cost from the Phoenix Division to the 1991 costs at the Tucson Division could be distortive in that the Phoenix Division's cost experience would not necessarily have any relation to the Tucson Division's cost experience. Accordingly, we have not changed our application of BIA to materials cost for these final results.

Comment 17: Respondent contends that the Department erred in disregarding all sales found to be below cost of production without considering whether CEMEX recovers its costs over a reasonable period of time. Respondent also contends that its home market sales were profitable during the period of review and that the costs of specific below-cost sales were recovered.

Petitioners point out that CEMEX concedes that below-cost sales were made over an extended period of time and in substantial quantities. Moreover, petitioners contend that CEMEX did not recover its costs on Type II sales.

Department's Position: We agree that CEMEX's sales below cost were made over an extended period of time without fully recovering cost. Section 773(b) of the Act provides that the Department will determine whether sales are made at less than the cost of producing the subject merchandise. If such sales are not at prices which permit recovery of all costs within a reasonable period of time, such sales shall be disregarded in the determination of FMV. Review of the legislative history regarding this provision indicates that Congress recognized that certain industries have enormous start-up costs which might cause initial sales to be below the COP. These industries, such as the commercial airliner industry mentioned in the House and Senate reports, may incur large research and development or technology costs which are not immediately recovered by sales (see, *e.g.*, House Report No. 571, 93rd Cong., 1st Sess. 71 (1973)). However, because it is clear that these costs benefit future sales, Congress would not have the Department disregard the below-cost sales if the costs would be recovered, by those future sales, in a reasonable period of time.

The Mexican cement industry is a mature industry, and CEMEX is an established manufacturer. We determined through our analysis that between 10% and 90% of CEMEX's home market sales were made at prices below cost. Given the lack of information on record to support a belief that CEMEX experienced high start-up costs, or other unusually high expenses in the review period, which would have been recovered by, and benefitted, future sales, we eliminated from our analysis those sales found to be below cost over an extended period of time.

Comment 18: CEMEX argues that inventory carrying expenses should not be subtracted in the calculation of net U.S. purchase price.

Petitioners state that this issue is moot because all sales reported by CEMEX as PP sales are actually ESP sales.

Department's Position: We agree with CEMEX. For those sales determined to be PP sales, the Department has corrected the net PP calculation, excluding inventory carrying costs from the final calculation.

Comment 19: CEMEX argues that the Department incorrectly removed handling and packing revenues from home market prices for comparison to the cost of production in the Department's sales-below-cost test.

Petitioners assert that the Department was correct in excluding handling and packing revenues from the sales-below-cost equation because handling and packing revenues were not included in the cost of production calculation. Consequently, handling and packing revenues are properly not part of the home market net price equation.

Department's Position: We agree with CEMEX. The equation for home market net price used in the preliminary results contained a clerical error. Unlike imputed revenue, handling and packing revenues are properly part of the home market net price equation because they represent actual revenues derived from sales. Accordingly, we have made the appropriate changes for our final results.

Comment 20: CEMEX claims that the Department incorrectly subtracted, rather than added the field SPECIALE in both the profit and the net U.S. price calculations. Because the field SPECIALE represents actual income realized from Sunward's further manufactured sales, CEMEX contends that it should be added to, rather than subtracted from, price to reach net price.

Petitioners argue that the Department was correct to subtract the field SPECIALE in calculating net U.S. price and profit on sales by Sunward because CEMEX failed to explain in the record what is included in the field SPECIALE and how it should be treated in calculating Sunward's net U.S. price and profit.

Department's Position: We agree with CEMEX. The Department examined the field SPECIALE during its verification of sales made by Sunward. The field SPECIALE represents extra income realized for special charges for coloring, Sunday deliveries, etc. Therefore, the Department has made the necessary correction in the final results.

Uncollected Taxes: On March 19, 1993, the United States Court of Appeals for the Federal Circuit, in affirming the decision in *Zenith Electronics Corp.* v. *United States* (*Zenith Electronics* v. *United States*), Appeals 92–1043, –1044, –1045, –1046 (Fed. Cir. March 19, 1993), ruled that section 772(d)(1)(C) of the Act provides for an addition to U.S. price to account for taxes which the exporting country would have assessed on the merchandise had it been sold in the home market, and that section 773(a)(4)(B) of the Act does not allow circumstance-of-sale adjustments to FMV for differences in taxes. Accordingly, we have changed our practice and will no longer calculate a hypothetical tax on the U.S. product, but will, for the time being, add to the U.S. price the absolute amount of tax on the comparison merchandise sold in the country of exportation. By adding the amount of home market tax to U.S. price, absolute dumping margins are not inflated or deflated by differences between taxes included in FMV and those added to U.S. price.

In addition, we will propose a change in 19 CFR 353.2(f)(2) to provide that we will calculate weighted-average dumping margins by dividing the aggregated dumping margins, calculated as described above, by the aggregated U.S. prices net of taxes. This change would result in weighted-average dumping margin rates which are neither inflated nor deflated on account of our

methodology of accounting for taxes paid in the home market but rebated or not collected by reason of exportation. We are in the process of drafting this proposed change, and we will begin the rule making process as soon as possible.

Clerical Errors: The Department corrected certain clerical errors which petitioners and respondent noted, as well as clerical errors the Department identified in completing its final results.

Final Results of Review

As a result of our review, we determine the weighted-average dumping margins for the period April 12, 1990, through July 31, 1991, to be:

Company	Margin Percentage
CEMEX, S.A.	30.44
Apasco, S.A. de C.V	[1]53.26

[1] For the period April 12, 1990 – July 31, 1991, Apasco, S.A. de C.V. made no shipments. In the final determination of sales at less than fair value, the Department determined a margin percentage of 53.26% for Apasco, S.A. de C.V.

The Department will instruct the Customs Service to assess antidumping duties on all appropriate entries. Individual differences between USP and FMV may vary from the percentages stated above. The Department will issue appraisement instructions directly to the Customs Service.

Furthermore, the following deposit requirements will be effective upon publication of these final results of administrative review for all shipments of the subject merchandise entered, or withdrawn from warehouse for consumption, as provided by section 751(a)(1) of the Act: (1) The cash deposit rate for the reviewed companies will be the rates as listed above; (2) for previously reviewed or investigated companies not listed above, the cash deposit rate will continue to be the company-specific rate published for the most recent period; (3) if the exporter is not a firm covered in this review, a prior review, or the original less-than-fair-value investigation, but the manufacturer is, the cash deposit rate will be the rate established for the most recent period for the manufacturer of the merchandise; and (4) the cash deposit rate for all other manufacturers or exporters will be the "all other" rate of 30.74 percent. This rate represents the highest rate for any firm with shipments in this review, other than those firms receiving a rate based entirely on best information available.

These deposit requirements shall remain in effect until publication of the final results of the next administrative review.

This notice also serves as a final reminder to importers of their responsibility under 19 CFR 353.26 to file a certificate regarding the reimbursement of antidumping duties prior to liquidation of the relevant entries during this review period. Failure to comply with this requirement could result in the Secretary's presumption that reimbursement of antidumping duties occurred and the subsequent assessment of double antidumping duties.

This notice also serves as the only reminder to parties subject to administrative protective order (APO) of their responsibility concerning the return or destruction of proprietary information disclosed under APO in accordance with 19 CFR 353.34(d). Failure to comply is a violation of the APO.

This administrative review and notice are in accordance with section 751(a)(1) of the Tariff Act (19 U.S.C. 1675(a)(1)) and 19 CFR 353.22.

Dated: April 21, 1993.

Joseph A. Spetrini,

Acting Assistant Secretary for Import Administration.

[FR Doc. 93–9958 Filed 4–27–93; 8:45 am]

BILLING CODE 3510–DS–P

National Oceanic and Atmospheric Administration

Endangered Species; Permits

AGENCY: National Marine Fisheries Service (NMFS), NOAA, Commerce.

ACTION: Notice of receipt of applications for four scientific research and enhancement permits (P503E,F,G,H).

Notice is hereby given that the Idaho Department of Fish and Game (IDFG) has applied in due form for scientific research and enhancement permits to take endangered and threatened species as authorized by the Endangered Species Act (ESA) of 1973 (16 U.S.C. 1531–1543) and the National Marine Fisheries Service (NMFS) regulations governing endangered fish and wildlife permits (50 CFR Parts 217–227). These applications involve the artificial propagation of Pacific salmon species listed under the ESA.

Artificial Propagation of Pacific Salmon Under the ESA

In determining whether to issue Pacific salmon enhancement permits, NMFS will rely heavily on its Interim Policy on Artificial Propagation of Pacific Salmon under the ESA (58 FR 17573). The policy provides guidance on the use of artificial propagation in the conservation of listed Pacific salmon species. The use of artificially propagated Pacific salmon in recovery programs depends on available information regarding the similarity of the naturally and artificially propagated fish in genetic, phenotypic, and life-history traits, and in habitat characteristics. Artificial propagation of listed salmon species for recovery must attempt to avoid risks by preserving the genetic and ecological distinctiveness of the listed species. Artificial propagation of a listed salmon species is not a substitute for eliminating the factors causing or contributing to the species' decline.

Use of Hatchery Population Under ESA Enhancement Permits

Whether a natural population is considered distinct and hence a "species" under the ESA is determined solely by the two criteria that define an evolutionarily significant unit (ESU)—its reproductive isolation and its contribution to the biological species' evolutionary legacy. Genetic resources important to the species' evolutionary legacy may reside in hatchery fish as well as in natural fish, in which case the hatchery fish can be considered part of the biological ESU in question.

If available information indicates that existing hatchery fish can be considered part of the biological ESU, then these hatchery fish could be considered for use in recovery efforts. In this case, integration of natural broodstock of the listed species into the existing hatchery population is possible under an enhancement permit. If the hatchery population is managed for purposes other than ESA recovery efforts, directed take of natural fish from the listed species for broodstock would be prohibited.

If available information indicates that either: (1) The hatchery population in question is of a different genetic lineage than the listed natural populations, (2) artificial propagation has produced appreciable changes in the hatchery population in characteristics that are believed to have a genetic basis, or (3) there is substantial uncertainty about the relationship between existing hatchery fish and the natural population, the existing hatchery fish will not be considered part of the biological ESU. In this case, direct take of fish from the listed species for broodstock would not be permitted.

Summary of Applications

The IDFG requests authorization to conduct four (4) one-year hatchery

programs in the Snake River Basin involving research on and enhancement of Snake River spring/summer chinook salmon: (1) Pahsimeroi River summer chinook salmon at Pahsimeroi Fish Hatchery (FH) (P503E); (2) South Fork of the Salmon River summer chinook salmon at McCall Fish Hatchery (P503F); (3) East Fork Salmon River (EFSR) spring chinook salmon at Sawtooth Fish Hatchery (P503G); and (4) Headwaters of the Salmon River spring chinook salmon at Sawtooth Fish Hatchery (P503H).

NMFS has made a preliminary determination that the Pahsimeroi River hatchery population cannot be considered part of the biological ESU and therefore cannot be considered for use in enhancement programs (Schiewe, 1993). NMFS has also made a preliminary determination that the South Fork Salmon River stock of spring/summer chinook salmon held at McCall FH, the headwaters of the Salmon River stock of spring/summer salmon held at Sawtooth FH, and the EFSR stocks of spring/summer chinook salmon held at Sawtooth FH, can be considered part of the biological ESU and therefore can be considered for use in enhancement programs (Schiewe, 1993). However, NMFS notes that there is considerable controversy regarding the return rate of Sawtooth FH fish. NMFS believes it is likely that this program has adversely affected the natural population by taking broodstock to support an unsuccessful hatchery operation. However, monitoring and evaluation efforts have not been adequate to fully resolve this issue. It is essential that this be remedied if further artificial propagation under the ESA is contemplated for Sawtooth FH (Schiewe, 1993).

IDFG estimates adult broodstock takes for enhancement (mitigation production) of listed Snake River spring/summer chinook salmon as follows: 570 for Pahsimeroi FH, 760 for McCall FH, 5 for Sawtooth FH (EFSR), and 21 for Sawtooth FH (headwaters of Salmon River). In addition, as part of the research (supplementation studies), IDFG proposes to release a certain percentage of the returns to the weirs upstream to spawn naturally, 33 percent in the Pahsimeroi FH, McCall FH, and Sawtooth FH (headwaters of Salmon River) programs and 50 percent in the Sawtooth FH (EFSR) program. Proposals to release progeny of the broodstock will be submitted separately.

Written data or views, or requests for a public hearing on these applications, should be submitted to the Director, Office of Protected Resources, National Marine Fisheries Service, 1335 East-West Hwy., room 8268, Silver Spring, MD 20910, within 30 days of the publication of this notice. Those individuals requesting a hearing should set forth the specific reasons why a hearing on any of these particular applications would be appropriate. The holding of such hearings is at the discretion of the Assistant Administrator for Fisheries.

Documents submitted in connection with the above applications, the NMFS Interim Policy on Artificial Propagation under the ESA (58 FR 17573), and NMFS' preliminary determinations on the relationship of the hatchery populations to the natural population in the ESU of the listed species (Schiewe, 1993) are available for review by interested persons in the following offices by appointment:

Office of Protected Resources, National Marine Fisheries Service, 1335 East-West Hwy., suite 8268, Silver Spring, MD 20910 (301/713–2322); and

Environmental and Technical Services Division, National Marine Fisheries Service, 911 North East 11th Ave., room 620, Portland, OR 97232 (503/230–5400).

Dated: April 22, 1993.

Herbert W. Kaufman,

Acting Director, Office of Protected Resources, National Marine Fisheries Service, National Oceanic and Atmospheric Administration.

[FR Doc. 93–9902 Filed 4–27–93; 8:45 am]

BILLING CODE 3510–22–M

Endangered Species; Modification to Scientific Research Permit No. 777; Coastal Ecology Group, Environmental Laboratory, Waterways Experiment Station, U.S. Army Corps of Engineers

Notice is hereby given that pursuant to the provisions of the Endangered Species Act of 1973 (16 U.S.C. 1531–1543) (ESA) and the regulations governing endangered fish and wildlife (50 CFR parts 217–222), and the Conditions hereinafter set out, Scientific Research Permit No. 777, issued to the U.S. Army Corps of Engineers' Coastal Ecology Group, on April 27, 1992 (57 FR 15286), has been modified to add an increased number of takes of those species previously authorized, in order to conduct telemetric studies.

This modification grants authority for an increased directed take of up to 15 loggerhead sea turtles and 5 Kemp's ridleys to be fitted with backpack-mounted satellite tags for the purpose of monitoring the turtles' seasonal movements into and out of U.S. East coast channels coast via the ARGOS satellite. Two-hundred-fifty loggerhead and twenty-five Kemp's ridley sea turtles may be taken by trawler, equipped with radio and depth sensitive sonic tags, and monitored to assess the baseline behavior and the relocation behavior of sea turtles in dredged channels of the Southeastern United States. Trawling tests for determining sea turtle abundance in channels will be evaluated concurrently.

This modification became effective upon signature.

Documents pertaining to this Modification and the original Permit are available for review in the following offices:

Office of Protected Resources, National Marine Fisheries Service, 1335 East West Hwy., room 7324, Silver Spring, Maryland 20910; and

Director, Southeast Region, National Marine Fisheries Service, 9450 Koger Blvd., St. Petersburg, FL 33702.

Dated: April 22, 1993.

William W. Fox, Jr.,

Dirctor, Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. 93–9903 Filed 4–27–93; 8:45 am]

BILLING CODE 3510–22–M

Endangered Species; Permits

AGENCY: National Marine Fisheries Service, (NMFS) NOAA, Commerce.

ACTION: Issuance of Permit; Oregon Department of Fish and Wildlife (P211C).

On September 14, 1992, notice was published (57 FR 41921) that an application had been filed by Oregon Department of Fish and Wildlife, to take listed spring/summer chinook salmon (*Oncorhynchus tshawytscha*) for the purposes of scientific research as authorized by the Endangered Species Act of 1973 (ESA) (16 U.S.C. 1531–1543) and the NMFS regulations governing listed fish and wildlife (50 CFR parts 217–222).

Notice is hereby given that on April 22, 1993, as authorized by the provisions of the ESA (16 U.S.C. 1531–1543), NMFS issued Permit Number 818 for the above taking subject to certain conditions set forth therein.

Issuance of this Permit, as required by the ESA, was based on a finding that such Permit: (1) Was applied for in good faith; (2) will not operate to the disadvantage of the listed species which is the subject of this Permit; (3) is consistent with the purposes and policies set forth in Section 2 of the ESA. This Permit was also issued in accordance with and is subject to Parts 217–222 of Title 50 CFR, the NMFS regulations governing listed species permits.

The application, Permit, and supporting documentation are available for review by interested persons in the following offices by appointment:

Office of Protected Resources, National Marine Fisheries Service, 1335 East-West Highway, Suite 8268, Silver Spring, MD 20910 (301/713–2322); and

Environmental and Technical Services Division, National Marine Fisheries Service, 911 North East 11th Ave., Room 620, Portland, OR 97232 (503/230–5400).

Dated: April 22, 1993.

William W. Fox, Jr.,

Director, Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. 93–9904 Filed 4–27–93; 8:45 am]

BILLING CODE 3510–22–M

Marine Mammals

AGENCY: National Marine Fisheries Service (NMFS), NOAA, Commerce.

ACTION: Receipt of Application for a Scientific Research Permit (P394C).

Notice is hereby given that Glacier Bay National Park and Preserve, P.O. Box 140, Gustavus, AK 99826–0140, Alaska 99603, requests authorization to approach, up to 15 times each, up to 200 humpback whales (*Megaptera novaeangliae*) annually over a five-year period during the course of photo-identification studies in Alaskan waters. Authorization is also being requested to conduct opportunistic photographic identification of approximately 20 minke whales (*Balaenoptera acutorostrata*) and 200 killer whales (*Orcinus orca*) during the proposed humpback whale studies.

Concurrent with the publication of this notice in the **Federal Register**, the Secretary of Commerce is forwarding copies of this application to the Marine Mammal Commission and its Committee of Scientific Advisors.

Written data or views, or requests for a public hearing on this application should be submitted to the Assistant Administrator for Fisheries, National Marine Fisheries Service, U.S. Department of Commerce, NOAA, 1335 East-West Hwy., room 7324, Silver Spring, MD 20910, within 30 days of the publication of this notice. Those individuals requesting a hearing should set forth the specific reasons why a hearing on this particular application would be appropriate. The holding of such hearing is at the discretion of the Assistant Administrator for Fisheries. All statements and opinions contained in this application are summaries of those of the applicant and do not necessarily reflect the views of the National Marine Fisheries Service.

Documents submitted in connection with the above application are available for review by interested persons in the following offices (by appointment):

Office of Protected Resources, National Marine Fisheries Service, NOAA, 1335 East-West Hwy., suite 7324, Silver Spring, MD 20910 (301/713–2289); and

Director, Alaska Region, National Marine Fisheries Service, NOAA, Federal Annex, 9109 Mendenhall Mall Rd., suite 6, Juneau, AK 99802 (907/586–7221).

Dated: April 22, 1993.

William W. Fox, Jr.,

Director, Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. 93–9899 Filed 4–27–93; 8:45 am]

BILLING CODE 3510–22–M

Marine Mammals

AGENCY: National Marine Fisheries Service (NMFS), NOAA, Commerce.

ACTION: Receipt of application for a scientific research permit (P538).

Notice is hereby given that Mr. Jan Ostman-Lind and Ms. Ania Driscoll-Lind, P.O. Box 4044, Kailua-Kona, Hawaii 96745, request authorization to approach up to 2300 spinner dolphins (*Stenella longirostris*) up to 25 times each annually, up to 7000 spotted dolphins (*Stenella attenuata*) up to 50 times each annually, and up to 2000 bottlenose dolphins (*Tursiops truncatus*) up to 50 times each annually, over a five-year period during the course of photo-identification studies. Activities will be carried out in Hawaiian waters.

Concurrent with the publication of this notice in the **Federal Register**, the Secretary of Commerce is forwarding copies of this application to the Marine Mammal Commission and its Committee of Scientific Advisors.

Written data or views, or requests for a public hearing on this application should be submitted to the Assistant Administrator for Fisheries, National Marine Fisheries Service, NOAA, U.S. Department of Commerce, 1335 East-West Hwy., room 7324, Silver Spring, MD 20910, within 30 days of the publication of this notice. Those individuals requesting a hearing should set forth the specific reasons why a hearing on this particular application would be appropriate. The holding of such hearing is at the discretion of the Assistant Administrator for Fisheries. All statements and opinions contained in this application are summaries of those of the applicant and do not necessarily reflect the views of the National Marine Fisheries Service.

Documents submitted in connection with the above application are available for review by interested persons in the following offices (by appointment):

Office of Protected Resources, National Marine Fisheries Service, NOAA, 1335 East-West Hwy., suite 7324, Silver Spring, MD 20910 (301/713–2289); and

Director, Southwest Region, National Marine Fisheries Service, NOAA, 501 W. Ocean Boulevard, Suite 4200, Long Beach, CA 90802–4213 (310/980–4016).

Dated: April 22, 1993.

Herbert W. Kaufman,

Acting Director, Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. 93–9898 Filed 4–27–93; 8:45 am]

BILLING CODE 3510–22–M

COMMODITY FUTURES TRADING COMMISSION

Financial Products Advisory Committee; Fourth Renewal

The Commodity Futures Trading Commission has determined to renew for a period of two years its advisory committee designated as the "Commodity Futures Trading Commission Financial Products Advisory Committee." As required by section 14(a)(2)(A) of the Federal Advisory Committee Act, 5 U.S.C. app. 2, section 14(a)(2)(A), and 41 CFR 101–6.1007 and 101–6.1029, the Commission has consulted with the Committee Management Secretariat of the General Services Administration, and the Commission certifies that the renewal of the advisory committee is in the public interest in connection with duties imposed on the Commission by the Commodity Exchange Act, 7 U.S.C. 1, *et seq.*, as amended.

The objectives and scope of activities of the Financial Products Advisory Committee are to conduct public meetings and submit reports and recommendations on issues concerning individuals and industries interested in or affected by financial markets regulated by the Commission.

Commissioner Sheila C. Bair serves as Chairman and Designated Federal Official of the Financial Products Advisory Committee. The Committee's membership represents a cross-section of interested and affected persons and groups including representatives of newer institutional market participants, such as broker-dealers, pension sponsors and investment companies; traditional market participants, such as

futures commission merchants, commodity pool operators and commodity trading advisors; and representatives of the academic, legal and accounting communities and other appropriate public participants.

Interested persons may obtain information or make comments by writing to the Commodity Futures Trading Commission, 2033 K Street, NW., Washington, DC 20581.

Issued in Washington, DC, on April 23, 1993, by the Commission.

Jean A. Webb,

Secretary of the Commission.

[FR Doc. 93–9924 Filed 4–27–93; 8:45 am]

BILLING CODE 6351–01–M

Agricultural Advisory Committee Meeting

This is to give notice, pursuant to section 10(a) of the Federal Advisory Committee Act, 5 U.S.C. app. 2, Section 10(a) and 41 CFR 101–6.1015(b), that the Commodity Futures Trading Commission's Agricultural Advisory Committee will conduct a public meeting in the Hearing Room on the basement level of the Commission's Washington, DC headquarters, 2033 K Street, NW., Washington, DC on May 17, 1993, beginning at 8:30 a.m. and lasting until 1:30 p.m. The agenda will consist of:

Agenda

I. Introductory remarks, Commissioner Joseph B. Dial;
II. Discussion of delivery issues, points, and specifications;
III. Discussion of contracts under consideration and/or being discussed by various industry groups (weaned calf, boxed beef, dairy);
IV. Discussion of speculative position limits;
V. Discussion of CFTC reauthorization issues;
VI. Enforcement presentation—investigation of futures trading;
VII. Discussion of single regulator theory;
VIII. Discussion of *Arkansas Best*;
IX. Discussion of a Risk Management Symposium for 1995;
X. Other Committee Business; and
XI. Closing Remarks by Commissioner Joseph B. Dial.

The purpose of this meeting is to solicit the views of the Committee on the above-listed agenda matters. The Advisory Committee was created by the Commodity Futures Trading Commission for the purpose of receiving advice and recommendations on agricultural issues. The purposes and objectives of the Advisory Committee are more fully set forth in the May 6, 1991 fourth renewal charter of the Advisory Committee.

The meeting is open to the public. The Chairman of the Advisory Committee, Commissioner Joseph B. Dial, is empowered to conduct the meeting in a fashion that will, in his judgment, facilitate the orderly conduct of business. Any member of the public who wishes to file a written statement with the Advisory Committee should mail a copy of the statement to the attention of: the Commodity Futures Training Commission Agricultural Advisory Committee c/o Kimberly N. Griles, Commodity Futures Trading Commission, 2033 K Street, NW., Washington, DC 20581, before the meeting. Members of the public who wish to make oral statements should also inform Ms. Griles in writing at the foregoing address at least three business days before the meeting. Reasonable provision will be made, if time permits, for an oral presentation of no more than five minutes each in duration.

Issued by the Commission in Washington, DC on April 22, 1993.

Jean A. Webb,

Secretary of the Commission.

[FR Doc. 93–9855 Filed 4–27–93; 8:45 am]

BILLING CODE 6351–01–M

DEPARTMENT OF DEFENSE

Department of the Army

Privacy Act of 1974; Amend Systems of Records

AGENCY: Department of the Army, DOD.

ACTION: Amend systems of records.

SUMMARY: The Department of the Army is amending five systems of records notices in its existing inventory of records system subject to the Privacy Act of 1974 (5 U.S.C. 552a), as amended.

DATES: This proposed action will be effective without further notice on May 28, 1993, unless comments are received which result in a contrary determination.

ADDRESS: U.S. Army Information Systems Command, ATTN: ASOP-MP, Fort Huachuca, AZ 85613–5000.

FOR FURTHER INFORMATION CONTACT: Ms. Pat Turner at (602) 538-6856 or DSN 879-6856.

SUPPLEMENTARY INFORMATION: The Department of the Army systems of records notices subject to the Privacy Act of 1974, (5 U.S.C. 552a), as amended, have been published in the **Federal Register** and are available from the address above.

The specific changes to the records systems being amended are set forth below followed by the notices, as amended, published in their entirety. The proposed amendments are not within the purview of the provision of subsection (r) of the Privacy Act of 1974 (5 U.S.C. 552a), as amended, which requires the submission of new or altered system reports.

Dated: April 20, 1993.

L. M. Bynum,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

AMENDMENTS

A0040–66aDASG

SYSTEM NAME:

Medical Staff Credentials File *(February 22, 1993, 58 FR 10063).*

CHANGES:

* * * * *

CATEGORIES OF RECORDS IN THE SYSTEM:

Add 'and medical malpractice case files' after 'clinical performance.'

* * * * *

RETENTION AND DISPOSAL:

Add 'Medical malpractice case files are destroyed after 10 years' to entry.

* * * * *

A0040–66aDASG

SYSTEM NAME:

Medical Staff Credentials File.

SYSTEM LOCATION:

Medical treatment facilities at Army commands, installations and activities. Official mailing addresses are published as an appendix to the Army's compilation of record systems notices.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Individuals performing clinical practice in medical treatment facilities.

CATEGORIES OF RECORDS IN THE SYSTEM:

Documents reflecting delineation of clinical privileges and clinical performance and medical malpractice case files.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

5 U.S.C. 301; 10 U.S.C. 1071; and E.O. 9397.

PURPOSE(S):

To determine and assess capability of practitioner's clinical practice.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

In specific instances, clinical privileged information from this system

of records may be provided to civilian and military medical facilities, Federation of State Medical Boards of the United States, State Licensure Authorities and other appropriate professional regulating bodies for use in assuring high quality health care.

The 'Blanket Routine Uses' set forth at the beginning of the Army's compilation of systems of records notices apply to this system.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Paper records in file folders.

RETRIEVABILITY:

By individual's surname.

SAFEGUARDS:

Records are maintained in areas accessible only to the medical treatment facility commander and credentials committee members.

RETENTION AND DISPOSAL:

Records are retained in medical treatment facility of individual's last assignment. Records of military members are transferred to individual's Military Personnel Records Jacket upon separation or retirement. Records on civilian personnel are destroyed 5 years after employment terminates.

Medical malpractice case files are destroyed after 10 years.

SYSTEM MANAGER(S) AND ADDRESS:

Office of the Surgeon General, Headquarters, Department of the Army, 5109 Leesburg Pike, Falls Church, VA 22041–3258.

NOTIFICATION PROCEDURE:

Individuals seeking to determine whether information about themselves is contained in this system should address written inquiries to the commander of the medical treatment where practitioner provided clinical service. Official mailing addresses are published as an appendix to the Army's compilation of record systems notices.

For verification purposes, the individual should provide the full name, Social Security Number, and signature.

RECORD ACCESS PROCEDURES:

Individuals seeking access to records about themselves contained in this record system should address written inquiries to the commander of the medical treatment where practitioner provided clinical service. Official mailing addresses are published as an appendix to the Army's compilation of record systems notices.

For verification purposes, the individual should provide the full name, Social Security Number, and signature.

CONTESTING RECORD PROCEDURES:

The Army's rules for accessing records, contesting contents, and appealing initial determinations are contained in Army Regulation 340–21; 32 CFR part 505; or may be obtained from the system manager.

RECORD SOURCE CATEGORIES:

Interviewer, individual's application, medical audit results, other administrative or investigative records obtained from civilian or military sources.

EXEMPTIONS CLAIMED FOR THE SYSTEM:

None.

A0040–905DASG

SYSTEM NAME:

Privately Owned Animal Record Files *(February 22, 1993, 58 FR 10066).*

CHANGES:

* * * * *

SYSTEM LOCATION:

Delete entry and replace with 'Veterinary service at medical facilities on Army installations and activities. Official mailing addresses are published as an appendix to the Army's compilation of systems of records notices.'

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Delete entry and replace with 'Persons who own animals authorized medical care, i.e., persons enrolled in the Defense Enrollment/Eligibility Reporting System (DEERS).'

CATEGORIES OF RECORDS IN THE SYSTEM:

Delete entry and replace with 'Name, Social Security Number, home address and telephone number of animal's owner; record of treatment of animal; and related information.'

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

Delete entry and replace with '10 U.S.C. 3010, 5013, and 8013; and E.O. 9397'.

PURPOSE(S):

Change 'Veterinary Animal Disease Prevention and Control Facility in connection with the Veterinary Preventive Medicine and Zoonotic Disease Control Program.' to read 'Veterinary Treatment Facility.

Add a new paragraph 'Used by veterinarians and health care authorities to identify the animal, verify ownership, record history, and to insure veterinary care, treatment and immunizations provided to animals of authorized owners is recorded; to compile statistical data; conduct research; teach; assist in law enforcement, to include investigation and litigation; and evaluate the care provided.'

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

Delete entry and replace with 'The information may be disclosed to aid in preventive health and communicable disease control programs, report medical conditions required by law to Federal, state, and local agencies.'

* * * * *

STORAGE:

Add 'and other computerized or machine readable media' after 'folders'.

RETRIEVABILITY:

Add 'and Social Security Number' after 'name'.

* * * * *

RETENTION AND DISPOSAL:

Delete entry and replace with 'Destroy upon death of the animal, transfer of owner, or 2 years after last entry in the record.'

SYSTEM MANAGER(S) AND ADDRESS:

Delete entry and replace with 'Office of the Surgeon General, Headquarters, Department of the Army, ATTN: DASG-VCS, 5109 Leesburg Pike, Falls Church, VA 22041–3258.'

* * * * *

A0040–905DASG

SYSTEM NAME:

Privately Owned Animal Record Files.

SYSTEM LOCATION:

Veterinary service at medical facilities on Army installations and activities. Official mailing addresses are published as an appendix to the Army's compilation of systems of records notices.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Persons whose privately owned animals receive veterinary care.

CATEGORIES OF RECORDS IN THE SYSTEM:

Name, Social Security Number, home address and telephone number of animal's owner; record of treatment of animal; and related information.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

10 U.S.C. 3010, 5031 and 8012; and E.O. 9397.

PURPOSE(S):

To record registration, vaccination, and/or treatment of animals; to compile statistical data; and to identify animals registered with the Veterinary Treatment Facility.

Used by veterinarians and health care authorities to identify the animal, verify ownership, record history, and to insure veterinary care, treatment and immunizations provided to animals of authorized owners is recorded; to compile statistical data; conduct research; teach; assist in law enforcement, to include investigation and litigation; and evaluate the care provided.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

The information may be used to aid in preventive health and communicable disease control programs, report medical conditions required by law to Federal, state, and local agencies.

The 'Blanket Routine Uses' set forth at the beginning of the Army's compilation of systems of records notices apply to this system.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Paper records in file folders and other computerized or machine readable media.

RETRIEVABILITY:

By name and Social Security Number of the animal's owner.

SAFEGUARDS:

Records are maintained in buildings which are locked when unattended and are accessed only by authorized personnel having an official need-to-know.

RETENTION AND DISPOSAL:

Destroy upon death of the animal, transfer of owner, or 2 years after last entry in the record.

SYSTEM MANAGER(S) AND ADDRESS:

Office of the Surgeon General, Headquarters, Department of the Army, ATTN: DASG-VCS, 5109 Leesburg Pike, Falls Church, VA 22041–3258.

NOTIFICATION PROCEDURE:

Individuals seeking to determine if information about themselves is contained in this record system should address written inquiries to the veterinary facility at the installation where the animal was treated or euthanized. Official mailing addresses are published in the Army's compilation of record systems notices.

Animal owner should provide the full name, Social Security Number, home address and telephone number and the animal's rabies vaccination number.

RECORD ACCESS PROCEDURES:

Individuals seeking access to records about themselves contained in this record system should address written inquiries to the veterinary facility at the installation where the animal was treated or euthanized. Official mailing addresses are published in the Army's compilation of record systems notices.

Animal owner should provide the full name, Social Security Number, home address and telephone number and the animal's rabies vaccination number. Personal visits may be made to the veterinary facility where animal was treated. Owner must provide personal identification such as a valid military identification card or driver's license.

CONTESTING RECORD PROCEDURES:

The Army's rules for accessing records, contesting contents, and appealing initial determinations are contained in Army Regulation 340–21; 32 CFR part 505; or may be obtained from the system manager.

RECORD SOURCE CATEGORIES:

From the animal owner, veterinarian reports, and similar or related documents.

EXEMPTIONS CLAIMED FOR THE SYSTEM:

None.

A0095–1TRADOC

SYSTEM NAME:

Individual Flight Records Folder *(February 22, 1993, 58 FR 10073).*

CHANGES:

* * * * *

SYSTEM IDENTIFIER:

Change system identifier to 'A0095–1aTRADOC'.

SYSTEM LOCATION:

Delete entry and replace with 'Records are located at flight operations sections and contractor facilities at fixed Army airfields and other aviation units for all personnel on whom flight records are maintained. Including activities who approve contractor aircraft flight and ground operations procedures or use contractor personnel who operate aircraft for the government.

In addition to above locations, copies of individual flight records are maintained for active Army and Army Reserve officers at U.S. Total Army Personnel Command, ATTN: TAPC-OPE-V, 200 Stovall Street, Alexandria, VA 22332–0400;

Active Army warrant officers at U.S. Total Army Personnel Command, ATTN: TAPC-OPW-AV, 200 Stovall Street, Alexandria, VA 22332–0400;

Active Army Medical Service Corps (MSC) officers at Headquarters, Department of the Army (HQDA), ATTN: DASG-HCO-A, Skyline Place, Building 6, Falls Church, VA 22041–3258.

Army reservists not on extended active duty at U.S. Army Reserve Personnel Center, St. Louis, MO 63132–5200; National Guard Personnel at the National Guard Bureau, Aberdeen Proving Grounds, MD 21005–5000; Contractor personnel by the designated Government Flight Representative (GFR) at the contractor facility.'

* * * * *

CATEGORIES OF RECORDS IN THE SYSTEM:

Delete entry and replace with 'DA Forms 759 and 759–1 (Individual Flight and Flight Certificate Army, Section I, II, and III); DA Form 4186 (Medical Recommendation for Flying Duty); DA Form 4507 (Standard Evaluation/ Training Gradeslip); DD Form 1821 (Contractor - Crewmember Record); Name, Social Security Number, home address, date of birth, security clearance data, education, waivers, qualifications, disqualifications, re-qualifications, training, proficiency, and experience data, medical and physiological data, approvals to operate Government aircraft, requests for approval of contractor flight crewmember and contractor qualification training, and similar relevant documents.'

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

Add 'Army Regulation 95–20, Contractor Flight Operations'.

PURPOSE(S):

Add at end of sentence 'and to monitor and manage individual contractor flight and ground personnel records.'

STORAGE:

Delete entry and replace with 'Paper records in file folders, notebooks, and selected data automated on computer tapes and discs for management purposes.'

RETRIEVABILITY:

Delete entry and replace with 'Manual records are retrieved by individual surname.

Automated records are retrieved by name, plus any numeric identifier such as date of birth, Social Security Number, or Army serial number.'

SAFEGUARDS:

Add at end of sentence 'Automated systems employ computer hardware/software safeguard features and controls which meet the administrative, physical, and technical safeguards of Army Regulation 380–19, Information Systems Security.'

RETENTION AND DISPOSAL:

Delete entry and replace with 'Active paper records are retained by the Flight Operations Facility until individual is transferred or separated. The records are transferred with the military personnel records jacket or civilian personnel folders, as appropriate.

Upon separation or retirement of individual, the records are retired to the National Personnel Records Center (Civilian Personnel Records), 111 Winnebago Street, St Louis, MO 63118 and U.S. Army Personnel Center (Military Personnel Records), and U.S. Army Reserve Components Personnel and Administration Center (Reserve Personnel), 9700 Page Boulevard, St Louis, MO 63132–5200; retained for 75 years after date of birth or 60 years after date of earliest document in the folder if date of birth cannot be ascertained.

If determined by the contracting officer, contractor flight personnel records with definite legal and administrative value to or required by the Army will be preserved with Army records to which they pertain and destroyed when no longer needed. Automated management information at system locations is retained until no longer needed for current operations.'

* * * * *

NOTIFICATION PROCEDURE:

Delete entry and replace with 'Individuals seeking to determine if information about themselves is contained in this record system should send written inquiries to the Flight Operations Section of their current unit or contractor facility; if not on active duty, send written inquiries to addresses listed in 'system location' or to Commander, U.S. Army Aviation Center, ATTN: ATZQ-ESO, Fort Rucker, AL 36362–5000.

Individual should provide the full name, Social Security Number, details which will help locate the records, current address, and signature.'

RECORD ACCESS PROCEDURES:

Delete entry and replace with 'Individuals seeking access to records about themselves contained in this record system may visit or send written inquiry to the Flight Operations Section of their current unit or contractor facility; if not on active duty, send written inquiries to addresses listed in 'system location' or to Commander, U.S. Army Aviation Center, ATTN: ATZQ-ESO, Fort Rucker, AL 36362–5000.

Individual should provide the full name, Social Security Number, details which will help locate the records, current address, and signature.'

* * * * *

A0095–1aTRADOC

SYSTEM NAME:

Individual Flight Records Folder.

SYSTEM LOCATION:

Records are located at flight operations sections and contractor facilities at fixed Army airfields and other aviation units for all personnel on whom flight records are maintained. Including activities who approve contractor aircraft flight and ground operations procedures or use contractor personnel who operate aircraft for the government.

In addition to above locations, copies of individual flight records are maintained for active Army and Army Reserve officers at U.S. Total Army Personnel Command, ATTN: TAPC-OPE-V, 200 Stovall Street, Alexandria, VA 22332–0400;

Active Army warrant officers at U.S. Total Army Personnel Command, ATTN: TAPC-OPW-AV, 200 Stovall Street, Alexandria, VA 22332–0400;

Active Army Medical Service Corps (MSC) officers at Headquarters, Department of the Army (HQDA), ATTN: DASG-HCO-A, Skyline Place, Building 6, Falls Church, VA 22041–3258.

Army reservists not on extended active duty at U.S. Army Reserve Personnel Center, St. Louis, MO 63132–5200;

National Guard Personnel at the National Guard Bureau, Aberdeen Proving Grounds, MD 21005–5000;

Contractor personnel by the designated Government Flight Representative (GFR) at the contractor facility.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Army aviators who are members of the Active and Reserve Components and qualified and current in the aircraft to be flown; civilian employees of Government agencies and Government contractors who have appropriate certifications or ratings, flight surgeons or aeromedical physicians' assistants in aviation service, enlisted crew chief/crew members, aerial observers, personnel in non-operational aviation positions, and those restricted or prohibited by statute from taking part in aerial flights.

CATEGORIES OF RECORDS IN THE SYSTEM:

DA Forms 759 and 759–1 (Individual Flight and Flight Certificate Army (Sections I, II, and III); DA Form 4186 (Medical Recommendations for Flying Duty), DA Form 4507 (Standard Evaluation/Training Gradeslip), DD Form 1021 (Contractor - Crewmember Record); Name, Social Security Number, home address, date of birth, security clearance data, education, waivers, qualifications, disqualifications, re-qualifications, training, proficiency, and experience data, medical and physiological data, approvals to operate Government aircraft, requests for approval or contractor flight crewmember and contractor qualification training, and similar relevant documents.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

5 U.S.C. 301; 10 U.S.C. 3013; E.O. 9397; and Army Regulation 95–20, Contractor Flight Operations.

PURPOSE(S):

To record the flying experience and qualifications data of each aviator, crew member, and flight surgeon in aviation service; and to monitor and manage individual contractor flight and ground personnel records.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

Information may be disclosed to the Federal Aviation Agency and/or the National Transportation Safety Board.

The 'Blanket Routine Uses' set forth at the beginning of the Army's compilation of system of record notices apply to this record system.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Paper records in file folders, notebooks, and selected data automated on computer tapes and discs for management purposes.

RETRIEVABILITY:

Manual records are retrieved by individual surname.

Automated records are retrieved by name, plus any numeric identifier such as date of birth, Social Security Number, or Army serial number.

SAFEGUARDS:

Records are maintained in secure areas available only to designated persons having official need for the record.

Automated systems employ computer hardware/software safeguard features and controls which meet the administrative, physical, and technical safeguards of Army Regulation 380–19, Information Systems Security.

RETENTION AND DISPOSAL:

Active paper records are retained by the Flight Operations Facility until individual is transferred or separated. The records are transferred with the military personnel records jacket or civilian personnel folders, as appropriate.

Upon separation or retirement of individual, the records are retired to the National Personnel Records Center (Civilian Personnel Records), 111 Winnebago Street, St Louis, MO 63118 and U.S. Army Personnel Center (Military Personnel Records), and U.S. Army Reserve Components Personnel and Administration Center (Reserve Personnel), 9700 Page Boulevard, St Louis, MO 63132–5200; retained for 75 years after date of birth or 60 years after date of earliest document in the folder if date of birth cannot be ascertained.

If determined by the contracting officer, contractor flight personnel records with definite legal and administrative value to or required by the Army will be preserved with Army records to which they pertain and destroyed when no longer needed. Automated management information at system locations is retained until no longer needed for current operations.

SYSTEM MANAGER(S) AND ADDRESS:

Commander, U.S. Army Training and Doctrine Command, ATTN: ATIM-SR, Fort Monroe, VA 23651–5000.

NOTIFICATION PROCEDURE:

Individuals seeking to determine if information about themselves is contained in this record system should address written inquiries to the Flight Operations Section of their current unit or contractor facility; if not on active duty, send written inquiries to addresses listed in 'system location' or to Commander, U.S. Army Aviation Center, ATTN: ATZQ-ESO, Fort Rucker, AL 36362–5000.

Individual should provide the full name, Social Security Number, details which will help locate the records, current address, and signature.

RECORD ACCESS PROCEDURES:

Individuals seeking access to records about themselves contained in this record system may visit or address written inquiries to the Flight Operations Section of their current unit or contractor facility; if not on active duty, furnishing full name and Social Security Number; if not on active duty, send written inquiries to addresses listed in 'system location' or to Commander, U.S. Army Aviation Center, ATTN: ATZQ-ESO, Fort Rucker, AL 36362–5000.

Individual should provide the full name, Social Security Number, details which will help locate the records, current address, and signature.

CONTESTING RECORD PROCEDURES:

The Army's rules for accessing records, contesting contents, and appealing initial determinations are contained in Army Regulation 340–21; 32 CFR part 505; or may be obtained from the system manager.

RECORD SOURCE CATEGORIES:

From the individual, Federal Aviation Administration, flight surgeons, evaluation reports, proficiency and readiness tests, and other relevant records and reports.

EXEMPTIONS CLAIMED FOR THE SYSTEM:

None.

A0095–2dTRADOC-ATC

SYSTEM NAME:

Air Traffic Controller Records *(February 22, 1993, 58 FR 10074).*

CHANGES:

SYSTEM NAME:

Delete entry and replace with 'Air Traffic Controller/Maintenance Technician Records'.

* * * * *

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Delete entry and replace with 'Air Traffic Controllers and Air Traffic Control Maintenance Technicians employed by the Department of the Army.'

CATEGORIES OF RECORDS IN THE SYSTEM:

Delete entry and replace with 'Name, Social Security Number, Air Traffic Controller and Maintenance Technician qualifications and certifications, training, proficiency data and ratings, date assigned to current facility, and similar relevant documents.'

* * * * *

PURPOSE(S):

Delete entry and replace with 'To determine proficiency of Air Traffic Controllers and Air Traffic Control Maintenance Technicians and the reliability of the Air Traffic Control system operations within the Department of the Army.'

* * * * *

STORAGE:

Delete entry and replace with 'Paper records in file folders and on cards. Selected data is automated on tapes and discs for management purposes.'

* * * * *

SAFEGUARDS:

Delete entry and replace with 'Records are maintained in secure areas available only to designated persons having official need for the record. Automated systems employ computer hardware/software safeguard features and control which meet the administrative, physical, and technical safeguards of Army Regulation 380–19, Information Systems Security.'

RETENTION AND DISPOSAL:

Delete entry and replace with 'Active paper records are retained by the Air Traffic Control facility until individual is transferred. The records are transferred with the military personnel records jacket (MPRJ) or civilian personnel folders, as appropriate.

Upon separation or retirement of individual, the records are retired to the National Personnel Records Center (Civilian Personnel Records), 111 Winnebago Street, St Louis, MO 63118 and U.S. Army Personnel Center, and U.S. Army Reserve Components Personnel and Administration Center, 9700 Page Boulevard, St. Louis, MO 63132–5200; retain for 75 years after date of birth or 60 years after date of earliest document in the folder if date of birth cannot be ascertained. Automated management information at the primary location is retained until no longer needed for current operations.'

* * * * *

RECORD SOURCE CATEGORIES:

Delete entry and replace with 'From the individual, individual's supervisor, Army and Federal Aviation Administration physicians, Air Traffic Control Facility Personnel Status Report (DA Form 3479–6–R), and Air Traffic Control Maintenance Personnel Certification Record.'

* * * * *

A0095–2dTRADOC-ATC

SYSTEM NAME:

Air Traffic Controller/Maintenance Technician Records.

SYSTEM LOCATION:

Primary system is at U.S. Army Aviation Center, Fort Rucker, AL 36362–5000.

Segments are located at Army Air Traffic Control facilities at fixed Army airfields and other aviation units

requiring Air Traffic Control personnel. Official mailing addresses are published as an appendix to the Army's compilation of record systems notices.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Air Traffic Controllers and Air Traffic Control Maintenance Technicians employed by the Department of the Army.

CATEGORIES OF RECORDS IN THE SYSTEM:

Name, Social Security Number, Air Traffic Controller and Maintenance Technician qualifications and certifications, training and proficiency data and ratings, date assigned to current facility, and similar relevant documents.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

Federal Aviation Act of 1958, 49 U.S.C. 313, 601, 1354, and 1421; and E.O. 9397.

PURPOSE(S):

To determine proficiency of Air Traffic Controllers and Air Traffic Control Maintenance Technicians and the reliability of the Air Traffic Control system operations within the Department of the Army.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

Information may be disclosed to the Federal Aviation Administration, the National Transportation Safety Board, and similar authorities in connection with aircraft accidents, incidents, or traffic violations.

The 'Blanket Routine Uses' published at the beginning of the Army's compilation of system of record notices also apply to this record system.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Paper records in file folders and on cards. Selected data is automated on tapes and discs for management purposes.

RETRIEVABILITY:

Manually by individual surname; automated records are retrieved by name, plus any numeric identifier such as date of birth, Social Security Number, or Army serial number.

SAFEGUARDS:

Records are maintained in secure areas available only to designated persons having official need for the record. Automated systems employ computer hardware/software safeguard features and controls which meet the administrative, physical, and technical safeguards of Army Regulation 380–19, Information Systems Security.

RETENTION AND DISPOSAL:

Active paper records are retained by the Air Traffic Control facility until individual is transferred. The records are transferred with the military personnel records jacket or civilian personnel folders, as appropriate.

Upon separation or retirement of individual, the records are retired to the National Personnel Records Center (Civilian Personnel Records), 111 Winnebago Street, St Louis, MO 63118 and U.S. Army Personnel Center, and U.S. Army Reserve Components Personnel and Administration Center, 9700 Page Boulevard, St Louis, MO 63132–5200; retained for 75 years after date of birth or 60 years after date of earliest document in the folder if date of birth cannot be ascertained. Automated management information at the primary location is retained until no longer needed for current operations.

SYSTEM MANAGER(S) AND ADDRESS:

Commander, U.S. Army Training and Doctrine Command, ATTN: ATIM-SR, Fort Monroe, VA 23651–5000.

NOTIFICATION PROCEDURE:

Individuals seeking to determine if information about themselves is contained in this record system should address written inquiries to the Air Traffic Control facility where assigned or to Commander, U.S. Army Aviation Center, Fort Rucker, AL 36362–5000.

Individual should provide the full name, Social Security Number, details which will facilitate locating the records, current address and signature.

RECORD ACCESS PROCEDURES:

Individuals seeking access to records about themselves contained in this record system should address written inquiries to the Air Traffic Control facility where assigned or to Commander, U.S. Army Aviation Center, Fort Rucker, AL 36362–5000.

Individual should provide the full name, Social Security Number, details which will help locate the records, current address, and signature.

CONTESTING RECORD PROCEDURES:

The Army's rules for accessing records, contesting contents, and appealing initial determinations are contained in Army Regulation 340–21; 32 CFR part 505; or may be obtained from the system manager.

RECORD SOURCE CATEGORIES:

From the individual, individual's supervisor, Army or Federal Aviation Administration physicians, Air Traffic Control Facility Personnel Status Reports (DA Form 3479–6–R), and Air Traffic Control Maintenance Personnel Certification Record.

EXEMPTIONS CLAIMED FOR THE SYSTEM:

None.

A0405–10bCE

SYSTEM NAME:

Homeowners Assistance Case Files *(February 22, 1993, 58 FR 10130).*

CHANGES:

SYSTEM IDENTIFIER:

Change system identifier to read 'A0405–10qCE'.

SYSTEM LOCATION:

Delete entry and replace with 'Chief of Engineers, Headquarters U.S. Army Corps of Engineers, ATTN: CERE-R, 20 Massachusetts Avenue, NW, Washington, DC 20314–1000.

Segments of this system are also at Corps of Engineers Major Subordinate Commands and District Commands. Official mailing addresses are published as an appendix to the Army's compilation of systems of records notices.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Delete entry and replace with 'Eligible federal civilian employees and military personnel who submit personal and financial information to apply for homeowners assistance benefits.'

CATEGORIES OF RECORDS IN THE SYSTEM:

Line 4, after i.e., add 'applicant's name; Social Security Number; property address;'.

Line 19, after appraisal reports, add 'appraisal price, purchase price, benefits,'.

* * * * *

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

Add two new paragraphs 'Internal Revenue Service (IRS) to determine tax liability for sale of property to the Government.

The 'Blanket Routine Uses' set forth at the beginning of the Army's compilation of systems of records notices apply to this record system.'

STORAGE:

At the end of the entry, add 'and weekly print outs.'

RETRIEVABILITY:

Delete entry and replace with 'By applicant's name; Social Security Number; application number; street

address; service and type of employment i.e. civilian or armed services member and installation name.'

* * * * *

SYSTEM MANAGER(S) AND ADDRESS:

Delete entry and replace with 'Chief of Engineers, Headquarters U.S. Army Corps of Engineers, ATTN: CERE-R, 20 Massachusetts Avenue, NW, Washington, DC 20314–1000.'

NOTIFICATION PROCEDURE:

Delete the first sentence and replace with 'Individuals seeking to determine whether information about themselves is contained in this system should address written inquiries to the Chief of Engineers, Headquarters U.S. Army Corps of Engineers, ATTN: CERE-R, 20 Massachusetts Avenue, NW, Washington, DC 20314–1000.'

* * * * *

A0405–10qCE

SYSTEM NAME:

Homeowners Assistance Case Files.

SYSTEM LOCATION:

Chief of Engineers, Headquarters U.S. Army Corps of Engineers, ATTN: CERE-R, 20 Massachusetts Avenue, NW, Washington, DC 20314–1000.

Segments of this system are also at Corps of Engineers Major Subordinate Commands and District Commands. Official mailing addresses are published as an appendix to the Army's compilation of systems of records notices.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Eligible federal civilian employees and military personnel who submit personal and financial information to apply for homeowners assistance benefits

CATEGORIES OF RECORDS IN THE SYSTEM:

Documents relating to the application of persons sustaining losses in real estate because of closure or reduction of military bases; e.g., applicant's name; Social Security Number; property address; employment verification; income and expense figures; information concerning offer to sell real property or similar written offer; negotiator's report; title evidence and opinions; surveys, leases; Certificate of Inspection and Possession; Payment and Closing Sheet and Receipt for US Treasurer's check; market impact data; insurance and tax data; Disclaimer by Person of Possession; DD Form 1607 (Application for Homeowners' Assistance); FHA Form 1174 (Transmittal of Recorded Deed and Title Assembly-Military Acquisition); appraisal reports, appraisal price, purchase price, benefits, docket sheets, questionnaires, copies of deeds and mortgages, mortgage settlement data, evidence of proof of ownership and occupancy of residence, applicant appeals and final decisions thereon, comparable forms and related correspondence.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

Section 1013, Demonstration Cities and Metropolitan Development Act of 1966, Pub. L. 89–754, 80 Stat. 1290 (1966), (42 U.S.C. 3374), as amended; and E.O. 9397.

PURPOSE(S):

To process applications for homeowners assistance benefits and consider appeals; to review market studies and appraisals; to review final title assemblies of deeds of conveyance to the Government for properties acquired under the program.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

Department of Housing and Urban Development/FHA when assuming custody of acquired homes, to manage and dispose of such properties on behalf of the Secretary of Defense.

FHA/Department of Veterans Affairs in accepting subsequent purchaser in private sales when property is encumbered by a mortgage loan guaranteed or insured by them.

Department of Justice to review final title and deeds of conveyance to the Government for properties acquired under the program, pursuant to their responsibilities under Pub L. 91–393.

Internal Revenue Service (IRS) to determine tax liability for sale of property to the Government.

The 'Blanket Routine Uses' set forth at the beginning of the Army's compilation of systems of records notices apply to this system.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Paper records in file folders; magnetic tapes/disks; cards and weekly print outs.

RETRIEVABILITY:

By applicant's name; Social Security Number; application number; street address; type of employment i.e. civilian or armed services member; and installation name.

SAFEGUARDS:

All information is protected by physical security devices which include guards to the buildings and limited access only to authorized personnel having official need therefor. Access or update of information in automated media is by a system of passwords, thereby preserving integrity of the data.

RETENTION AND DISPOSAL:

Files are destroyed 10 years after final action or decision on appeals, as applicable.

SYSTEM MANAGER(S) AND ADDRESS:

Chief of Engineers, Headquarters U.S. Army Corps of Engineers, ATTN: CERE-R, 20 Massachusetts Avenue, NW, Washington, DC 20314–1000.

NOTIFICATION PROCEDURE:

Individuals seeking to determine whether information about themselves is contained in this system should address written inquiries to the Chief of Engineers, Headquarters U.S. Army Corps of Engineers, ATTN: CERE-R, 20 Massachusetts Avenue, NW, Washington, DC 20314–1000.

Individuals must provide their full name, current address and telephone number, Social Security Number, name and location of the installation closed or announced for closure, and signature.

RECORD ACCESS PROCEDURES:

Individuals seeking access to information about themselves contained in this system should address written inquiries to the Chief of Engineers, Headquarters U.S. Army Corps of Engineers, ATTN: CERE-R, 20 Massachusetts Avenue, NW, Washington, DC 20314–1000.

Individuals must provide their full name, current address and telephone number, Social Security Number, name and location of the installation closed or announced for closure, and signature.

CONTESTING RECORD PROCEDURES:

The Army's rules for access to records and for contesting contents and appealing initial determinations are contained in Army Regulation 340–21; 32 CFR part 505; or may be obtained from the systems manager.

RECORD SOURCE CATEGORIES:

From the individual.

EXEMPTIONS CLAIMED FOR THE SYSTEM:

None.

[FR Doc. 93–9849 Filed 4–27–93; 8:45 am]

BILLING CODE 5000–04–F

Defense Logistics Agency

Privacy Act of 1974; Amend a Record System

AGENCY: Defense Logistics Agency, DOD

ACTION: Amend a record system.

SUMMARY: The Defense Logistics Agency proposes to amend an existing system of records in the DLA inventory of systems of records notices subject to the Privacy Act of 1974 (5 U.S.C. 552a), as amended.

DATES: This action will be effective without further notice on May 28, 1993, unless comments are received that would result in a contrary determination.

ADDRESSES: Send comments to the Privacy Act Officer, Administrative Management Branch, Planning and Resource Management Division, Defense Logistics Agency, Room 5A120, Cameron Station, Alexandria, VA 11304–6100.

FOR FURTHER INFORMATION CONTACT: Ms. Susan Salus at (703) 617–7583.

SUPPLEMENTARY INFORMATION: The complete inventory of Defense Logistics Agency record system notices subject to the Privacy Act of 1974 (5 U.S.C. 552a), as amended, can be obtained from the address listed above.

The amendments are not within the purview of subsection (r) of the Privacy Act (5 U.S.C. 552a), as amended, which requires the submission of an altered system report. The specific changes to the record system being amended are set forth below followed by the system notice as amended, in its entirety.

Dated: April 21, 1993.

L. M. Bynum,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

Amendment

S322.01 DMDC

SYSTEM NAME:

Defense Outreach Referral System (DORS) *(February 22, 1993, 58 FR 10870).*

CHANGES:

* * * * *

CATEGORIES OF INDIVIDUALS COVERED:

Add a new paragraph 'Individuals covered under Pub. L. 102-484, who have applied for public employment.'

* * * * *

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

Add 'Pub. L. 102-484' to entry.

PURPOSE(S):

Change first paragraph, fourth line 'Federal' to 'public'. Delete second paragraph.

Add a new paragraph 'For former military members covered under Pub. L. 102-484, the information will be used to track the participants public employment and to verify the participant's public employment history for DoD retirement and pay eligibility.'

* * * * *

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

Delete entry and replace with 'The 'Blanket Routine Uses' set forth at the beginning of DLA's compilation of systems of records notices apply to this system.'

* * * * *

RETENTION AND DISPOSAL:

Change 'one year' to 'five years'.

* * * * *

S322.01 DMDC

SYSTEM NAME:

Defense Outreach Referral System (DORS).

SYSTEM LOCATION:

W.R. Church Computer Center, Naval Postgraduate School, Monterey, CA 93940–5000.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Current and former Defense military and civilian personnel and their spouses, who have applied for participation in the job placement program.

Individuals covered under Pub. L. 102-484, who have applied for public employment.

CATEGORIES OF RECORDS IN THE SYSTEM:

Computerized records consisting of name, Social Security Number, correspondence address, branch of service, date of birth, separation status, travel availability, U.S. citizenship, occupational interests, geographic location work preferences, pay grade, rank, last unit of assignment, educational levels, dates of military or civilian service, language skills, flying status, security clearances, civilian and military occupation codes, and self reported personal comments for the purpose of providing prospective employers with a centralized system for locating potential employees.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

10 U.S.C. 136, 1143, 1144, 2358; Pub. L. 102-484; and E.O. 9397.

PURPOSE(S):

The purpose of this system is to facilitate the transition of military and civilian Defense personnel, and their spouses, to private industry and public employment in the event of a downsizing of the Department of Defense.

For former military members covered under Pub. L. 102-484, the information will be used to track the participants public employment and to verify the participant's public employment history for DoD retirement and pay eligibility.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

The 'Blanket Routine Uses' set forth at the beginning of DLA's compilation of systems of records notices apply to this system.

POLICIES AND PRACTICES OF STORING, RETRIEVING, ACCESSING, RETAINING AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Electronic storage.

RETRIEVABILITY:

Retrieved by Social Security Number or occupational or geographic preference of the individual.

SAFEGUARDS:

Computerized records are maintained in a controlled area accessible only to authorized personnel. Entry to these areas is restricted to those personnel with a valid requirement and authorization to enter. Physical entry is restricted by the use of locks, guards, administrative procedures (e.g., fire protection regulations).

Access to personal information is restricted to those who require the records in the performance of their official duties, and to the individuals who are the subject of the record or their authorized representative. Access to personal information is further restricted by the use of passwords which are changed periodically.

RETENTION AND DISPOSAL:

Records are maintained on-line for five years and then are archived as an historical data base.

SYSTEM MANAGER(S) AND ADDRESS:

Director, Defense Manpower Data Center, 1600 Wilson Boulevard, Suite 400, Arlington, VA 22209–2593.

NOTIFICATION PROCEDURE:

Individuals seeking to determine if information about themselves is contained in this record system should address written inquiries to the Director, Defense Manpower Data Center, 1600 Wilson Boulevard, Suite 400, Arlington, VA 22209–2593.

RECORD ACCESS PROCEDURES:

Individuals seeking access to information about themselves contained

in this record system should address written inquiries to the Director, Defense Manpower Data Center, 1600 Wilson Boulevard, Suite 400, Arlington, VA 22209–2593.

Written requests for information should contain the full name, Social Security Number, date of birth, and current address and telephone number of the individual.

For personal visits, the individual should be able to provide some acceptable identification such as driver's license, or military or other identification card.

CONTESTING RECORD PROCEDURES:

The DLA rules for access to records and for contesting contents and appealing initial determination are contained in DLA Regulation 5400.21; 32 CFR part 323; or may be obtained from the system manager.

RECORD SOURCE CATEGORIES:

The Military Services, DOD Components, and from the subject individual via application into the program.

EXEMPTIONS CLAIMED FOR THE SYSTEM:

None.

[FR Doc. 93–9848 Filed 4–27–93; 8:45 am]

BILLING CODE 5000–04–F

DEPARTMENT OF EDUCATION

[CFDA No. 84.116J]

Fund for the Improvement of Postsecondary Education—Special Focus Competition (Invitational Priority: Higher Education Collaboration and Exchange Between the United States and the European Community); Notice Inviting Applications for New Awards for Fiscal Year (FY) 1993

Purpose of Program: To provide grants or enter into cooperative agreements to improve postsecondary education opportunities.

Eligible Applicants: Institutions of higher education or combinations of such institutions and other public and private nonprofit institutions and agencies.

Deadline for Transmittal of Applications: July 20, 1993.

Deadline for Intergovernmental Review: September 18, 1993.

Applications Available: May 20, 1993.

Available Funds: It is estimated that approximately $1,500,000 will be available for an estimated 30 new awards under this competition.

Estimated Range of Awards: $42,000 to $51,000.

Estimated Average Size of Awards: $50,000.

Estimated Number of Awards: 30.

Note: The Department is not bound by any estimates in this notice.

Project Period: 24 months.

Applicable Regulations: (a) The Education Department General Administrative Regulations (EDGAR) in 34 CFR parts 74, 75, 77, 79, 80, 82, 85, and 86, with the exceptions noted in 34 CFR 630.4(b); and (b) the regulations for this program in 34 CFR part 630.

Priorities

Absolute Priority: Under 34 CFR 75.105(c)(3) and 34 CFR 630.11(b)(1) the Secretary gives an absolute preference to applications that meet the following priority. The Secretary funds under this competition only applications that meet this absolute priority:

Projects addressing a particular problem area or improvement approach in postsecondary education.

Invitational Priority: Within the absolute priority specified in this notice, the Secretary is particularly interested in applications that meet the following invitational priority. Under 34 CFR 75.105(c)(1), however, an application that meets this invitational priority does not receive competitive or absolute preference over other applications:

Projects to develop new types of collaboration and exchange between institutions of higher education in the United States and their counterparts in the 12 member states of the European Community.

Selection Criteria

In evaluating applications for grants under this program competition, the Secretary uses the following selection criteria chosen from those listed in 34 CFR 630.32:

(a) *Significance for Postsecondary Education.* The Secretary reviews each proposed project for its significance in improving postsecondary education by determining the extent to which it would—

(1) Address an important problem or need;

(2) Represent an improvement upon, or important departure from, existing practice;

(3) Involve learner-centered improvements;

(4) Achieve far-reaching impact through improvements that will be useful in a variety of ways and in a variety of settings; and

(5) Increase the cost-effectiveness of services.

(b) *Feasibility.* The Secretary reviews each proposed project for its feasibility by determining the extent to which—

(1) The proposed project represents an appropriate response to the problem or need addressed;

(2) The applicant is capable of carrying out the proposed project, as evidenced by, for example—

(i) The applicant's understanding of the problem or need;

(ii) The quality of the project design, including objectives, approaches, and evaluation plan;

(iii) The adequacy of resources, including money, personnel, facilities, equipment, and supplies;

(iv) The qualifications of key personnel who would conduct the project; and

(v) The applicant's relevant prior experience;

(3) The applicant and any other participating organizations are committed to the success of the proposed project, as evidenced by, for example—

(i) Contribution of resources by the applicant and by participating organizations;

(ii) Their prior work in the area; and

(iii) The potential for continuation of the proposed project beyond the period of funding (unless the project would be self-terminating); and

(4) The proposed project demonstrates potential for dissemination to or adaptation by other organizations, and shows evidence of interest by potential users.

(c) *Appropriateness of funding projects.* The Secretary reviews each application to determine whether support of the proposed project by the Secretary is appropriate in terms of availability of other funding sources for the proposed activities.

The Secretary gives equal weight to the selection criteria on significance, feasibility, and appropriateness. Within each of these criteria, the Secretary gives equal weight to each of the subcriteria listed above. In applying the criteria, the Secretary first analyzes an application in terms of each individual criterion and subcriterion. The Secretary then bases the final judgment of an application on an overall assessment of the degree to which the applicant addresses all selection criteria.

FOR APPLICATIONS OR INFORMATION CONTACT: Fund for the Improvement of Postsecondary Education (FIPSE), U.S. Department of Education, 400 Maryland Avenue, SW., room 3100, ROB–3, Washington, DC 20202–5175. Telephone: (202) 205–0082 to order applications; or (202) 708–5750 for information. Hearing-impaired individuals may call the Federal Dual Party Relay Service at 1–800–877–8339

(in the Washington, DC 202 area code, telephone 708–9300) between 8 a.m. and 7 p.m., Eastern time.

Program Authority: 20 U.S.C. 1135–1135a–11.

Dated: April 20, 1993.

Maureen A. McLaughlin,

Acting Assistant Secretary for Postsecondary Education.

[FR Doc. 93–9860 Filed 4–27–93; 8:45 am]

BILLING CODE 4000–01–U

National Education Commission on Time and Learning; Meeting

AGENCY: National Education Commission on Time and Learning, Education.

ACTION: Notice of public meeting.

SUMMARY: This notice sets forth the schedule and proposed agenda of a forthcoming public Meeting of the National Education Commission on Time and Learning. This notice also describes the functions of the Commission. Notice of this Meeting is required under section 10(a)(2) of the Federal Advisory Committee Act.

DATE, TIME AND LOCATION: May 13, 1993 from 1 p.m. to 4:30 p.m. Washington Marriott Hotel, 1221 22nd Street, NW., Washington, DC.

FOR FURTHER INFORMATION CONTACT: Julia Anna Anderson, Deputy Executive Director, 1255 22nd Street, NW., suite 502, Washington, DC 20202–7591. Telephone: (202) 653–5063.

SUPPLEMENTARY INFORMATION: The National Education Commission on Time and Learning is established under section 102 of the Education Council Act of 1991 (20 U.S.C. 1221–1). The Commission is established to examine the quality and adequacy of the study and learning time of elementary and secondary students in the United States, including issues regarding the length of the school day and year, how time is being used for academic subjects, the use of incentives, how time is used outside of school, the extent and role of homework, year-round professional opportunities for teachers, the use of school facilities for extended learning programs, a model for adopting a longer day or year (if appropriate), suggested changes for state laws and regulations, and an analysis and estimate of the additional costs.

The Meeting of the Commission is open to the public. The proposed agenda for May 13 includes: Presentations by and discussions with representatives of curriculum standard-setting organizations. Records are kept of all Commission proceedings, and are available for public inspection at the Office of the Commission at 1255 22nd Street, NW., suite 502, Washington, DC 20202–7591 from the hours of 9 a.m. to 5:30 p.m.

Dated: April 22, 1993.

John Hodge Jones,

Chairman, National Education Commission on Time and Learning.

[FR Doc. 93–9941 Filed 4–27–93; 8:45 am]

BILLING CODE 4000–01–M

DEPARTMENT OF ENERGY

Office of Environmental Restoration and Waste Management

Interim Mixed Waste Inventory Report: Waste Streams, Treatment Capacities and Technologies

AGENCY: Office of Environmental Restoration and Waste Management, DOE.

ACTION: Notice of availability.

SUMMARY: The Department of Energy (DOE) has prepared an Interim Mixed Waste Inventory Report on Waste Streams, Treatment Capacities and Technologies (Report). The Report responds to the requirement of section 105(a) of the Federal Facility Compliance Act of 1992 (Pub. L. 102–386) (the Act) that the Department prepare a mixed waste inventory report within 180 days of enactment.

The Act requires that this report be submitted to the Administrator of the Environmental Protection Agency and the Governor of each State in which the DOE stores or generates mixed waste. There are currently 50 sites in 22 States that store, generate, or are expected to generate in the next five years, DOE-managed mixed wastes covered by the Act. Mixed wastes are wastes that contain both hazardous waste, regulated by the Resource Conservation and Recovery Act, and source, special nuclear or by-product material subject to the Atomic Energy Act of 1954.

Comments on the content of the Report will be considered from interested persons, organizations, and agencies in the development of the final Report.

DATES: Written comments to DOE should be received by July 26, 1993.

ADDRESSES: The report will be available to the public in late April in the following DOE Reading Rooms:

Albuquerque Operations Office, U.S. Department of Energy, National Atomic Museum, Building 20358, Wyoming Blvd, PO Box 5400, Albuquerque, New Mexico 87115

Boston Support Office, Chicago Operations Office, U.S. Department of Energy, 10 Causeway Street, Room 1197, Boston, MA 02222–1035

Headquarters, U.S. Department of Energy, Room 1E–190, 1000 Independence Avenue, SW, Washington, DC 20585

Bartlesville Project, Office/National, Institute for Petroleum and Energy Research (NIPER) Library, U.S. Department of Energy, 220 N. Virginia Avenue, PO Box 2128, Bartlesville, OK 74003

Chicago Operations Office, 9800 South Cass Avenue, Argonne, IL 60439

INEL Technical Library, 1776 Science Center Drive, PO Box 1625, Idaho Falls, ID 83415–2300.

Morgantown Energy Tech Ctr Library, 3610 Collins Ferry Road, PO Box 880, Morgantown, WV 26507-0880

Oak Ridge Operations Office, U.S. Department of Energy, Office of Chief Counsel, 200 Administration Road, PO Box 2001, Oak Ridge, TN 37831-8510

Richland Operations Office, U.S. Department of Energy, 825 Jadwin Avenue, PO Box 1970, A1–65, Richland, Washington 99352

Public Reading Room, U.S. Department of Energy, 1333 Broadway Wells Fargo Bldg, Oakland, California 94612

Nevada Operations Office, U.S. Department of Energy, 2753 South Highland Drive, PO Box 98518, Las Vegas, Nevada 98518

Pittsburgh Energy Tech Ctr, U.S. Department of Energy, Cochran Mill Road, Bldg 95, PO Box 10940, Pittsburgh, PA 15236-0940

Rocky Flats Area Office, c/o Front Range Community College, 3645 West 112 Avenue, Westminster, Colorado 80030

Gregg-Granite Library, Savannah River Operations Office, University of South Carolina-Aiken, 171 University Parkway, Aiken, South Carolina 29801

Southeastern Power Administration, U.S. Department of Energy, Legal Library, Samuel Elbert Building, Public Square, Elberton, Georgia 30635

The Report can also be obtained from the National Technical Information Service, U.S. Department of Commerce, 5285 Port Royal Road, Springfield, Virginia 22161. The Executive Summary of the report and other summary information can be requested by calling (301) 903–7488.

Comments should be sent to: U.S. Department of Energy, Director, Office of Technical Support, EM–35, ATTN: Inventory Report, Trevion II Building, Washington, DC 20585-0002.

FOR FURTHER INFORMATION CONTACT: The Office of Technical Support (301) 903–7488.

SUPPLEMENTARY INFORMATION: As specifically required by section 105(a) of the Act, the Report contains the following information: (1) A national inventory of all mixed wastes in the DOE system, including waste currently in storage and wastes expected to be generated over the next five years; and (2) a national inventory of mixed waste treatment capacities and technologies.

The Act requires that the Administrator of the Environmental Protection Agency and the States provide any comments they might have within 90 days of issuance of the Report.

The Act also requires that DOE publish a schedule for submitting site treatment plans for the development of treatment technologies and capacities. This schedule was published in the Federal Register on April 6, 1993 (58 FR 17875).

The mixed waste inventory contains specific waste stream information by State for each of the sites, in the form of waste profile sheets (WPS) for each mixed waste stream in storage or expected to be generated over the next five years. The mixed waste treatment capacity inventory contains descriptions and locations of existing and proposed treatment facilities, an estimate of the available treatment capacity for each waste described in the report, and a description of the technological approaches the DOE anticipates will need to be developed for wastes with no existing treatment technology.

The Report is comprised of several volumes, including an overview volume, four State and site-specific volumes, and an Appendix volume. Volume I contains a discussion of the Report's scope and organization; an overview of DOE-managed mixed wastes and treatment facilities, existing and planned; and an overview of the technology development program for the management of these wastes. The overview also provides a guide to State and site-specific information, including waste profile sheets (WPS). Volumes II–V contain specific information for each site in the 22 States in which DOE stores or generates mixed wastes. Information in these volumes is organized alphabetically by State. Volume II contains site-specific information for California through Iowa; Volume III for Kentucky through New York; Volume IV for Ohio through South Carolina; and Volume V for Tennessee through Washington. The Appendix contains the text of the Act; detailed information on the technology development program; a description of materials not characterized as mixed waste by sampling and analysis, including radioactive low-level waste and spent nuclear fuel; and a glossary of terms.

The Report provides specific information on the following 50 sites which are located in 22 States:

California
- Energy Technology Engineering Center (ETEC)
- General Atomics
- General Electric Vallecitos Nuclear Center
- Lawrence Berkeley Laboratory
- Lawrence Livermore National Laboratory
- Laboratory for Energy-Related Health Research
- Mare Island Naval Shipyard
- Sandia National Laboratories—California

Colorado
- Grand Junction Project Office
- Rocky Flats Plant

Connecticut
- Knolls Atomic Power Laboratory—Windsor

Florida
- Pinellas Plant

Hawaii
- Pearl Harbor Naval Shipyard

Idaho
- Argonne National Laboratory-West
- Idaho National Engineering Laboratory

Illinois
- Argonne National Laboratory-East
- Site A/Plot M Palos Forest Preserve

Iowa
- Ames Labortory

Kentucky
- Paducah Gaseous Diffusion Plant

Maine
- Portsmouth Naval Shipyard

Missouri
- Kansas City Plant
- University of Missouri
- Weldon Spring Site Remedial Action Project

Nevada
- Nevada Test Site

New Jersey
- Middlesex Sampling Plant
- Princeton Plasma Physics Laboratory

New Mexico
- Inhalation Toxicology Research Institute
- Los Alamos National Laboratory
- Sandia National Laboratories—New Mexico
- Waste Isolation Pilot Plant (WIPP)

New York
- Brookhaven National Laboratory
- Colonie Interim Storage Site
- Knolls Atomic Power Laboratory
- Knolls Atomic Power Laboratory—Kesselring
- West Valley Demonstration Project

Ohio
- Battelle Columbus Laboratories Decommissioning Project
- Fernald Environmental Management Project
- Mound Plant
- Portsmouth Gaseous Diffusion Plant
- RMI Titanium Incorporated

Pennsylvania
- Bettis Atomic Power Laboratory

South Carolina
- Charleston Naval Shipyard
- Savannah River Site

Tennessee
- Oak Ridge K–25 Site
- Oak Ridge National Laboratory
- Oak Ridge Y–12 Plant

Texas
- Pantex Plant

Virginia
- Norfolk Naval Shipyard

Washington
- Hanford
- Puget Sound Naval Shipyard

The Report is approximately 4,000 pages in length. Due to the distribution complexity and high reproduction and postage costs associated with providing the Report in its entirely, DOE is encouraging interested persons, organizations, and agencies to either review the report at DOE Reading Rooms, purchase a copy of the Report through NTIS, or utilize the summary information which can be provided through the Inventory Report Information telephone number listed above.

Issued in Washington, DC, on April 22, 1993.

Paul D. Grimm,

Acting Assistant Secretary for Environmental Restoration and Waste Management.

[FR Doc. 93–10096 Filed 4–96–93; 2:22 pm]

BILLING CODE 6450–01–M

SECURITIES AND EXCHANGE COMMISSION

Self-Regulatory Organizations; Application for Unlisted Trading Privileges and of Opportunity for Hearing; Philadelphia Stock Exchange, Inc.

April 22, 1993.

The above named national securities exchange has filed an application with the Securities and Exchange Commission ("Commission") pursuant to section 12(f)(1)(B) of the Securities Exchange Act of 1934 and Rule 12f–1 thereunder for unlisted trading privileges in the following security:

TIG Holding Inc.
Common Stock, $.01 Par Value (File No. 10506)

This security is listed and registered on one or more other national securities exchange and is reported in the consolidated transaction reporting system.

Interested persons are invited to submit on or before May 17, 1993, written data, views and arguments concerning the above-referenced application. Persons desiring to make written comments should file three copies thereof with the Secretary of the Securities and Exchange Commission, 450 5th Street, NW., Washington, DC 20549. Following this opportunity for hearing, the Commission will approve the application if it finds, based upon all the information available to it, that the extension of unlisted trading privileges pursuant to such application is consistent with the maintenance of fair and orderly markets and the protection of investors.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.

Jonathan G. Katz,

Secretary.

[FR Doc. 93–9888 Filed 4–27–93; 8:45 am]

BILLING CODE 8010–01–M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket Nos. ER93–157–000, et al.]

Puget Sound Power & Light Co., et al.; Electric Rate, Small Power Production, and Interlocking Directorate Filings

Take notice that the following filings have been made with the Commission:

1. Puget Sound Power & Light Company

[Docket No. ER93–157–000]

April 20, 1993.

Take notice that on April 12, 1993, Puget Sound Power & Light Company (Puget) tendered for filing a Certificate of Concurrence and Cost Support Information related to the sale of the output of the Skookumchuck Hydroelectric Project to Puget Sound Power and Light.

Copies of this agreement have been served on the distribution list, as included in the filing.

Comment date: May 4, 1993, in accordance with Standard Paragraph E at the end of this notice.

2. Puget Sound Power & Light Company

[Docket No. ER93–183–000]

April 20, 1993.

Take notice that on April 12, 1993, Puget Sound Power & Light Company (Puget) tendered for filing an amendment in the above-referenced docket.

Comment date: May 4, 1993, in accordance with Standard Paragraph E at the end of this notice.

3. West Penn Power Company

[Docket No. ER93–515–000]

April 20, 1993.

Take notice that on April 9, 1993, West Penn Power Company tendered for filing an amendment to its original filing filed in this docket on March 31, 1993.

Comment date: May 4, 1993, in accordance with Standard Paragraph E at the end of this notice.

4. Central Louisiana Electric Company

[Docket No. ER93–498–000]

April 20, 1993.

Take notice that on April 2, 1993, Central Louisiana Electric Company tendered for filing an amendment in the above-referenced docket.

Comment date: May 4, 1993, in accordance with Standard Paragraph E at the end of this notice.

5. Union Electric Company

[Docket No. ER93–420–000]

April 20, 1993.

Take notice that on April 9, 1993, Union Electric Company (UE) tendered for filing Amendment—Certificate of Concurrence to filing of the Service Area Boundary Agreement dated March 12, 1991 and Amendment—Certificate of Concurrence to filing of the Interchange Agreement dated August 2, 1990 both between Arkansas Power and Light Company and UE. UE asserts that the purpose of the amendments is to allow for assignment of rate schedule designations.

Comment date: May 3, 1993, in accordance with Standard Paragraph E at the end of this notice.

6. Consumers Power Company

[Docket No. ER93–481–000]

April 20, 1993.

Take notice that on March 22, 1993, Consumers Power Company (Consumers) tendered for filing a Notice of Termination of Consumers' Rate Schedule FERC Nos. 64 and 65 and a Notice of Termination of PSI Energy, Inc.'s Rate Schedule FERC Nos. 243 and 244.

Comment date: May 4, 1993, in accordance with Standard Paragraph E at the end of this notice.

7. Electric Energy, Inc.

[Docket No. ER93–236–001]

April 20, 1993.

Take notice that on March 30, 1993, Electric Energy, Inc. (EEInc.) tendered for filing its compliance refund report in the above-referenced docket.

Comment date: May 4, 1993, in accordance with Standard Paragraph E at the end of this notice.

8. The Montana Power Company

[Docket No. ER93–207–000]

April 20, 1993.

Take notice that on April 14, 1993, The Montana Power Company (Montana) tendered for filing with the Federal Energy Regulatory Commission pursuant to 18 CFR 35.13 a supplement to its original filing of Amendments No. 1 and No. 2, as well as various Revised Exhibits, to Rate Schedule FERC No. 148, a Contract for Interconnections, Transmission Service and Inter-Utility Operations Between The Montana Power Company and the Western Area Power Administration. This supplemental filing provides additional information requested through a deficiency letter issued under this docket.

Copies of the filing were served upon the Western Area Power Administration.

Comment date: May 4, 1993, in accordance with Standard Paragraph E at the end of this notice.

9. Consolidated Edison Company of New York, Inc.

[Docket No. ER93–349–000]

April 20, 1993.

Take notice that on April 12, 1993, Consolidated Edison Company of New York, Inc. (Con Edison) tendered for filing revised proposed supplements to its Rate Schedule FERC No. 96 and FERC No. 92.

The revised proposed supplement No. 7 to Rate Schedule FERC No. 96 increases the rates and charges for electric delivery service furnished to public customers of the New York Power Authority (NYPA) by $24,495,000 annually based on the 12-month period ending March 31, 1994.

The revised proposed supplement No. 8 to Rate Schedule FERC No. 96, applicable to electric delivery service to NYPA's non-public, economic development customers, and the revised proposed supplement No. 4 to Rate Schedule FERC No. 92, applicable to electric delivery service to commercial and industrial economic development customers of the County of Westchester Public Service Agency (COWPUSA) and the New York City Public Utility Service (NYCPUS), increase the rates and charges for the service by $582,000 annually based on the 12-month period ending March 31, 1994.

These supplements would supersede proposed supplements No. 7 and 8 to Rate Schedule FERC No. 96 and proposes supplement No. 4 to Rate Schedule FERC No. 92 which Con Edison tendered to the Commission on January 29, 1993. These supplements have never been made effective and should be deemed superseded upon grant of the relief requested in the present filing.

Con Edison seeks permission to make the rate increases to NYPA, COWPUSA and NYCPUS effective as of April 1, 1993.

A copy of this filing has been served on NYPA, COWPUSA, NYCPUS, and the New York Public Service Commission.

Comment date: May 4, 1993, in accordance with Standard Paragraph E at the end of this notice.

10. Consumers Power Company

[Docket Nos. ER92–331–000 and ER92–332–001]

April 21, 1993.

Take notice that on April 8, 1993, Consumers Power Company (Consumers) tendered for filing a supplemental filing in the above-referenced dockets.

Comment date: May 5, 1993, in accordance with Standard Paragraph E at the end of this notice.

11. Central Power and Light Company

[Docket No. ER93–562–000]

April 21, 1993.

Take notice that on April 13, 1993, Central Power and Light Company (CPL) tendered for filing a Letter Agreement dated March 12, 1993 between CPL and Magic Valley Electric Cooperative, Inc. (MVEC). Under the Letter Agreement CPL agreed to install temporary metering facilities in order to assist MVEC in providing continuous service to its customers while it completed a transmission construction project.

CPL requests that the Commission waive its notice requirements and permit the Letter Agreement to become effective as of March 22, 1993, the date on which the temporary metering point was installed at MVEC's request.

Copies of the filing have been sent MVEC and the Public Utility Commission of Texas, which regulates MVEC's rates for retail sales. Copies of this transmittal letter only have been sent to CPL's other wholesale requirements customers to advise them of the present for waiver of the notice requirements.

Comment date: May 5, 1993, in accordance with Standard Paragraph E at the end of this notice.

12. Louisiana Energy and Power Authority v. Central Louisiana Electric Company, Inc.

[Docket No. EL93–33–000]

April 21, 1993.

Take notice that on April 16, 1993, the Louisiana Energy and Power Authority (LEPA), on behalf of the Cities of Boyce and Elizabeth, Louisiana, tendered for filing a complaint against Central Louisiana Electric Company, Inc. (CLECO) requesting the initiation of an investigation to determine whether CLECO's present rates for wholesale firm power to Boyce and Elizabeth, contained in CLECO's FERC Rate Schedule Nos. 22 and 23, respectively, are unjust, unreasonable and unduly discriminatory and, if so, to modify those rates to a just, reasonable and non-unduly discriminatory level. LEPA also requests that the Commission set a refund effective date of not more than 60 days after the filing of the complaint and to consolidate this docket with Docket No. ER93–498–000.

Comment date: May 21, 1993, in accordance with Standard Paragraph E at the end of this notice.

13. Louis A. Simpson

[Docket No. ID–2780–000]

April 21, 1993.

Take notice that on March 25, 1993, Louis A. Simpson (Applicant) tendered for filing an application under Section 305(b) of the Federal Power Act to hold the following positions:

Director—Potomac Electric Power Company
Director—Salomon Inc.

Comment date: May 5, 1993, in accordance with Standard Paragraph E at the end of this notice.

14. Southern California Edison Company

[Docket No. ER93–552–000]

April 21, 1993.

Take notice that on April 8, 1993, Southern California Edison Company (Edison) tendered for filing the following agreements between Edison and the State of California Department of Water Resources (CDWR) which have been executed concurrently on February 24, 1993:

Amendment No. 2 (Amendment) to the Power Contract Between Southern California Edison Company and State of California, Department of Water Resources
Devil Canyon, Additional Facilities and Firm Transmission Service Agreement (Agreement) Between Southern California Edison Company and State of California, Department of Water Resources

Comment date: May 5, 1993, in accordance with Standard Paragraph E at the end of this notice.

15. Central Illinois Public Service Company

[Docket No. ER93–418–000]

April 21, 1993.

Take notice that on April 18, 1993, Central Illinois Public Service Company (CIPS) tendered for filing an amendment to its March 2, 1993 filing in this docket.

Comment date: May 5, 1993, in accordance with Standard Paragraph E at the end of this notice.

16. Louisville Gas and Electric Company

[Docket No. ER92–533–001]

April 21, 1993.

Take notice that Louisville Gas and Electric Company (LG&E), tendered for filing on April 7, 1993 the following revised rate schedules: (1) Generation Sales Service (Rate Schedule GSS) and (2) Coordination Transmission Service (Rate Schedule CT).

In the filing, Rate Schedule GSS is modified to make the interest rate used for the determination of late payment charges (paragraph 6.1) consistent with Rate Schedules CT and T, pursuant to the Commission's Order dated January 14, 1993, and Rate Schedule CT is modified to clarify the use of an umbrella agreement.

A copy of the filing was served upon the Kentucky Public Service Commission and the Indiana Utility Regulatory Commission.

Comment date: May 5, 1993, in accordance with Standard Paragraph E at the end of this notice.

Standard Paragraphs

E. Any person desiring to be heard or to protest said filing should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). All such motions or protests should be filed on or before the comment date. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a motion to intervene. Copies of this filing are on file with the Commission and are available for public inspection.

Lois D. Cashell,

Secretary.

[FR Doc. 93–9881 Filed 4–27–93; 8:45 am]

BILLING CODE 6717–01–M

[Docket No. PL92–1–001]

Incentive Ratemaking for Interstate Natural Gas Pipelines, Oil Pipelines, and Electric Utilities; Order Denying Rehearing

Issued April 22, 1993.

AGENCY: Federal Energy Regulatory Commission, DOE.

ACTION: Order denying rehearing.

SUMMARY: The Commission issued a policy statement in this proceeding on October 30, 1992, addressing incentive regulation as an alternative to traditional cost-of-service regulation for companies with market power. A number of parties filed requests for

rehearing and clarification of the policy statement. This order denies the requests for rehearing and clarification.

EFFECTIVE DATE: This order will become effective on the date of issuance, April 22, 1993.

FOR FURTHER INFORMATION CONTACT: Mary E. Benge, Office of the General Counsel, Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, DC 20426 (202) 208–1214.

SUPPLEMENTARY INFORMATION: In addition to publishing the full text of this document in the Federal Register, the Commission also provides all interested persons an opportunity to inspect or copy the contents of this document during normal business hours in room 3104, 941 North Capitol Street, NE., Washington, DC 20426.

The Commission Issuance Posting System (CIPS), an electronic bulletin board service, provides access to the texts of formal documents issued by the Commission. CIPS is available at no charge to the user and may be accessed using a personal computer with a modem by dialing (202) 208–1397. To access CIPS, set your communications software to use 300, 1200, or 2400 bps, full duplex, no parity, 8 data bits, and 1 stop bit. CIPS can also be accessed at 9600 bps by dialing (202) 208–1781. The full text of this rule will be available on CIPS for 30 days from the date of issuance. The complete text on diskette in WordPerfect format may also be purchased from the Commission's copy contractor, La Dorn Systems Corporation, also located in room 3104, 941 North Capitol Street, NE., Washington, DC 20426.

Order Denying Rehearing

Before Commissioners: Elizabeth Anne Moler, Chair; Jerry J. Langdon and Branko Terzic.

On October 30, 1992, the Commission issued a policy statement in the instant docket, which defined the essential elements of an incentive ratemaking policy and set guidelines for experimental incentive rate proposals for natural gas and oil pipelines and investor-owned electric utilities.[1] In the policy statement, the Commission did not prescribe any particular incentive rate mechanism that should be implemented by utilities wishing to propose an incentive plan; rather, the Commission suggested a range of mechanisms so that specific proposals can be flexibly adjusted to address the particular circumstances of particular utilities. The Commission stated that it would consider proposals for an experimental period, during which the Commission would consider and evaluate the success of incentive rate proposals on a case-by-case basis.

A number of parties have filed comments requesting either rehearing or clarification of the Commission's October 30, 1992 policy statement. Rather than address these requests at this time, the Commission deems it more appropriate to develop and refine its policies concerning incentive regulation in individual cases, based on the records in those cases, rather than further addressing these issues in this policy statement proceeding. This approach will provide the Commission the most latitude to assess both the merits of incentive rate proposals in the context of the facts of a specific case and the Commission's ongoing effort to streamline its regulatory oversight.

As a policy statement, this proceeding did not establish any binding norms, but merely announced the Commission's tentative intentions for future consideration of rate proposals.[2] An agency cannot apply or rely on a general statement of policy as law, but must justify its actions in individual cases based on the records in those cases. Thus, when, as here, the Commission acts through a policy statement, its contemplation is that it will develop and refine its policies on a case-by-case basis. That is particularly true in this instance, since the purpose of the policy statement was not to establish any generic incentive rate mechanism, but to encourage utilities to develop and propose incentive plans tailored to the needs of individual utilities. The Commission believes that its new policies concerning incentive regulation are best developed and refined in individual cases, where the Commission can consider the various issues in light of concrete factual circumstances.

The Commission orders: The requests for rehearing are denied.

By the Commission.

Lois D. Cashell,

Secretary.

[FR Doc. 93–9909 Filed 4–27–93; 8:45 am]

BILLING CODE 6717–01–M

[1] 61 FERC ¶ 61,168 (1992); 57 FR 55231, November 24, 1992.

[2] *Pacific Gas & Electric Co.* v. *FPC*, 506 F.2d 33, 38 (D.C. Cir. 1974).

[Docket Nos. CP93–301–000, et al.]

United Gas Pipe Line Co., et al.; Natural Gas Certificate Filings

April 20, 1993.

Take notice that the following filings have been made with the Commission:

1. United Gas Pipe Line Company

[Docket No. CP93–301–000]

Take notice that on April 16, 1993, United Gas Pipe Line Company (United), P.O. Box 1478, Houston, Texas 77251–1478, filed in Docket No. CP93–301–000 a request pursuant to § 157.205 of the Commission's Regulations under the Natural Gas Act (18 CFR 157.205), for authorization to install 206 feet of 4-inch pipeline, and to construct and operate a sales tap which includes a 4-inch meter station, a 2-inch regulator station and flow computer to enable United to transport natural gas to serve United Gas Services Company (UGS) in St. James Parish, Louisiana, under the certificate issued to United in Docket No. CP82–430–000 pursuant to section 7 of the Natural Gas Act, all as more fully set forth in the request which is on file with the Commission and open to public inspection.

It is stated that United is authorized to provide natural gas transportation service, on an interruptible basis, to UGS under a transportation agreement dated December 19, 1990. It is further stated that the proposed facilities are required to comply with the terms of the interruptible transportation agreement to enable United to deliver 60,000 MMBtu per day of natural gas to UGS to serve Occidental's Convent Chemical Plant in St. James Parish, Louisiana. United estimates the cost of the facilities to be $105,220, which will be reimbursed by UGS.

Comment date: June 4, 1993, in accordance with Standard Paragraph F at the end of this notice.

2. Arkla Energy Resources Company

[Docket No. CP93–298–000]

Take notice that on April 15, 1993, Arkla Energy Resources Company (AER), P.O. Box 21734, Shreveport, Louisiana 71151, filed in Docket No. CP93–298–000 a request pursuant to §§ 157.205, 157.211 and 157.212 of the Commission's Regulations under the Natural Gas Act (18 CFR 157.205, 157.211, 157.212) for authorization to construct and operate certain facilities under AER's blanket certificate issued in Docket No. CP82–384–000, et al. pursuant to section 7 of the Natural Gas Act, all as more fully set forth in the request that is on file with the

Commission and open to public inspection.

AER proposes to upgrade an existing meter station to facilitate increased deliveries of natural gas to Arkansas Louisiana Gas Company (ALG) for resale to domestic customers. AER states that the existing 1-inch meter station on Line S, originally installed to serve ALG's domestic customer, J.A. Lowe in Bossier Parish, Louisiana, would be upgraded to a 1-inch U-Shape meter station to serve domestic customers on ALG's new Rural Extension No. 1318. AER advises that the annual and peak day volumes of delivered gas would be about 1,700 Mcf and 30 Mcf, respectively. AER states that ALG would reimburse it for all construction costs, estimated to be $11,000.

Comment date: June 4, 1993, in accordance with Standard Paragraph F at the end of this notice.

3. United Gas Pipe Line Company

[Docket No. CP93–300–000]

Take notice that on April 15, 1993, United Gas Pipe Line Company (United), Post Office Box 1478, Houston, Texas 77251–1478, filed a prior notice request with the Commission in Docket No. CP93–300–000 pursuant to § 157.205 of the Commission's Regulations under the Natural Gas Act (NGA) for authorization to install pipeline, metering and regulating facilities, and communications equipment for an interruptible transportation service to United Gas Services Company (UGS), under United's blanket certificates issued in Docket Nos. CP82–430–000 and CP88–6–000, all as more fully set forth in the application which is open to public inspection.

United proposes to install approximately 90 feet of 6-inch pipe, a four-inch tap, a four-inch meter station, a three-inch regulator station, and a flow computer to provide interruptible transportation service to UGS on its existing 20-inch City Service pipeline in Calcasieu Parish, Louisiana, in order to deliver 20,000 MMBtu of natural gas per day for UGS' account to the Occidental Chemical Company's Lake Charles Chemical Plant. UGS would reimburse United for the $154,028 estimated construction cost of the proposed facilities. United states that its tariff does not prohibit the proposed modification of facilities. United also states that it would transport gas for UGS under United's FERC Rate Schedule ITS.

Comment date: June 4, 1993, in accordance with Standard Paragraph F at the end of this notice.

4. United Gas Pipe Line Company

[Docket No. CP93–299–000]

Take notice that on April 15, 1993, United Gas Pipe Line Company (United), P.O. Box 1478, Houston, Texas 77251–1478, filed in Docket No. CP93–299–000 a request pursuant to §§ 157.205 and 157.211(a)(2) of the Regulations under the Natural Gas Act for authorization to construct and install a one-inch sales tap through which United will make natural gas deliveries in Copiah County, Mississippi to Entex, Inc. (Entex) a jurisdictional sales customer under United's DG Rate Schedule, pursuant to United's blanket certificate issued in Docket No. CP82–430–000. United makes such request, all as more fully set forth in its request which is on file with the Commission and open to public inspection.

United states that it currently makes natural gas sales to Entex in its Brookhaven billing area pursuant to a service agreement dated October 1, 1991. United states that it is authorized in Docket Nos. CP91–1669–000 and RP91–126–000 to provide Entex's natural gas requirements for resale and distribution through its Brookhaven billing area. United further states that the volumes proposed to be delivered to Entex at the new tap would be within the currently effective entitlements of 20,501 MMBtu per day for the Brookhaven billing area.

United further states it would revise, construct and operate the proposed facilities in compliance with 18 CFR, part 157, subpart F, and that the proposed activities would not affect United's ability to serve its other existing customers.

Comment date: June 4, 1993, in accordance with Standard Paragraph F at the end of this notice.

Standard Paragraphs

F. Any person desiring to be heard or make any protest with reference to said filing should on or before the comment date file with the Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, DC 20426, a motion to intervene or a protest in accordance with the requirements of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214) and the Regulations under the Natural Gas Act (18 CFR 157.10). All protests filed with the Commission will be considered by it in determining the appropriate action to be taken but will not serve to make the protestants parties to the proceeding. Any person wishing to become a party to a proceeding or to participate as a party in any hearing therein must file a motion to intervene in accordance with the Commission's Rules.

Take further notice that, pursuant to the authority contained in and subject to jurisdiction conferred upon the Federal Energy Regulatory Commission by sections 7 and 15 of the Natural Gas Act and the Commission's Rules of Practice and Procedure, a hearing will be held without further notice before the Commission or its designee on this filing if no motion to intervene is filed within the time required herein, if the Commission on its own review of the matter finds that a grant of the certificate is required by the public convenience and necessity. If a motion for leave to intervene is timely filed, or if the Commission on its own motion believes that a formal hearing is required, further notice of such hearing will be duly given.

Under the procedure herein provided for, unless otherwise advised, it will be unnecessary for the applicant to appear or be represented at the hearing.

Lois D. Cashell,

Secretary.

[FR Doc. 93–9908 Filed 4–27–93; 8:45 am]

BILLING CODE 6717–01–M

[Docket No. JD93–02860T Wyoming–39]

State of Wyoming; NGPA Amended Notice of Determination by Jurisdictional Agency Designating Tight Formation

April 22, 1993.

Take notice that on April 19, 1993, the Wyoming Oil and Gas Conservation Commission (Wyoming) amended its notice of determination that was filed in the above-referenced proceedings on January 8, 1993 pursuant to § 271.703(c)(3) of the Commission's regulations. The January 8, 1993 notice determined that the Lance Formation underlying a portion of Sublette County, Wyoming, qualifies as a tight formation under section 107(b) of the Natural Gas Policy Act of 1978.

The amended notice of determination reduces the geographical area recommended for tight formation designation to 46,080 acres. The amended area covers only Townships 28 and 29 North, Range 108 West.

The notice of determination also contains Wyoming's and the Bureau of Land Management's findings that the referenced portion of the Lance Formation meets the requirements of the Commission's regulations set forth in 18 CFR part 271.

The application for determination is available for inspection, except for material which is confidential under 18

CFR 275.206, at the Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, DC 20426. Persons objecting to the determination may file a protest, in accordance with 18 CFR 275.203 and 275.204, within 20 days after the date this notice is issued by the Commission.

Lois D. Cashell,

Secretary.

[FR Doc. 93–9878 Filed 4–27–93; 8:45 am]

BILLING CODE 6717–01–M

[Docket No. RS93–2–000]

Algonquin LNG, Inc.: Change in FERC Docket Number and Compliance Filing With Order No. 636

April 23, 1993.

Take notice that on February 1, 1993, Algonquin LNG, Inc. (ALNG) tendered for filing the following proposed tariff sheets to its FERC Gas Tariff:

First Revised Volume No. 1:
Original Sheet No. 1 through Original Sheet No. 200
Fourth Revised Volume No. 2:
Original Sheet No. 1 through Original Sheet No. 103

This filing was previously noticed on February 11, 1993, under Docket Nos. CP92–166–002 and CP92–166–001. The notice appeared in the **Federal Register** on February 17, 1993 (58 FR 8938). Details of this filing may be found in that notice. This filing has now been redocketed under Docket No. RS93–2–000.

Copies of the filing were served upon the company's jurisdictional customers and interested state commissions. Any person desiring to be heard or to protest said filing should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, DC 20426, in accordance with §§ 385.214 and 385.211 of the Commission's Rules and Regulations. All such motions or protests should be filed on or before April 30, 1993. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a motion to intervene. Copies of this filing are on file with the Commission and are available for public inspection in the Public Reference Room.

Lois D. Cashell,

Secretary.

[FR Doc. 93–9911 Filed 4–27–93; 8:45 am]

BILLING CODE 6717–01–M

[Docket No. RP92–45–003]

ANR Pipeline Co.; Proposed Changes in FERC Gas Tariff

April 22, 1993.

Take notice that on April 16, 1993, ANR Pipeline Company ("ANR") tendered for filing with the Federal Energy Regulatory Commission ("Commission") Second Substitute Eighth Revised Sheet No. 570 under Rate Schedule X–64 of Original Volume No. 2 of its FERC Gas Tariff to be effective for refund purposes for the period January 1, 1992 through December 31, 1992.

ANR states that this compliance filing is being made to reduce the monthly charge under Rate Schedule X–64 to reflect the final depreciation rate in HIOS Docket No. RP92–50. The reduction to the monthly charge is in accordance with the Commission's Letter Orders dated October 26, 1992 and January 8, 1993 in Docket Nos. RP92–45–001 and RP92–45–002, respectively.

Any person desiring to protest said filing should file a protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, DC 20426, in accordance with Rule 211 of the Commission's Rules of Practice and Procedure 18 CFR 385.211. All such protests should be filed on or before April 29, 1993. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Copies of this filing are on file with the Commission and are available for public inspection.

Lois D. Cashell,

Secretary.

[FR Doc. 93–9875 Filed 4–27–93; 8:45 am]

BILLING CODE 6717–01–M

[Docket No. EG93–45–000]

Belize Electric Co. Ltd.; Application for Commission Determination of Exempt Wholesale Generator Status

April 21, 1993.

On April 14, 1993, Belize Electric Company Limited ("BECOL") filed with the Federal Energy Regulatory Commission an application for determination of exempt wholesale generator status pursuant to part 365 of the Commission's regulations.

BECOL, a Belizean corporation, is owned in part by Dominion Energy Central America, Inc., a Belizean corporation and a wholly-owned subsidiary of Dominion Energy, Inc. ("DEI"), which is a wholly-owned subsidiary of Dominion Resources, Inc. ("Dominion"). DEI and Dominion are Virginia corporations.

BECOL is constructing and will own a 24 MW hydroelectric eligible facility on the Macal River in Cayo District, Belize, Central America.

Any person desiring to be heard concerning the application for exempt wholesale generator status should file a motion to intervene or comments with the Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, DC 20426, in accordance with §§ 385.211 and 385.214 of the Commission's Rules of Practice and Procedure. The Commission will limit its consideration of comments to those that concern the adequacy or accuracy of the application. All such motions and comments should be filed on or before May 7, 1993 and must be served on the applicant (c/o Michael W. Maupin, Esq., Hunton & Williams, Riverfront Plaza, East Tower, 951 East Byrd Street, Richmond, Virginia 23219). Any person wishing to become a party must file a motion to intervene. Copies of this filing are on file with the Commission and are available for public inspection.

Lois D. Cashell,

Secretary.

[FR Doc. 93–9880 Filed 4–27–93; 8:45 am]

BILLING CODE 6717–01–M

[Docket No. RP93–4–000]

Mississippi River Transmission Corp.; Informal Settlement Conference

April 22, 1993.

Take notice that an informal settlement conference will be convened in this proceeding on May 10, 1993, at 1 p.m., and continue on May 11, 1993 at 10 a.m., at the offices of the Federal Energy Regulatory Commission, 810 First Street, NE., Washington, DC, for the purpose of exploring the possible settlement of issues in the above-referenced docket.

Any party, as defined by 18 CFR 385.102(c), or any participant, as defined in 18 CFR 385.102(b), is invited to attend. Persons working to become a party must move to intervene and receive intervenor status pursuant to the Commission's regulations (18 CFR 385.214).

For additional information, contact Warren C. Wood at (202) 208–2091 or John J. Keating at (202) 208–0762.

Lois D. Cashell,

Secretary.

[FR Doc. 93–9873 Filed 4–27–93; 8:45 am]

BILLING CODE 6717–01–M

[Docket No. RP93–103–000]

National Fuel Gas Supply Corp.; Proposed Changes in FERC Gas Tariff

April 22, 1993.

Take notice that on April 19, 1993, National Fuel Gas Supply Corporation (National) tendered for filing, as a rate decrease, Third Revised Volume No. 1, First Revised Sheet Nos. 5 and 6, to be effective on the date National's restructuring filing at Docket No. RS92–21–000 is made effective.

National states that the purpose of these tariff sheets is to decrease National's rates to the limited extent necessary to reflect the end of National's gas acquisition function. National states that as a consequence of National's implementation of Order No. 636 and the resulting elimination of the gas acquisition function within National, this function will be transferred on the effective date of National's restructuring to National's affiliate, National Fuel Gas Distribution Corporation.

National states that copies of the letter are being mailed to each of National's jurisdictional customers and interested state commissions.

Any person desiring to be heard or to protest said filing should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, DC 20426, in accordance with 18 CFR 385.214 and 385.211 of the Commission's Rules and Regulations. All such motions or protests should be filed on or before April 29, 1993. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a motion to intervene. Copies of this filing are on file with the Commission and are available for public inspection in the public reference room.

Lois D. Cashell,

Secretary.

[FR Doc. 93–9877 Filed 4–27–93; 8:45 am]

BILLING CODE 6717–01–M

[Docket No. PR93–9–000]

Seagull Shoreline System; Petition for Rate Approval

April 23, 1993.

Take notice that on April 13, 1993, Seagull Shoreline System filed pursuant to § 284.123(b)(2) of the Commission's regulations, a petition for rate approval requesting that the Commission approve as fair and equitable a maximum rate of 9.06 cents per MMBtu for transportation of natural gas under section 311(a)(2) of the Natural Gas Policy Act of 1978 (NGPA).

Seagull Shoreline's petition states that it owns an intrastate pipeline extending approximately fifty-three miles from state tract MAT Block 624 to a Texas onshore interconnection with Houston Pipe Line Company and then extending thirteen miles to interconnections with Valero Transmission, L.P. and Texas Eastern Transmission Corporation. Seagull Shoreline's previous rate was 7.5 cents per MMBtu and was approved by the Commission in Docket No. PR90–5–000 on January 23, 1991.

Pursuant to § 284.123(b)(2)(ii), if the Commission does not act within 150 days of the filing date, the rate will be deemed to be fair and equitable and not in excess of an amount which interstate pipelines would be permitted to charge for similar transportation service. The Commission may, prior to the expiration of the 150 day period, extend the time for action or institute a proceeding to afford parties an opportunity for written comments and for the oral presentation of views, data and arguments.

Any person desiring to participate in this rate proceeding must file a motion to intervene in accordance with §§ 385.211 and 385.214 of the Commission's Rules of Practice and Procedures. All motions must be filed with the Secretary of the Commission on or before May 11, 1993. The petition for rate approval is on file with the Commission and is available for public inspection.

Lois D. Cashell,

Secretary.

[FR Doc. 93–9913 Filed 4–27–93; 8:45 am]

BILLING CODE 6717–01–M

[Docket No. ER93–492–000]

South Carolina Electric & Gas Co.; Filing

April 23, 1993.

Take notice that on March 23, 1993, South Carolina Electric & Gas Company (SCEG) tendered for filing an amendment to its original filing filed in this docket on March 5, 1993.

Any person desiring to be heard or to protest said filing should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 18 CFR 385.214). All such motions or protests should be filed on or before May 4, 1993. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a motion to intervene. Copies of this filing are on file with the Commission and are available for public inspection.

Lois D. Cashell,

Secretary.

[FR Doc. 93–9912 Filed 4–27–93; 8:45 am]

BILLING CODE 6717–01–M

[Docket No. RP92–162–006]

Superior Offshore Pipeline Co.; Compliance Filing

April 23, 1993.

Take notice that Superior Offshore Pipeline Company (SOPCO) on March 9, 1993, tendered for filing as part of its FERC Gas Tariff, First Revised Volume No. 1, the following revised tariff sheets reflecting the new rates for Firm and Interruptible transportation services Upstream and Downstream of the Lowry Gas Plant:

Second Revised Sheet No. 5
Second Revised Sheet No. 6

SOPCO states that the revised tariff sheets are being filed pursuant to the Stipulation and Agreement as filed on December 29, 1992 and approved by Commission's letter order issued February 24, 1993.

Any person desiring to protest said filing should file a protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, DC 20426, in accordance with Rule 211 of the Commission's Rules of Practice and Procedure 18 CFR 385.211. All such protests should be filed on or before April 30, 1993. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Copies of this filing are on file with the Commission and are available for public inspection.

Lois D. Cashell,

Secretary.

[FR Doc. 93–9910 Filed 4–27–93; 8:45 am]

BILLING CODE 6717–01–M

[Docket Nos. RP86–119–028, RP92–220–004, RP86–119–031, and RP92–220–000]

Tennessee Gas Pipeline Co.; Compliance Filing

April 22, 1993.

Take notice that on April 15, 1993, Tennessee Gas Pipeline Company ("Tennessee"), P.O. Box 2511, Houston, Texas 77252, filed the following tariff sheets:

To be effective July 1, 1992

Substitute Original Sheet No. 94
Substitute Original Sheet No. 103
Substitute Original Sheet No. 111
First Revised Sheet No. 142
First Revised Sheet No. 147
2nd Substitute Original Sheet No. 293

To be effective October 1, 1992

Substitute First Revised Sheet No. 94
Substitute First Revised Sheet No. 103
Substitute First Revised Sheet No. 111

The purpose of this filing is to comply with the Commission's Order on Compliance Filing in this docket issued on March 17, 1993. The Commission ordered Tennessee to file revised tariff sheets to: (1) Include the methodology used to determine the applicable fuel rate for Tennessee's storage rate schedules, (2) revise the interruption provision of its Rate Schedule FSST to be consistent with the revisions made to Rate Schedule SST, and (3) revise the Excuse of Performance provision of its tariff to eliminate certain language that created ambiguity.

Tennessee states that copies of the filing have been mailed to all of its jurisdictional customers and affected state regulatory commission.

Any person desiring to protest said filing should file a protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, DC 20426, in accordance with Rule 211 of the Commission's Rules of Practice and Procedure 18 CFR 385.211. All such protests should be filed on or before April 29, 1993. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Copies of this filing are on file with the Commission and are available for public inspection.

Lois D. Cashell,

Secretary.

[FR Doc. 93–9876 Filed 4–27–93; 8:45 am]

BILLING CODE 6717–01–M

[Docket Nos. RP93–56–001 and RP93–86–001]

Transwestern Pipeline Co.; Compliance Filing

April 22, 1993.

Take notice that Transwestern Pipeline Company (Transwestern) on April 15, 1993, tendered for filing as part of its FERC Gas Tariff, Second Revised Volume No. 1, the following tariff sheets:

Effective April 1, 1993

Substitute Alternate 100th Revised Sheet No. 5
Substitute 6th Revised Sheet No. 5A
Substitute 2nd Revised Sheet No. 5A.01
Substitute 2nd Revised Sheet No. 5A.02
Substitute 2nd Revised Sheet No. 5A.03
Substitute 2nd Revised Sheet No. 5A.04
Substitute 7th Revised Sheet No. 87
Substitute 8th Revised Sheet No. 87

Transwestern states that the above-referenced tariff sheets and the Mcf-miles allocation methodology information are being filed to comply with the Commission's Order issued March 31, 1993 in Docket Nos. RP93–56–000 and RP93–86–000. The Order required Transwestern to refile revised tariff sheets within fifteen (15) days of the date of the order to state in § 25.1(b) of the General Terms and Conditions that Section 25.9 applies to the described TCR mechanism. Transwestern states it is also submitting corrected rate sheets which reflect Transwestern's transportation rates filed on January 29, 1993 and approved in Docket No. RS92–87.

The Order also directed Transwestern to provide its customers with all information necessary to allow those customers to assess the impact of its change in allocation methodology from Mcf-miles to an exit-point volumetric surcharge. Transwestern further states that it is submitting a study which calculates the TCR C surcharge rates using the Mcf-miles allocation methodology. The Order permitted parties to file comments with the Commission within 45 days of the date of the order.

Transwestern states that copies of the filing were served on its jurisdictional customers, interested state commissions, and all parties to this proceeding.

Any person desiring to file comments on the filing or protest said filing should file comments and/or protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, DC 20426, in accordance with Rule 211 of the Commission's Rules of Practice and Procedure 18 CFR 385.211. All such comments and/or protests should be filed on or before May 17, 1993. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Copies of this filing are on file with the Commission and are available for public inspection.

Lois D. Cashell,

Secretary.

[FR Doc. 93–9879 Filed 4–27–93; 8:45 am]

BILLING CODE 6717–01–M

[Docket No. TQ93–2–43–000]

Williams Natural Gas Co.; Proposed Changes In FERC Gas Tariff

April 22, 1993.

Take notice that Williams Natural Gas Company (WNG) on April 19, 1993 tendered for filing the following tariff sheets to its FERC Gas Tariff, First Revised Volume No. 1:

Second Revised Fourteenth Revised Sheet No. 6
Second Revised Fifteenth Revised Sheet No. 6A
First Revised Fifteenth Revised Sheet No. 9

WNG states that it is filing an Out-of-Cycle Purchased Gas Adjustment filing to increase its rates effective April 1, 1993 to reflect an increase of $.2157 in the Cumulative Adjustment consistent with its revised service agreements approved July 17, 1992 in Docket No. GT92–21–000.

WNG states that copies of its filing were served on all jurisdictional customers and interested state commissions.

Any person desiring to be heard or to protest said filing should file a motion to intervene or a protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, DC 20426, in accordance with §§ 385.211 and 385.214 of the Commission's Rules and Regulations. All such motions or protests should be filed on or before April 29, 1993. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a motion to intervene. Copies of this filing are on file with the Commission and are available for public inspection in the Public Reference Room.

Lois D. Cashell,

Secretary.

[FR Doc. 93–9874 Filed 4–27–93; 8:45 am]

BILLING CODE 6717–01–M

ENVIRONMENTAL PROTECTION AGENCY

[FRL 4618–8]

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; where appropriate, it includes the actual data collection instrument.

DATES: Comments must be submitted on or before May 28, 1993.

FOR FURTHER INFORMATION CONTACT: Sandy Farmer at EPA, (202) 260–2740.

SUPPLEMENTARY INFORMATION:

Office of Solid Waste and Emergency Response

Title: Response Action Contractor Indemnification; EPA ICR #1595.02. This ICR requests approval of a new collection.

Abstract: Section 119(c) of the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA, 1980 and 1986) provides that the Federal Government may indemnify Response Action Contractors (RACs) for negligent actions that cause the release of a hazardous substance, pollutant or contaminant from a Superfund site. Before government indemnificaton, the government must determine that the liability coverage in an indemnification agreement exceeds or is not covered by insurance available at a fair and reasonable price.

This ICR identifies the minimum information needed for the government to determine that a RAC has made a diligent effort to locate pollution liability insurance to cover third-party liability. The information collected also forms the basis for the government's determination of whether or not the insurance is adequate and whether or not the premium is fair and reasonable.

The following information must be submitted to EPA in writing before the government will consider providing indemnification under CERCLA section 119:

(1) A copy of the declaration page from a current pollution liability insurance policy; or

(2) Letters from three pollution liability insurance vendors indicating that such pollution liability insurance is not available and why; or

(3) A written quotation for pollution liability insurance. The quotation must be in the form of a letter from an insurance broker indicating that the broker contacted three different insurance companies. The quotation should include the following information: Name of insurer, type of policy, policy period, premium, projected annual receipts, retroactive date, limits, deductibles, major exclusions, services covered, and expiration date of contract.

Burden Statement: The estimated annual reporting burden for this collection of information is estimated to average between 275 hours and 591 hours per response, and to require three hours of recordkeeping. This includes the time for reviewing instructions, searching existing data sources, gathering and maintaining the needed data, and completing and reviewing the collection of information. The burden for providing this information will vary, depending on whether the RAC already has a pollution liability insurance policy in place, the RAC works through an insurance broker, or the RAC submits separate insurance applications to three different insurance vendors.

Estimated No. of Respondents: 312 prime or subcontractors.

Estimated Total Annual Burden on Respondents: 130,776 hours.

Frequency of Collection: varies; RACs with site-specific contracts will only have to locate pollution liability insurance once; RACs with multi-site contracts may be required to make an effort to locate insurance on an annual basis, and every time remedial action work begins at a new site.

Send comments regarding the burden estimate, or any other aspect of this information collection, including suggestions for reducing the burden, to:

Sandy Farmer, U.S. Environmental Protection Agency, Information Policy Branch (PM–223Y), 401 M Street, SW., Washington, DC 20460,
and
Tim Hunt, Office of Management and Budget, Office of Information and Regulatory Affairs, 725 17th Street, NW., Washington, DC 20530.

Dated: April 22, 1993.

Paul Lapsley,

Director, Regulatory Management Division.

[FR Doc. 93–9955 Filed 4–27–93; 8:45 am]

BILLING CODE 6560–50–M

[FRL–4618–4]

Science Advisory Board, Ecological Processes and Effects Committee, Biological Criteria Subcommittee; Open Meeting

May 13–14, 1993.

Pursuant to the Federal Advisory Committee Act, Public Law 92–463, notice is hereby given that the Biological Criteria Subcommittee (the Subcommittee) of the Ecological Processes and Effects Committee of the Science Advisory Board will meet on May 13–14, 1993, at the Quality Inn Capitol Hill, 415 New Jersey Avenue, NW., Washington, DC 20001. The meeting is open to the public, and will begin on both days at 8:30 a.m. and end no later than 4:30 p.m. on May 14. Seating at the meeting will be on a first come basis.

Background

The Subcommittee will meet to review the draft document "Biological Criteria: Technical Guidance for Streams and Small Rivers." As part of the Charge to the Subcommittee, the Agency has requested the SAB to evaluate the adequacy of the proposed methodology in four areas:

1. Will the recommended multimetric approach to evaluating aquatic communities adequately characterize the resource?

2. Does the recommended approach to sampling frequency adequately account for seasonal variability?

3. Are the options presented for selecting reference conditions scientifically sound?

4. Does the recommended approach to selection and aggregation of biological information provide a sound basis for the development of biological criteria?

Availability of Documents and Information

Single copies of the draft guidance document and background materials provided to the Subcommittee for this review are available from Dr. George Gibson, U.S. EPA, Office of Science and Technology, Health and Ecological Criteria Division, 401 M Street, SW. (WH–586), telephone (202) 260–7580. For additional information concerning this meeting or to obtain a draft agenda, please contact Ms. Stephanie Sanzone, Designated Federal Official, or Mrs. Marcia Jolly, Staff Secretary, at (202) 260–6552, Ecological Processes and Effects Committee, Science Advisory Board (A–101F), U.S. Environmental Protection Agency, 401 M Street, SW., Washington, DC 20460. Anyone wishing to make a presentation at the meeting must notify Mrs. Jolly and forward twenty-five copies of a written statement to her no later than May 3, 1993. Oral comments to the Subcommittee will be limited to five minutes per individual, and should not be repetitive of previously submitted written statements.

Dated: April 15, 1993.

A.R. Flaak,

Acting Staff Director, Science Advisory Board.

[FR Doc. 93–9953 Filed 4–27–93; 8:45 am]

BILLING CODE 6560–50–P

[OPP–30336B; FRL–4582–4]

Ciba-Geigy Corp.; Approval of Pesticide Product Registrations

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice announces Agency approval of applications submitted by Ciba-Geigy Corporation to conditionally register the pesticide products Primo and Cimectacarb Technical containing a new active ingredient not included in any previously registered products pursuant to the provisions of section 3(c)(7)(C) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended.

FOR FURTHER INFORMATION CONTACT: By mail: Joanne I. Miller, Product Manager (PM) 23, Registration Division (H7505C), Office of Pesticide Programs, 401 M St., SW., Washington, DC 20460. Office location and telephone number: Rm. 237, CM #2, Environmental Protection Agency, 1921 Jefferson Davis Hwy, Arlington, VA 22202, (703–305–7850).

SUPPLEMENTARY INFORMATION: EPA issued a notice published in the **Federal Register** of May 29, 1992 (57 FR 22749), which announced that Ciba-Geigy Corp., PO Box 18300, Greensboro, NC 27419, had submitted an application to register the pesticide product Primo (EPA File Symbol 100–TEO) containing 12 percent of the active ingredient cimectacarb 4-(cyclopropyl-alpha-hydroxy-methylene)-3,5-dioxo-cyclohexanecarboxylic acid ethyl ester, an active ingredient not included in any previously registered product.

EPA also received an application from Ciba-Geigy to register the product *Cimectacarb Technical* (EPA File Symbol 100–TET), which was inadvertently omitted from the notice that published in the **Federal Register** of May 29, 1992. The product contains 92 percent of the same active ingredient as listed above. However, since the notice of receipt of application for *Cimectacarb Technical* was not published in the **Federal Register**, as required by section 3(c)(4) of FIFRA, as amended, interested parties may submit written comments within 30 days from the date of publication of this notice for this product only.

These applications were approved on February 11, 1993 as Primo (EPA Registration Number 100–729) for managing growth, improving quality, and edging of warm and cool season turfgrasses and Cimectacarb Technical (EPA Registration Number 100–727) for formulating into end use turf growth regulators intended for use in managing growth of warm and cool season turfgrasses.

A conditional registration may be granted under section 3(c)(7)(C) of FIFRA for a new active ingredient where certain data are lacking because a period reasonably sufficient for generation of the data has not elapsed since the Administrator first imposed the data requirements, on condition that such data are received by the end of the conditional registration period and do not meet or exceed the risk criteria set forth in 40 CFR 154.7; that use of the pesticide during the conditional registration period will not cause unreasonable adverse effects on the environment; and that use of the pesticide is in the public interest.

The Agency has considered the available data on the risks associated with the proposed use of cimectacarb 4-(cyclopropyl-alpha-hydroxy-methylene)-3,5-dioxo-cyclohexanecarboxylic acid ethyl ester, and information on social, economic, and environmental benefits to be derived from such use. Specifically, the Agency has considered the nature of the chemical and its pattern of use, application methods and rates, and level and extent of potential exposure. Based on these reviews, the Agency was able to make basic health and safety determinations which show that use of cimectacarb 4-(cyclopropyl-alpha-hydroxy-methylene)-3,5-dioxo-cyclohexanecarboxylic acid ethyl ester during the period of conditional registration is not expected to cause any unreasonable adverse effect on the environment, and that use of the pesticide is in the public interest.

Consistent with section 3(c)(7)(C), the Agency has determined that these conditional registrations are in the public interest. Use of the pesticides are of significance to the user community, and appropriate labeling, use directions, and other measures have been taken to ensure that use of the pesticides will not result in unreasonable adverse effects to man and the environment.

More detailed information on these conditional registrations is contained in the EPA Pesticide Fact Sheet, Number 239, for cimectacarb 4-(cyclopropyl-alpha-hydroxy-methylene)-3,5-dioxo-cyclohexanecarboxylic acid ethyl ester.

A copy of the fact sheet, which provides a summary description of the chemical, use patterns and formulations, science findings, and the Agency's regulatory position and rationale, may be obtained from the National Technical Information Service (NTIS), 5285 Port Royal Road, Springfield, VA 22161.

In accordance with section 3(c)(2) of FIFRA, a copy of the approved label and the list of data references used to support registration are available for public inspection in the office of the Product Manager. The data and other scientific information used to support registration, except for material specifically protected by section 10 of FIFRA, are available for public inspection in the Public Response and Program Resources Branch, Field Operations Division (H7506C), Office of Pesticide Programs, Environmental Protection Agency, rm. 1128, CM #2, Arlington, VA 22202 (703–305–5805). Requests for data must be made in accordance with the provisions of the Freedom of Information Act and must be addressed to the Freedom of Information Office (A–101), 401 M St., SW., Washington, DC 20460. Such requests should: (1) Identify the product name and registration number and (2) specify the data or information desired.

Authority: 7 U.S.C. 136.

Dated: April 19, 1993.

Douglas D. Campt,

Director, Office of Pesticide Programs.

[FR Doc. 93–9811 Filed 4–27–93; 8:45 am]

BILLING CODE 6560–50–F

[OPP–30328A; FRL–4580–5]

Sandoz Agro, Inc.; Approval of Pesticide Product Registrations

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice announces Agency approval of applications submitted by Sandoz Agro, Inc., to conditionally register the pesticide products Frontier Herbicide and San 582H, containing a new active ingredient not included in any previously registered products pursuant to the provisions of section 3(c)(7)(C) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended.

FOR FURTHER INFORMATION CONTACT: By mail: Cynthia Giles-Parker, Product Manager (PM) 22, Registration Division (H7505C), Office of Pesticide Programs, 401 M St., SW., Washington, DC 20460. Office location and telephone number: Rm. 229, CM #2, Environmental Protection Agency, 1921 Jefferson Davis Hwy, Arlington, VA 22202, (703–305–5540).

SUPPLEMENTARY INFORMATION: EPA issued a notice published in the **Federal Register** of December 11, 1991 (56 FR 64624), which announced that Sandoz Crop Protection Corp., 1300 East Touhy

Avenue, Des Plaines, IL 60018, had submitted applications to register the pesticide products San 582 7.5L Herbicide and San 582H (EPA File Symbols 55947–RUN and 55947–RUR) containing the active ingredient 2-chloro-*N*-[(1-methyl-2-methoxy)ethyl]-*N*-(2,4-dimethyl-thien-3-yl)acetamide at 78.5 and 94 percent respectively, an active ingredient not included in any previously registered products.

These applications were approved on March 5, 1993, as Frontier Herbicide (formerly San 582H 7.5L Herbicide), for weed control in field corn (EPA Registration Number 55947–140) and San 582H for manufacturing use only (EPA Registration Number 55947–141).

A conditional registration may be granted under section 3(c)(7)(C) of FIFRA for a new active ingredient where certain data are lacking because a period reasonably sufficient for generation of the data has not elapsed since the Administrator first imposed the data requirements, on condition that such data are received by the end of the conditional registration period and do not meet or exceed the risk criteria set forth in 40 CFR 154.7; that use of the pesticide during the conditional registration period will not cause unreasonable adverse effects on the environment; and that use of the pesticide is in the public interest.

The Agency has considered the available data on the risks associated with the proposed use of dimethenamid 2-chloro-*N*-[(1-methyl-2-methoxy)ethyl]-*N*-(2,4-dimethyl-thien-3-yl)-acetamide, and information on social, economic, and environmental benefits to be derived from such use. Specifically, the Agency has considered the nature of the chemical and its pattern of use, application methods and rates, and level and extent of potential exposure. Based on these reviews, the Agency was able to make basic health and safety determinations which show that use of dimethenamid 2-chloro-*N*-[(1-methyl-2-methoxy)ethyl]-*N*-(2,4-dimethyl-thien-3-yl)-acetamide during the period of conditional registration is not expected to cause any unreasonable adverse effect on the environment, and that use of the pesticide is in the public interest.

Consistent with section 3(c)(7)(C), the Agency has determined that these conditional registrations are in the public interest. Use of the pesticides are of significance to the user community, and appropriate labeling, use directions, and other measures have been taken to ensure that use of the pesticides will not result in unreasonable adverse effects to man and the environment.

More detailed information on these conditional registrations is contained on an EPA Pesticide Fact Sheet for dimethenamid 2-chloro-*N*-[(1-methyl-2-methoxy)ethyl]-*N*-(2,4-dimethyl-thien-3-yl)-acetamide.

A copy of the fact sheet, which provides a summary description of the chemical, use patterns and formulations, science findings, and the Agency's regulatory position and rationale, may be obtained from the National Technical Information Service (NTIS), 5285 Port Royal Road, Springfield, VA 22161.

In accordance with section 3(c)(2) of FIFRA, a copy of the approved label and the list of data references used to support registration are available for public inspection in the office of the Product Manager. The data and other scientific information used to support registration, except for material specifically protected by section 10 of FIFRA, are available for public inspection in the Public Response and Program Resources Branch, Field Operations Division (H7506C), Office of Pesticide Programs, Environmental Protection Agency, rm. 1128, CM #2, Arlington, VA 22202 (703–305–5805). Requests for data must be made in accordance with the provisions of the Freedom of Information Act and must be addressed to the Freedom of Information Office (A–101), 401 M St., SW., Washington, DC 20460. Such requests should: (1) Identify the product name and registration number and (2) specify the data or information desired.

Authority: 7 U.S.C. 136.

Dated: April 12, 1993.

Douglas D. Campt,

Director, Office of Pesticide Programs.

[FR Doc. 93–9815 Filed 4–27–93; 8:45 am]

BILLING CODE 6560–50–F

[OPP–180891; FRL 4584–2]

Receipt of Application for Emergency Exemption to Use Tebuconazole; Solicitation of Public Comment

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: EPA has received a specific exemption request from the South Carolina Department of Fertilizer and Pesticide Control, Clemson University (hereafter referred to as the "Applicant") for use of the pesticide tebuconazole (CAS No. 107534–96–3) to control Rhizoctonia limb rot and Southern stem rot on up to 14,000 acres of peanuts in South Carolina. In accordance with 40 CFR 166.24, EPA is soliciting public comment before making the decision whether or not to grant the exemption.

DATES: Comments must be received on or before May 12, 1993.

ADDRESSES: Three copies of written comments, bearing the identification notation "OPP–180891," should be submitted by mail to: Public Response and Human Resource Branch, Field Operations Division (H7506C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person, bring comments to: Rm. 1128, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA. Information submitted in any comment concerning this notice may be claimed confidential by marking any part or all of that information as "Confidential Business Information." Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the comment that does not contain Confidential Business Information must be provided by the submitter for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice. All written comments filed pursuant to this notice will be available for public inspection in rm. 1128, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA, from 8 a.m. to 4 p.m., Monday through Friday, except legal holidays.

FOR FURTHER INFORMATION CONTACT: By mail: Susan Stanton, Registration Division (H7505W), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location and telephone number: 6th Floor, Crystal Station I, 2800 Jefferson Davis Highway, Arlington, VA 22202 (703–308–8327).

SUPPLEMENTARY INFORMATION: Pursuant to section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) (7 U.S.C. 136p), the Administrator may, at his discretion, exempt a State agency from any registration provision of FIFRA if he determines that emergency conditions exist which require such exemption. The Applicant has requested the Administrator to issue a specific exemption for the use of the fungicide, tebuconazole, available as Folicur 3.6F from Miles, Inc., to control Southern stem rot and Rhizoctonia limb rot on up to 14,000 acres of peanuts in South Carolina. Information in accordance with 40 CFR part 166 was submitted as part of this request.

According to the Applicant, Southern stem rot, caused by the fungus, *Sclerotium rolfsii*, is responsible for statewide yield losses of between 3 and 10 percent in South Carolina peanut

fields, with losses of 50 to 60 percent in some fields. Rhizoctonia limb rot, caused by the fungus, *Rhizoctonia solani*, has emerged as another important disease of peanuts in the southeastern U.S., causing statewide yield losses in South Carolina of 1.5 percent annually, with losses of up to 40 percent in some field tests in recent years. According to the Applicant, no registered pesticides or alternative practices are available that will adequately control these two diseases. If tebuconazole is not available for use, economic losses of more than $4 million are expected due to stem rot and limb rot.

Under the proposed exemption, up to 4 ground applications of Folicur 3.6F would be made at 0.5 pint of product (0.225 pounds a.i.) per acre. A maximum of 2.0 pints of product (0.9 pounds a.i.) would be applied per acre per season. No applications would be made within 14 days of harvest. A maximum of 3,500 gallons of product (12,600 pounds a.i.) would be needed to treat up to 14,000 acres of peanuts.

This notice does not constitute a decision by EPA on the application itself. The regulations governing section 18 require that the Agency publish notice of receipt in the **Federal Register** and solicit public comment on an application for a specific exemption proposing use of a new chemical (i.e., an active ingredient not contained in any currently registered pesticide) (40 CFR 166.24 (a)(1)). Tebuconazole is a new chemical. Accordingly, interested persons may submit written views on this subject to the Field Operations Division at the address above. The Agency will review and consider all comments received during the comment period in determining whether to issue the emergency exemption requested by the South Carolina Department of Fertilizer and Pesticide Control.

Dated: April 14, 1993.

Lawrence E. Culleen,

Acting Director, Registration Division, Office of Pesticide Programs.

[FR Doc. 93–9813 Filed 4–27–93; 8:45 am]

BILLING CODE 6560–50–F

[FRL–4616–7]

Labat-Anderson, Inc.; Access to Trade Secret Information

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: EPA has authorized Labat-Anderson, Incorporated of Arlington, Virginia, for access to information submitted to EPA pursuant to sections 303, 311, 312, 313, and 322 of the Emergency Planning and Community Right-to-Know Act of 1986 (EPCRA), also known as Title III of the Superfund Amendments and Reauthorization Act of 1986 (SARA). Specifically, access concerns trade secrecy claims by industry under sections 303, 311, 312, and 313.

DATES: Access to the trade secret information submitted to EPA will occur on May 6, 1993.

FOR FURTHER INFORMATION CONTACT: Dorothy McManus, Chemical Emergency Preparedness and Prevention Office (CEPPO), Office of Solid Waste and Emergency Response, OS–120, Environmental Protection Agency, Rm. 3101B, 401 M St., SW., Washington, DC 20460, Telephone: 202–260–8606.

SUPPLEMENTARY INFORMATION: Under Title III, facilities must send trade secrecy claims regarding their Section 303, 311, 312, and 313 submittals to EPA.

Under contract number 68–WO–0022, awarded to ICF Incorporated, Labat-Anderson, Incorporated under Subcontract No. EPA–99–03 will continue to assist the Chemical Emergency Preparedness and Prevention Office (Office of Solid Waste and Emergency Response) in receiving and processing the information submitted by industry. EPA has determined that Labat-Anderson, Incorporated will require access to trade secret information, and in so doing, Labat-Anderson, Incorporated will follow all required security procedures.

EPA is issuing this notice to inform all submitters of trade secret information under the aforementioned Title III sections that EPA will provide Labat-Anderson, Incorporated access to these trade secret materials. Upon termination of their contract, or prior to termination of their contract at EPA's request, Labat-Anderson, Incorporated will return all material to EPA.

EPA announced clearance to access to EPCRA trade secret information by Labat-Anderson, Incorporated in a notice published in the **Federal Register** of August 8, 1988 (53 FR No. 152). Pursuant to this notice, access to clearance to EPCRA trade secret information under this contract is extended and expected to expire on September 30, 1993.

Dated: April 21, 1993.

Richard J. Guimond,

Assistant Surgeon General, USPHS, Acting Assistant Administrator.

[FR Doc. 93–9952 Filed 4–27–93; 8:45 am]

BILLING CODE 6560–50–P

[FRL–4618–5]

Notice of Proposed Administration Settlement Pursuant to the Comprehensive Environmental Response, Compensation and Liability Act of 1980, as Amended by the Superfund Amendments and Reauthorization Act

AGENCY: Environmental Protection Agency.

ACTION: Notice; request for public comment.

SUMMARY: In accordance with section 122(i) of the Comprehensive Environmental Response, Compensation and Liability Act of 1980, as amended by the Superfund Amendments and Reauthorization Act of 1986 ("CERCLA"), 42 U.S.C. 9622(i), notice is hereby given that a proposed administrative cost recovery settlement concerning the Old City of York Site, York County, PA was issued by the Agency on April 12, 1993. The settlement resolves an EPA claim under section 107 of CERCLA, 42 U.S.C. 9607, against the City of York, PA. The settlement requires the City of York to pay a principal payment of $615,000 over a five year period, and an interest payment of $137,942.02 to the Hazardous Substances Superfund.

For thirty (30) days following the date of publication of this notice, the Agency will receive written comments relating to the settlement. The Agency's response to any comments received will be available for public inspection at the U.S. Environmental Protection Agency, Region III, 841 Chestnut Building, Philadelphia, PA 19107.

DATES: Comments must be submitted on or before May 28, 1993.

Availability

The proposed settlement and additional background information relating to the settlement are available for public inspection at the U.S. Environmental Protection Agency, Region III, 841 Chestnut Building, Philadelphia, PA 19107. A copy of the proposed settlement may be obtained from Susanne Canning, U.S. Environmental Protection Agency, Regional Docket Clerk (3RC00), 841 Chestnut Building, Philadelphia, PA 19107. Comments should reference the

"Old City of York Site" and "EPA Docket No. III–92–37 DC" and should be forwarded to Suzanne Canning at the above address.

FOR FURTHER INFORMATION CONTACT: Patricia C. Miller (3RC22), Assistant Regional Counsel, U.S. Environmental Protection Agency, 841 Chestnut Building, Philadelphia, PA 19107, (215) 597–3440.

Dated: April 20, 1993.

Stanley L. Laskowski,

Acting Regional Administrator, U.S. Environmental Protection Agency, Region III.

[FR Doc. 93–9956 Filed 4–27–93; 8:45 am]

BILLING CODE 6560–50–M

FEDERAL COMMUNICATIONS COMMISSION

Public Information Collection Requirement Submitted to Office of Management and Budget for Review

April 22, 1993.

The Federal Communications Commission has submitted the following information collection requirement to OMB for review and clearance under the Paperwork Reduction Act of 1980 (44 U.S.C. 3507).

Copies of this submission may be purchased from the Commission's copy contractor, International Transcription Service, Inc., 2100 M Street, NW., Suite 140, Washington, DC 20037, (202) 857–3800. For further information on this submission contact Judy Boley, Federal Communications Commission, (202) 632–7513. Persons wishing to comment on this information collection should contact Jonas Neihardt, Office of Management and Budget, Room 3235 NEOB, Washington, DC 20503, (202) 395–4814.

OMB Number: 3060–0009.

Title: Application for Consent to Assignment of Broadcast Station Construction Permit or License or Transfer of Control of Corporation Holding Broadcast Station Construction Permit or License.

Form Number: FCC Form 316.

Action: Revision of a currently approved collection.

Respondents: State or local governments, non-profit institutions, and businesses or other for-profit (including small businesses).

Frequency of Response: On occasion reporting.

Estimated Annual Burden: 920 responses; 3.25 hours average burden per response; 2,990 hours total annual burden.

Needs and Uses: Filing of FCC Form 316 is required when applying for authority for assignment of a radio broadcast station construction permit or license, or for consent to transfer control of corporation holding radio broadcast station construction permit or license where there is a little change in the relative interest or disposition of its interests; where transfer of interest is not a controlling one; where there is no substantial change in the beneficial ownership of the corporation; where the assignment is less than a controlling interest in a partnership; and where there is an appointment of an entity qualified to succeed to the interest of a deceased or legally incapacitated individual permittee, license or controlling stockholder. The data is used by FCC staff to determine if the applicant is qualified to become a Commission licensee or permittee of a commercial or noncommercial broadcast station.

Federal Communications Commission.

Donna R. Searcy,

Secretary.

[FR Doc. 93–9856 Filed 4–27–93; 8:45 am]

BILLING CODE 6712–01–M

FEDERAL EMERGENCY MANAGEMENT AGENCY

[FEMA–3097–EM]

Georgia; Amendment to Notice of an Emergency Declaration

AGENCY: Federal Emergency Management Agency (FEMA).

ACTION: Notice.

SUMMARY: This notice amends the notice of an emergency declaration for the State of Georgia (FEMA–3097–EM), dated March 15, 1993, and related determinations.

EFFECTIVE DATE: April 7, 1993.

FOR FURTHER INFORMATION CONTACT: Pauline C. Campbell, Disaster Assistance Programs, Federal Emergency Management Agency, Washington, DC 20472, (202) 646–3606.

SUPPLEMENTARY INFORMATION: The notice of an emergency declaration for the State of Georgia dated March 15, 1993, is hereby amended to include the following areas among those areas determined to have been adversely affected by the catastrophe declared an emergency by the President in his declaration of March 15, 1993: Assistance for required emergency measures for a period of five (5) days beginning on March 13 for opening critical emergency access on collector roads and streets, minor and principal arterial roads for emergency vehicles. In addition, assistance is authorized for debris removal and emergency protective measures in the counties of: Colquitt, Houston, Liberty, Newton, Screven, and Upson.

(Catalog of Federal Domestic Assistance No. 83.516, Disaster Assistance)

Richard W. Krimm,

Deputy Associate Director, State and Local Programs and Support.

[FR Doc. 93–9916 Filed 4–27–93; 8:45 am]

BILLING CODE 6718–02–M

[FEMA–3097–EM]

Georgia; Amendment to Notice of an Emergency Declaration

AGENCY: Federal Emergency Management Agency (FEMA).

ACTION: Notice.

SUMMARY: This notice amends the notice of an emergency declaration for the State of Georgia, (FEMA–3097–EM), dated March 15, 1993, and related determinations.

EFFECTIVE DATE: April 2, 1993.

FOR FURTHER INFORMATION CONTACT: Pauline C. Campbell, Disaster Assistance Programs, Federal Emergency Management Agency, Washington, DC 20472, (202) 646–3606.

SUPPLEMENTARY INFORMATION: The notice of an emergency declaration for the State of Georgia dated March 15, 1993, is hereby amended to include the following areas among those areas determined to have been adversely affected by the catastrophe declared an emergency by the President in his declaration of March 15, 1993: Assistance for required emergency measures for a period of five (5) days beginning on March 13 for opening critical emergency access on collector roads and streets, minor and principal arterial roads for emergency vehicles. In addition, assistance is authorized for debris removal and emergency protective measures in the counties of: Baldwin, Bibb, Fayette, Henry, Oconee, and Walton.

(Catalog of Federal Domestic Assistance No. 83.516, Disaster Assistance)

Richard W. Krimm,

Deputy Associate Director, State and Local Programs and Support.

[FR Doc. 93–9917 Filed 4–27–93; 8:45 a.m.]

BILLING CODE 6718–02–M

[FEMA–983–DR]

Nebraska; Amendment to Notice of a Major Disaster Declaration

AGENCY: Federal Emergency Management Agency (FEMA).

ACTION: Notice.

SUMMARY: This notice amends the notice of a major disaster for the State of Nebraska, (FEMA–983–DR), dated April 2, 1993, and related determinations.

EFFECTIVE DATE: April 19, 1993.

FOR FURTHER INFORMATION CONTACT: Pauline C. Campbell, Disaster Assistance Programs, Federal Emergency Management Agency, Washington, DC 20472, (202) 646–3606.

SUPPLEMENTARY INFORMATION: The notice of a major disaster for the State of Nebraska dated April 2, 1993, is hereby amended to include the following areas among those areas determined to have been adversely affected by the catastrophe declared a major disaster by the President in his declaration of April 2, 1993: Adams and Hall Counties for Public Assistance.

(Catalog of Federal Domestic Assistance No. 83.516, Disaster Assistance.)

Richard W. Krimm,

Deputy Associate Director, State and Local Programs and Support.

[FR Doc. 93–9915 Filed 4–27–93; 8:45 am]

BILLING CODE 6718–02–M

[FEMA–3095–EM]

Tennessee; Amendment to Notice of an Emergency Declaration

AGENCY: Federal Emergency Management Agency (FEMA).

ACTION: Notice.

SUMMARY: This notice amends the notice of an emergency for the State of Tennessee (FEMA–3095–EM), dated March 14, 1993, and related determinations.

EFFECTIVE DATE: March 29, 1993.

FOR FURTHER INFORMATION CONTACT: Pauline C. Campbell, Disaster Assistance Programs, Federal Emergency Management Agency, Washington, DC 20472, (202) 646–3606.

SUPPLEMENTARY INFORMATION: The notice of an emergency for the State of Tennessee dated March 14, 1993, is hereby amended to include the following areas among those areas determined to have been adversely affected by the catastrophe declared an emergency by the President in his declaration of March 14, 1993: Assistance for required emergency measures for a period of five (5) days beginning on March 13 for opening critical emergency access on collector roads and streets, minor and principal arterial roads for emergency vehicles in the counties of: Bedford, Lawrence, Lincoln, Moore, Rutherford, and Wilson.

(Catalog of Federal Domestic Assistance No. 83.516, Disaster Assistance)

Richard W. Krimm,

Deputy Associate Director, State and Local Programs and Support.

[FR Doc. 93–9914 Filed 4–27–93; 8:45 am]

BILLING CODE 6718–02–M

FEDERAL MARITIME COMMISSION

Ocean Freight Forwarder License; Revocations

Notice is hereby given that the following ocean freight forwarder licenses have been revoked by the Federal Maritime Commission pursuant to section 19 of the Shipping Act of 1984 (46 U.S.C. app. 1718) and the regulations of the Commission pertaining to the licensing of ocean freight forwarders, 46 CFR part 510.

License Number: 3396
Name: SCAC California Inc.
Address: 9133 LaCienega Blvd., Ste. 250, Inglewood, CA 90301
Date Revoked: August 31, 1992
Reason: Surrendered license voluntarily.

License Number: 2594
Name: Federal Container Line, Inc.
Address: 291 Broadway, New York, NY 10007
Date Revoked: March 7, 1993
Reason: Failed to furnish a valid surety bond.

License Number: 3287
Name: Cargo Express International, Inc.
Address: 46 Seller Street, Kearny, NJ 07032
Date Revoked: March 13, 1993
Reason: Failed to furnish a valid surety bond.

License Number: 3354
Name: C. Kramer & Associates, Inc.
Address: 500A S. Douglas St., El Segundo, CA 90245
Date Revoked: March 18, 1993
Reason: Failed to furnish a valid surety bond.

License Number: 3488
Name: Southside Shipping Ltd.
Address: 500 Metropolitan Ave., Brooklyn, NY 11211
Date Revoked: March 18, 1993
Reason: Failed to furnish a valid surety bond.

License Number: 44
Name: Pace Shipping Co., Inc.
Address: 19 Rector Street, New York, NY 10006
Date Revoked: March 26, 1993
Reason: Failed to furnish a valid surety bond.

License Number: 3399
Name: Oceanbridge Shipping International, Inc.
Address: 22431 So. Vermont Ave., Torrance, CA 90502
Date Revoked: March 30, 1993
Reason: Failed to furnish a valid surety bond.

License Number: 3049
Name: Total Cargo Services, Inc.
Address: 6231 NE 112th Ave., Portland, OR 97220
Date Revoked: April 6, 1993
Reason: Surrendered license voluntarily.

License Number: 2891
Name: John G. Grillet dba J. Grillet International
Address: P.O. Box 35935, Houston, TX 77235
Date Revoked: April 15, 1993
Reason: Surrendered license voluntarily.

Bryant L. VanBrakle,

Director, Bureau of Tariffs, Certification and Licensing.

[FR Doc. 93–9919 Filed 4–27–93; 8:45 am]

BILLING CODE 6730–01–M

Ocean Freight Forwarder License Revocations

Notice is hereby given that the following ocean freight forwarder licenses have been revoked by the Federal Maritime Commission pursuant to section 19 of the Shipping Act of 1984 (46 U.S.C. app. 1718) and the regulations of the Commission pertaining to the licensing of ocean freight forwarders, 46 CFR part 510.

License Number: 3396
Name: SCAC California Inc.
Address: 9133 LaCienega Blvd., Ste. 250, Inglewood, CA 90301
Date Revoked: August 31, 1992
Reason: Surrendered license voluntarily.

License Number: 2594
Name: Federal Container Line, Inc.
Address: 291 Broadway, New York, NY 10007
Date Revoked: March 7, 1993
Reason: Failed to furnish a valid surety bond.

License Number: 3287
Name: Cargo Express International, Inc.
Address: 46 Seller Street, Kearny, NJ 07032
Date Revoked: March 13, 1993
Reason: Failed to furnish a valid surety bond.

License Number: 3354
Name: C. Kramer & Associates, Inc.
Address: 500A S. Douglas St., El Segundo, CA 90245
Date Revoked: March 18, 1993
Reason: Failed to furnish a valid surety bond.

License Number: 3488

Name: Southside Shipping Ltd.
Address: 500 Metropolitan Ave., Brooklyn, NY 11211
Date Revoked: March 18, 1993
Reason: Failed to furnish a valid surety bond.

License Number: 44
Name: Pace Shipping Co., Inc.
Address: 19 Rector Street, New York, NY 10006
Date Revoked: March 26, 1993
Reason: Failed to furnish a valid surety bond.

License Number: 3399
Name: Oceanbridge Shipping International, Inc.
Address: 22431 So. Vermont Ave., Torrance, CA 90502
Date Revoked: March 30, 1993
Reason: Failed to furnish a valid surety bond.

License Number: 2891
Name: John G. Grillet dba J. Grillet International
Address: P.O. Box 35935, Houston, TX 77235
Date Revoked: April 15, 1993
Reason: Surrendered license voluntarily.

Bryant L. VanBrakle,

Director, Bureau of Tariffs, Certification and Licensing.

[FR Doc. 93–9883 Filed 4–27–93; 8:45 am]

BILLING CODE 6730–01–M

SeaWay Forwarding Corp. and Danzas Seaway; Correction

By notice published in the **Federal Register** on Wednesday, February 17, 1993 (58 FR 8761) Seaway Forwarding Corporation and Danzas Seaway, Division of Seaway Forwarding Corporation was listed as having its ocean freight forwarder license (No. 1185) revoked because of a failure to furnish a valid bond. This is incorrect. Seaway Forwarding Corporation and Danzas Seaway, Division of Seaway Forwarding Corporation did not have its license revoked due to its failure to furnish a bond. Rather, Seaway Forwarding Corporation and Danzas Seaway, Division of Seaway Forwarding Corporation voluntarily surrendered its license for revocation.

Dated: April 23, 1993.

Bryant L. VanBrakle,

Director, Bureau of Tariffs, Certification and Licensing.

[FR Doc. 93–9918 Filed 4–27–93; 8:45 am]

BILLING CODE 6730–01–M

Ocean Freight Forwarder License; Applicants

Notice is hereby given that the following applicants have filed with the Federal Maritime Commission applications for licenses as ocean freight forwarders pursuant to section 19 of the Shipping Act of 1984 (46 U.S.C. app. 1718 and 46 CFR part 510).

Persons knowing of any reason why any of the following applicants should not receive a license are requested to contact the Office of Freight Forwarders, Federal Maritime Commission, Washington, DC 20573.

U.S. International Transport, Inc., 6508 N.W. 82nd Ave., Miami, FL 33166. Officers: Eduard Fabelo, President, Manuel Orestes Fabelo, Secretary, Zenaida Rodriquez, Vice President

Americargo International Forwarders, Inc., 5495 N.W. 72nd Avenue, Miami, FL 33166. Officers: Marc W. Machon, President, Arcadio Hernandez, Vice President

Bacarella Transportation Services, Inc., 225 Masarik Ave., Stratford, CT 06497. Officers: Anthony Bacarella, President, Rosario Bacarella, Vice President

Aero Expediting Inc., 29205 Airport Drive, Romulus, MI 48174. Officers: Colleen E. Taylor, President, Kathleen A. Raymor, Vice President, David M. Opra, Vice President International

Shipping International, 19811 Misty Pines Drive, Humble, TX 77346, William Eric Carroll, Sole Proprietor

Central Forwarding Inc., 1600 West Loop 340, Waco, TX 76712–0817. Officers: James H. Alexander, President/Treasury/Director, Philip L. Hering, Vice President

Ultra Cargo, Inc., 1540 Meridian Ave., Miami, FL 33139. Officers: Luis Parody, President, Teresita Parody, Vice President

Dated: April 22, 1993.

By the Federal Maritime Commission.

Joseph C. Polking,

Secretary.

[FR Doc. 93–9884 Filed 4–27–93; 8:45 am]

BILLING CODE 6730–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 92N–0139]

Food Labeling; Foods Derived From New Plant Varieties

AGENCY: Food and Drug Administration, HHS.

ACTION: Request for data and information.

SUMMARY: The Food and Drug Administration (FDA) is announcing a request for data and information on certain labeling issues pertaining to the agency's recent statement of policy concerning foods derived from new plant varieties that appeared in the **Federal Register** of May 29, 1992 (57 FR 22984). This request will provide an opportunity for interested persons to present data and other information on these specific issues.

DATES: Written comments by July 27, 1993.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: James H. Maryanski, Center for Food Safety and Applied Nutrition (HFS–13), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–205–4359.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of May 29, 1992 (57 FR 22984), FDA published a document entitled "Statement of Policy: Foods Derived from New Plant Varieties" that clarifies the agency's interpretation of the Federal Food, Drug, and Cosmetic Act (the act) with respect to foods derived from new plant varieties. This policy statement was issued to ensure that relevant scientific, safety, and regulatory issues are resolved prior to the introduction of such foods into the marketplace. In that notice, FDA invited interested persons to submit written comments on or before August 27, 1992. In response to a request, FDA reopened the comment period for an additional 30 days (to October 15, 1992) by a notice in the **Federal Register** of September 15, 1992 (57 FR 42588).

FDA's preliminary review of the comments reflects that several issues were raised frequently with respect to the policy statement, such as: (1) Appropriate labeling of foods derived from new plant varieties developed using "genetic engineering" techniques; (2) the potential allergenicity of foods derived from "genetically engineered" plants; (3) the need for premarket notification to FDA, or agency approval, of all new plant varieties developed using "genetic engineering" techniques; and (4) appropriate testing of foods derived from new plant varieties developed using "genetic engineering" techniques.

FDA seeks to foster public dialogue on issues related to the policy statement so that any needed refinement in the policy can be based on all relevant information and views. One set of issues raised by the comments concerns how foods derived from plants developed via "genetic engineering" should be labeled; FDA believes that this set of issues warrants further dialogue. Because this set of issues raises complex scientific and legal questions, FDA is

announcing this request for additional data and factual information relative to the labeling of foods derived from "genetically engineered" plants. FDA intends to evaluate the data and information received in response to this request to identify specific issues to be discussed at a public forum to be announced in a future issue of the **Federal Register**. FDA's goal is to foster substantive dialogue on how the legal principles under the act apply to the complex issues raised by the comments.

In the near future, FDA intends to engage the scientific community on the question of the potential for food allergy raised by foods derived from new plant varieties, and the agency will announce its plans regarding this question in a future issue of the **Federal Register**. If, upon further review of the comments and other relevant information, FDA determines that the resolution of other issues raised by the comments on the policy statement would benefit from additional information and public discussion, FDA will initiate appropriate proceedings to resolve those issues.

II. Requirements for Labeling

The act provides FDA with the authority to regulate the labeling of foods, including foods derived from new plant varieties. It is in the context of this legal authority that the labeling issues set out below in section III. of this document should be addressed. Here, FDA discusses the labeling requirements of the act and provides some examples to illustrate how the legal principles have been applied to require the disclosure of certain information in labeling for a food.

The requirements for food labeling are in section 403 of the act (21 U.S.C. 343). Under section 403(a)(1) of the act, a food is misbranded if its labeling is false or misleading. Under section 201(n) of the act (21 U.S.C. 321(n)), labeling is misleading if it fails to reveal all facts that are "material in light of * * * representations or material with respect to consequences which may result from the use of the article to which the labeling * * * relates under the conditions of use prescribed in the labeling * * * or under such conditions of use as are customary or usual."

Section 403(i) of the act and regulations promulgated thereunder require that a food product be described by its common or usual name or, in the absence thereof, an appropriately descriptive term (21 CFR 101.3). Section 403(i) of the act also requires that, in the case of foods fabricated from two or more ingredients, a food product bear on the label the common or usual name of each ingredient.

Many consumers commented that they had a right or desire to know that a food had been derived from a plant developed by "genetic engineering." Comments also requested that multi-ingredient foods that contain one or more ingredients developed by "genetic engineering" be so labeled. The principal legal theory that might support such a requirement is that such information is material within the meaning of section 201(n) of the act. In support of these requests, comments cited language in the final rule on food irradiation (April 18, 1986, 51 FR 13376), in which FDA stated:

> Whether information is material under section 201(n) of the act depends not on the abstract worth of the information but on whether consumers view such information as important and whether the omission of label information may mislead a consumer.

Historically, FDA has generally limited the scope of the materiality concept in section 201(n) of the act to information about the attributes of the food itself. With respect to the process of irradiation, FDA concluded that irradiation could cause changes in organoleptic properties of the finished food and that, without special labeling, consumers might assume that such foods were unprocessed (51 FR 13376, April 18, 1986). The fact that a food had been irradiated was, therefore, deemed to be material information that under section 201(n) of the act was required to be in labeling for the food. Importantly, however, FDA concluded (December 30, 1988, 53 FR 53176 at 53205) that the fact that an ingredient of a food had been irradiated was not material information required on the label of foods that contain such ingredient because:

> [T]he act does not require that the label declare details of processing for each ingredient. * * * FDA had no evidence that irradiation of an ingredient would affect the characteristics of a multiple ingredient food in any significant way. Therefore, the agency concluded that the labeling requirements for irradiated ingredients should be the same as for any other processed ingredients, namely, to declare them by their common or usual name without any requirement for stating whether they were processed * * *.

Proposed and final labeling requirements for protein hydrolysates also illustrate how the agency has applied section 201(n) of the act in conjunction with the requirement in section 403(i) of the act that each ingredient in a food be listed by its common or usual name. The agency recently promulgated a final rule requiring the common or usual name of a protein hydrolysate to include the identity of the food source from which the protein was derived (§ 102.22 (21 CFR 102.22)). The agency determined that, because the source of a protein hydrolysate has a significant effect on the product's composition and function, it must be identified in the common or usual name to describe adequately the basic nature of the ingredient, as required by § 102.5(a) (21 CFR 102.5(a)). (See the proposed rule on declaration of ingredients (56 FR 28592 at 28599, June 21, 1991) and the final rule on declaration of ingredients (58 FR 2850 at 2867, January 6, 1993)). For example, "hydrolyzed soy protein" is an acceptable name, but "hydrolyzed vegetable protein" is not (21 CFR 102.22(a)).

The agency also recognized that, for religious or cultural reasons, consumers are interested in being able to identify the source of a protein hydrolysate and determined that for these consumers the protein source of a protein hydrolysate is a material fact (56 FR 28592 at 28600; 58 FR 2850 at 2866). The agency determined, however, that more detailed source declarations, such as the identification of hydrolyzed casein as a milk-derived ingredient, were not necessary to inform consumers about the nature of the protein hydrolysate, although consumers requested the information based in part on religious or cultural dietary concerns (58 FR 2850 at 2867; 56 FR 28592 at 28600). The agency also rejected the suggestion that limiting the required declaration to "animal" or "vegetable" would be sufficient to address religious or cultural concerns, because such generic source labeling would not describe the basic nature of the protein hydrolysate and so would not fully comply with § 102.5(a) (58 FR 2850 at 2867).

At the same time as it issued the final rule requiring protein source declarations, the agency proposed to require the phrase "(contains glutamate)" to be part of the common or usual name of certain protein hydrolysates (58 FR 2950, January 6, 1993). Although consumers had expressed interest in this information for health reasons, the agency determined that no public health basis existed for imposing the requirement, and stated that its tentative decision to require the declaration was not based on any failure of labeling to reveal material facts regarding consequences that may result from the customary or usual use of the hydrolyzed protein (58 FR 2950 at 2951). Rather, the agency tentatively concluded that existing labeling of protein hydrolysates was not sufficiently informative and that the phrase "(contains glutamate)" is

necessary to describe adequately the basic nature or characterizing properties of certain protein hydrolysates and should therefore be part of their common or usual name under section 403(i)(1) of the act.

The agency's conclusion that the food source of a protein hydrolysate is information that must be revealed in labeling was reached in the context of the addition to food of food ingredients directly derived from animal or microbial sources (such as an animal protein hydrolysate or autolyzed yeast extract). That situation is different from the biotechnology context, which involves the presence in a plant chromosome of deoxyribonucleic acid (DNA) that was originally derived from an animal or microorganism but is now an inherent constituent of a plant. When using recombinant DNA techniques, scientists do not infuse the plant with the original genes that were removed from the animal. The animal genes are used to produce copies in the laboratory. Once the copies are transferred to the plant, they become an integral part of its genetic information, just like thousands of other genes that are present in the plant chromosome. There is a scientific basis to conclude that such genetic alterations do not change the essential nature of the plant, nor do they confer "animal-like" characteristics to the plant. For example, a tomato does not become "fish-like" following the addition of a copy of a fish gene that causes the production of a freeze-tolerant protein. This difference in context may bear directly on whether special labeling should be required for such "genetically engineered" products. Thus, in section III. of this document, FDA requests specific data and information that bear on these issues.

In developing the May 1992 policy statement, FDA was not aware of any information to suggest that the application of recombinant DNA techniques, commonly referred to as "genetic engineering," to the development of new plant varieties would result in foods which, as a class, exhibit attributes different from foods derived by other methods of plant breeding. Further, FDA notes that plant breeding methods are applied in the earliest stages of development of new plant varieties and are not processes applied to the finished food. Thus, in the May 1992 policy statement, FDA stated that the method of development of a new plant variety, including plants developed via "genetic engineering," is not information that is material under section 201(n) of the act and would not be required in labeling for the food (57 FR 22984 at 22991). This conclusion is consistent with the agency's historic interpretation of section 201(n) of the act, in that the method of plant breeding is not required to be disclosed in labeling.

III. Data and Information Requested

The subject of this request for data and information is limited to the labeling of foods derived from "genetically engineered" plants. While most of the comments on the policy statement raised the issue of labeling of foods derived from "genetically engineered" plants, most comments did not define "genetic engineering" or discuss characteristics that would distinguish a food derived from a "genetically engineered" plant from another food and, thus, might warrant labeling. Thus, FDA is soliciting additional data and factual information to define further "genetic engineering" as used in the comments; to clarify under what circumstances such labeling is believed to be necessary; to address how foods derived from "genetically engineered" plants differ from plants developed by other methods of plant breeding; to specify how such labeling, if required, would be accomplished as a practical matter; and other issues discussed in this notice.

FDA requests data and factual information that bear on whether certain labeling should be required under the act in the areas identified in sections III.A.1. through III.A.5. of this document and on labeling voluntarily placed on a food in the areas identified in section III.B. of this document. In addition, FDA invites data and information on other labeling issues for foods derived from "genetically engineered" plants that would be appropriate topics for the agency's consideration. Material submitted previously as comments on the policy statement will be reviewed by FDA in its deliberation on this topic. Therefore, FDA requests that such material not be resubmitted in response to this notice.

A. Required Labeling

1. Should All Foods Derived From New Plant Varieties Developed Using "Genetic Engineering" Techniques be Required to be Labeled as Such?

To explore this issue, FDA specifically seeks data and factual information on the following questions:

(a) How should "genetic engineering" be defined? For example, should "genetic engineering" be restricted to recombinant deoxyribonucleic acid (rDNA) techniques, or should the term include a broad range of genetic manipulation techniques, such as cell fusion, somaclonal variation, and embryo rescue?

(b) What specific characteristics of foods derived from "genetically engineered" plants distinguish such foods from other foods, and thus, such foods might warrant special labeling? Are there foods derived from "genetically engineered" plants that are without such characteristics and, thus, would not warrant labeling disclosing the method of production on the food? Does the purpose or intended technical effect of the genetic modification have any bearing on whether such disclosure labeling should be required?

The following are some examples of modifications of foods for which FDA requests additional data and factual information to help distinguish changes in foods derived from plants developed by "genetic engineering" from parallel changes in foods derived from plants developed using other methods of plant breeding:

(1) Foods that contain proteins not previously found in food, even if present in food at minute concentrations;

(2) Foods that contain proteins new to a particular food, but present in other foods;

(3) Foods that contain higher or lower concentrations of proteins native to that food;

(4) Foods that contain newly introduced but unexpressed genetic material;

(5) Foods that have improved nutritional or food processing characteristics;

(6) Food ingredients that are chemically unchanged as a result of the genetic modification of the plant (e.g., vegetable oil or food starch) because the genetic modification does not introduce new substances into the finished ingredient.

(c) What labeling should be required based on the form of the food at the time of sale? For example, is labeling appropriate for fresh produce, processed foods, or both? Why? In the case of processed foods, should labeling be required for all processed food? Why?

(d) What labeling, if any, should be required for a food derived from a plant that contains multiple traits that originated from different lines? What are the reasons for such a requirement?

(e) What labeling, if any, should be required for plant cultivars developed by traditional techniques (such as cross hybridization), when one (or both) parent line(s) was developed using "genetic engineering" techniques, or when one (or both) parent line(s) is derived from a progenitor line that was

developed using "genetic engineering" techniques? What are the reasons for such a requirement?

(f) What is the suggested text of any labeling for "genetically engineered" foods? Should different types of products or different modifications have different labeling texts?

(g) Are test methods available to permit FDA to enforce such labeling requirements?

(h) Can such labeling requirements be enforced, as a practical matter?

2. Should Labeling the Source of Introduced DNA be Required?

Several comments discussed the potential problems posed by fruits and vegetables modified to contain genetic material originally derived from animals, including the potential difficulties in maintaining a diet in accordance with religious, ethical, or health considerations. Some comments cited as reason for concern experiments in which copies of human genes have been introduced into plants and animals. Other comments requested that foods derived from plants using "genetic engineering" techniques be labeled to identify the source of any DNA, e.g., bacterial, viral, or animal, transferred to plants across natural mating barriers.

To explore this issue, FDA specifically seeks data and factual information on the following questions:

(a) What criteria could be used as a basis for source labeling for foods derived from new plant varieties? For example, should source labeling be required if the introduced substance (gene or its product):

(1) Has been taken directly from an animal?

(2) Has been derived originally from an animal, even though it is a bacterial or plant copy of the animal gene?

(3) Confers "animal-like" characteristics on the food?

(b) As a result of evolutionary conservation, plants, animals (including humans), and microorganisms share certain genes in common. Is this relevant to determining whether source labeling should be required?

(c) Should special criteria apply to copies of human genes that are introduced into food source organisms?

(d) What text should be used for source labeling?

(e) What test methods are available to enable enforcement if the source of a transferred gene is required to be disclosed in labeling?

(f) As a practical matter, could FDA enforce a requirement that the source of transferred DNA be disclosed in labeling?

3. Under What Circumstances is Ingredient Labeling Appropriate?

Some comments asserted that substances added to food using "genetic engineering" techniques are ingredients of foods and should be identified on the food's label consistent with section 403(i) of the act. Historically, ingredients are considered to be substances from which a food is fabricated. FDA has not previously considered new constituents of plants introduced via breeding to be ingredients. For example, most commercially produced tomatoes have introduced genetic traits derived from related weedy species which traits are designed to combat fungal disease.

To explore this issue further, FDA specifically seeks data and factual information on the following issues:

(a) Whether there is a basis in science to differentiate between constituents added by one type of genetic technique (such as rDNA) and constituents added by another type of genetic technique (such as cross-hybridization)?

(b) What criteria should be used to classify constituents as native or added, and the types and availability of data bases for various crops needed to evaluate and classify constituents?

(c) Are there circumstances in which a constituent that results from genetic engineering would constitute an ingredient? If so, what are those circumstances?

(d) Should such labeling be required on whole foods? On processed foods? What are the reasons for such a requirement?

4. How Can Required Labeling for Food Allergy be Accomplished?

As discussed above, the agency intends to engage the scientific community on technical issues associated with food allergy. Therefore, FDA intends to defer the discussion of the technical aspects of allergenicity until that time. Some examples of these issues include what foods should be considered "commonly allergenic;" whether testing for the presence and allergenic potential of transferred antigenic determinants is technically feasible; whether the allergenicity of proteins not currently consumed or not derived from a commonly allergenic food can be predicted; and whether data bases of food allergens can and should be established to aid in the identification of proteins that are allergenic.

FDA is aware that there are experimental plants currently under development that contain genes derived from foods known to be commonly allergenic to consumers (e.g., genes from fish and tree nuts). Under FDA's policy, such foods will be required to be labeled to alert consumers to potential allergenic substances derived from commonly allergenic foods, unless the developer can demonstrate scientifically that the introduced substance is not allergenic in the new food. Therefore, FDA requests data and factual information on how labeling to disclose potential allergenicity could be accomplished, when deemed necessary, for whole foods, processed foods, and fabricated foods.

Many consumers who are allergic to a variety of common fruits, vegetables, and grains expressed a concern that point-of-sale labeling would not protect them from allergens "hidden" in food consumed in restaurants or at social functions. FDA specifically seeks information from the food industry that responds or otherwise relates to this concern.

5. What are the Practical Difficulties and Economic Impact of Labeling "Genetically Engineered" Foods?

Representatives of various segments of the food industry such as developers of new plant varieties, distributors of raw agricultural commodities, food processors, grocery and specialty stores, restaurants, and trade associations representing these various segments of the food industry also submitted comments on the policy. Several of these comments described the practical difficulties of labeling foods derived from "genetically engineered" commodities (such as wheat or corn) at every stage of the food chain which extends from the farm to the grocery store. Restaurateurs, among other purveyors of food, expressed concern that inadequate labeling would not allow them to choose the foods that their customers desired, particularly in the case of customers who adhere to certain dietary restrictions.

To explore these issues, FDA specifically seeks information on the following issues:

(a) The feasibility and cost of labeling throughout the food chain "genetically engineered" commodities such as corn, soybeans, and wheat.

(b) The feasibility and cost of labeling throughout the food chain "genetically engineered" vegetables, such as tomatoes and squash, including packaged fresh produce, unpackaged fresh produce, and processed foods.

(c) The feasibility and cost of labeling throughout the food chain food ingredients derived from "genetically engineered" plants, such as vegetable oils and food starch.

B. Voluntary Labeling

FDA expects that in some circumstances producers and distributors of foods derived from "genetically engineered" commodities may decide to apply special labeling to their food on their own initiative. FDA requests information on current industry plans for such labeling.

After the publication of the policy statement, the Office of Technology Assessment of the U.S. Congress published a report (Ref. 1) that discussed options for labeling food products in which new methods of plant breeding, such as rDNA techniques, were used to develop the food crops. One option was that "Congress, through research and extension agencies, could encourage niche markets to be established to satisfy the concerns of those willing to pay high prices for labeled food signifying that it does not contain genetically engineered food." FDA specifically seeks information on the following questions that relate to these "niche" markets:

(1) Could niche markets satisfy consumer needs?

(2) Would such niche markets include fresh produce, processed foods, or both?

(3) What standards should apply to such niche markets, and what technical and monitoring issues would accompany such standards?

(4) What role should FDA, using its authority under the act, have in such a system (e.g., by monitoring for truth in labeling)?

(5) Would such labeling imply that products with such labeling are superior?

IV. Notice of Request

Individuals and organizations submitting data and information in response to this request should submit two copies of the information to the Dockets Management Branch (address above) by July 27, 1993. Each submission should be identified with the docket number found in brackets in the heading of this document. Submissions received may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

V. Reference

The following reference has been placed on display Dockets Management Branch (address above) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. U.S. Congress, Office of Technology Assessment, "A New Technological Era for American Agriculture," OTA–F–474, pp. 348–349, U.S. Government Printing Office, Superintendent of Documents, Mail Stop: SSOP, Washington DC 20402–9328, 1992.

Dated: April 22, 1993.

Michael R. Taylor,

Deputy Commissioner for Policy.

[FR Doc. 93–9846 Filed 4–27–93; 8:45 am]

BILLING CODE 4160–01–F

Health Resources and Services Administration

Final Funding Priorities and Special Consideration for Grants for Residency Training in General Internal Medicine and General Pediatrics

The Health Resources and Services Administration (HRSA) announces final funding priorities and special consideration for Grants for Residency Training in General Internal Medicine and General Pediatrics authorized under section 748 (previously section 784), title VII of the Public Health Service (PHS) Act, as amended by the Health Professions Education Extension Amendments of 1992, Public Law 102–408, dated October 13, 1992.

Approximately $12.8 million will be available in FY 1993 for this program. Total continuation support recommended is $6.3 million. It is anticipated that $6.5 million will be available to support 37 competing awards averaging $175,000 each.

Purpose

Section 748 authorizes the award of grants for planning, developing operating or participating in approved professional training programs (including approved residencies or internship programs) in the fields of internal medicine or pediatrics for medical (M.D. or D.O.) students, interns (including interns in internships in osteopathic medicine), residents or practicing physicians, which training program emphasizes training for the practice of general internal medicine or general pediatrics. In addition, section 748 authorizes assistance in meeting the cost of supporting medical students, interns, residents, practicing physicians or other medical personnel, who are participants in any such training program, and who plan to specialize or work in the practice of general internal medicine or general pediatrics. A separate grant program is in effect for the faculty development component of this authority.

Since this program was announced in FY 1992, the Health Professions Education Extension Amendments of 1992, Public Law 102–408, were passed by the Congress and signed by the President. This legislation resulted in the following changes for this program:

Section 784 has been renumbered section 748 of the PHS Act. Support of training in general internal medicine and general pediatrics, which was restricted to residency and faculty training has been broadened to also cover training of undergraduate medical students and practicing physicians.

Section 791(a) of the Act, as amended, includes a general funding preference for selected grant programs under title VII, including section 748, Grants for Residency Training in General Internal Medicine and General Pediatrics. Section 791(b) includes new information requirements for applicants under this program.

Statutory General Funding Preference

Under section 791(a) of the Act, preference will be given to any qualified applicant that: (A) Has a high rate for placing graduates in practice settings having the principal focus of serving residents of medically underserved communities; or (B) during the 2-year period preceding the fiscal year for which such an award is sought, has achieved a significant increase in the rate of placing graduates in such settings.

Preference will be given only for applications ranked above the 20th percentile of applications that have been recommended for approval by the appropriate peer review group. The Secretary may not give an applicant preference if the proposal of the applicant is ranked in or below the 20th percentile of proposals that have been recommended for approval by peer review groups.

Additional information concerning the implementation of this preference has been developed and a separate notice was published in the **Federal Register** dated February 22, 1993, at 58 FR 9570, establishing the final methodology for implementation of this new statutory funding preference, for this program, in FY 1993.

New Information Submission Requirement

Under section 791(b) of the Act, the Secretary may make an award under the Grants for Residency Training in General Internal Medicine and General Pediatrics program only if the applicant for the award submits to the Secretary information regarding the programs of the applicant. The provision for this new requirement was not implemented in FY 1993. Further information will be provided in program materials in any future cycles.

Final Funding Priorities and Special Consideration for FY 1993

Proposed funding priorities and a special consideration were published in the **Federal Register** dated September 21, 1992, 57 FR 43464, for public comment. No comments were received during the 30-day comment period. Therefore, as proposed the final funding priorities and special consideration will be retained as follows:

In making awards for fiscal year 1993, a funding priority will be given to:

1. Education Linkages to Medically Underserved Communities

Applications that propose to provide educational experiences to demonstrate to residents the provision of primary care services to underserved populations. These experiences must include substantial training involving one or more of the following entities:

(A) Underserved Geographical Area

Inpatient or outpatient health care facilities located in a Health Professional Shortage Area (HPSA), PHS Act, section 332, or in a Medically Underserved Area (MUA) designated under provisions of PHS Act, section 330(b)(3);

(B) Facilities Whose Purpose is Care of Underserved

Community Health Centers currently supported under PHS Act, section 330, Medically Underserved Population, defined under PHS Act, section 330(a)(3), Migrant Health Centers currently supported under PHS Act, section 329, Homeless Health Centers supported under PHS Act, section 340, facilities that have formal arrangements to provide primary health services to provide primary health services to public housing communities, hospitals or other health care facilities of the Indian Health Service and/or facilities operated by State or local health departments.

(C) Underserved Patient Populations

Facilities which do not qualify under (A) and (B) above can qualify for up to a full priority score based on the percentage of their patient visits/hospital admissions that are uncompensated or are compensated under the State Medicaid Program or local programs designed to reimburse health providers for services to indigent populations.

2. Minorities/Low-Income Populations

Programs which demonstrate either substantial progress over the last 3 years or a significant experience of 10 or more years in enrolling and graduating trainees from those minority or low-income populations identified as at-risk of poor health outcomes.

3. HIV/AIDS/Substance Abuse Activities

Applications that (1) Document collaboration with a Regional HIV/AIDS Educational Training Center and have implemented, or plan to implement no later than academic year 1993–94, a comprehensive training experience for all residents which includes counseling in the prevention of HIV infection, direct patient care and clinical management of HIV-infected individuals, and (2) provide all residents with an organized clinical experience in the diagnosis, counseling, treatment and referral of substance abuser patients/families or present plans for the implementation of such a curriculum no later than academic year 1993–94.

4. Clinical Preventive Services

Applications that demonstrate sufficient curricular time and offerings devoted to teaching all residents about the screening, counseling and immunization services recommended by the U.S. Preventive Services Task Force.

Final Special Consideration

Special consideration will be given to the extent to which applicants enroll and graduate trainees from underserved areas.

Additional Information

If additional programmatic information is required, contact: Ms. Sara Kearney, Residency Training Section, Division of Medicine, Bureau of Health Professions, Health Resources and Services Administration, 5600 Fishers Lane, Parklawn Building, room 4C–04, Rockville, Maryland 20857, Telephone (301) 443–6820, FAX: (301) 443–8890.

This program is listed at 93.884 in the *Catalog of Federal Domestic Assistance.* Applications submitted in response to this announcement are not subject to the provisions of Executive order 12372, Intergovernmental Review of Federal Programs, (as implemented through 45 CFR part 100).

This program is not subject to the Public Health System Reporting Requirements.

Dated: April 21, 1993.

Robert G. Harmon,

Administrator.

[FR Doc. 93–9929 Filed 4–27–93; 8:45 am]

BILLING CODE 4160–50–P

Final Funding Priorities and Special Consideration for Grants for Graduate Training in Family Medicine

The Health Resources and Services Administration (HRSA) announces the final funding priorities and special consideration for Grants for Graduate Training in Family Medicine authorized under section 747, (previously section 786(a)), title VII of the Public Health Service (PHS) Act, as amended by the Health Professions Education Extension Amendments of 1992, Pub. L. 102–408, dated October 13, 1992.

Approximately $12.8 million will be available in FY 1993 for this program. Total continuation support recommended is $10.1 million. It is anticipated that $2.7 million will be available to support 18 competing awards averaging $110,000.

Purpose

Section 747 of the PHS Act authorizes the Secretary to award grants to assist in meeting the costs of planning, developing and operating or participating in approved graduate training programs in the field of family medicine. In addition, section 747 authorizes assistance in meeting the cost of supporting trainees in such programs who plan to specialize or work in the practice of family medicine.

Since this program was announced on September 14, 1992, the Health Professions Education Extension Amendments of 1992, Public Law 102–408, were passed by the Congress and signed by the President.

Public Law 102–408 makes the following revisions to this program. Section 786 has been renumbered section 747 of the PHS Act. The authority for this program, which includes authority for Grants for Faculty Development in Family Medicine and Grants for Predoctoral Training in Family Medicine, has been combined with the authority for section 747(b), Grants for Departments of Family Medicine (previously section 780 of the PHS Act). A new statutory funding preference has been established and is outlined below. Under section 791(b), an information requirement provision has also been established.

Statutory Funding Preference

Preference will be given to qualified applicants that:(1) Have a high rate for placing graduates in practice settings having the principal focus of serving residents of medically underserved communities; or (2) have achieved, during the 2-year period preceding the fiscal year for which such an award is

sought, a significant increase in the rate of placing graduates in such settings.

This preference will only be applied to applications that rank above the 20th percentile of applications that have been recommended for approval by peer review groups under section 798(a) of the PHS Act, as amended.

Additional information concerning the implementation of this preference has been published in the **Federal Register** at 58 FR 9570, dated February 22, 1993.

Information Requirements Provision

Under section 791(b) of the Act, the Secretary may make an award under the Grants for Graduate Training in Family Medicine only if the applicant for the award submits to the Secretary information regarding the programs of the applicant. The provision for this new requirement was not implemented in FY 1993. Further information will be provided in program materials in any future cycles.

Final Funding Priorities and Special Consideration for FY 1993

Proposed funding priorities and a special consideration were published in the **Federal Register** dated September 14, 1992, 57 FR 41944, for public comment. No comments were received during the 30-day comment period. Therefore, as proposed, the following final funding priorities and special consideration will be retained:

Funding priority will be given to:

1. Educational Linkages to Medically Underserved Communities

Applications that propose to provide educational experiences to demonstrate to residents the provision of primary care services to underserved populations. These experiences must include substantial training involving one or more of the following eligible entities:

(A) Underserved Geographical Area

Inpatient or outpatient health care facilities located in a Health Professional Shortage Area (HPSA), PHS Act, section 332, or in a Medically Underserved Area (MUA), designated under provisions of the PHS Act, section 330(b)(3);

(B) Facilities Whose Purpose is Care of the Underserved

Community Health Centers currently supported under PHS Act, section 330, Migrant Health Centers currently supported under PHS Act, section 329, Homeless Health Centers supported under PHS Act, section 340, facilities that have formal arrangements to provide primary health services to public housing communities, hospitals or other health care facilities of the Indian Health Service and/or facilities operated by State or local health departments.

(C) Underserved Patient Populations

Facilities which do not qualify under (A) and (B) above can qualify for up to a full priority score based on the percentage of their patient visits/hospital admissions that are uncompensated or are compensated under the State Medicaid Program or local programs designed to reimburse health providers for services to indigent populations.

2. Minorities/Low Income Populations

Programs which demonstrate either substantial progress over the last 3 years or a significant experience of 10 or more years in enrolling and graduating residents from the minority or low-income populations identified as at risk of poor health outcomes. Consideration will also be given to the extent to which enrolled and graduating residents are from underserved areas.

3. HIV/AIDS/Substance Abuse Activities

Applications that (1) Document collaboration with a Regional HIV/AIDS Educational Training Center and have implemented, or plan to implement no later than academic year 1993–94, a comprehensive training experience for all residents which includes counseling in the prevention of HIV infection, direct patient care and clinical management of HIV-infected individuals; and (2) provide all residents with an organized clinical experience in the diagnosis, counseling, treatment and referral of substance abuser patient/families or present plans for the implementation of such a curriculum no later than academic year 1993–94.

4. Clinical Preventive Services

Applications that demonstrate sufficient curricular time and offerings devoted to teaching all residents about the screening counseling and immunization services recommended by the U.S. Preventive Services Task Force.

Special consideration will be given to the extent to which applicants enroll and graduate trainees from underserved areas.

Additional Information

If additional programmatic information is needed, contact: Ms. Elsie Quinones, Program Specialist, Primary Care Medical Education Branch, Division of Medicine, Bureau of Health Professions, Health Resources and Services Administration, 5600 Fishers Lane, room 4C–04, Parklawn Building, Rockville, Maryland 20782, Telephone: (301) 443–6820, FAX: (301) 443–8890.

This program is listed at 93.379 in the *Catalog of Federal Domestic Assistance*. It is not subject to the provisions of Executive Order 12372, Intergovernmental Review of Federal Programs (as implemented through 45 CFR part 100).

This program is not subject to the Public Health System Reporting Requirements.

Dated: April 22, 1993.

Robert G. Harmon,

Administrator.

[FR Doc. 93–9928 Filed 4–27–93; 8:45 am]

BILLING CODE 4160–15–P

DEPARTMENT OF THE INTERIOR

Office of the Secretary

Exxon Valdez Oil Spill Public Advisory Group; Meeting

AGENCY: Office of the Secretary, Interior.

ACTION: Notice of meeting.

SUMMARY: The Department of the Interior announces a public meeting of the Exxon Valdez Oil Spill Public Advisory Group to be held on May 25, 1993, at 9 a.m., in the first floor conference room, 645 "G" Street, Anchorage, Alaska.

FOR FURTHER INFORMATION CONTACT: Douglas Mutter, Department of the Interior, Office of Environmental Affairs, 1689 "C" Street, suite 119, Anchorage, Alaska (907) 271–5011.

SUPPLEMENTARY INFORMATION: The Public Advisory Group was created by Paragraph V.A.4 of the Memorandum of Agreement and Consent Decree entered into by the United States of America and the State of Alaska on August 27, 1991, and approved by the United States District Court for the District of Alaska in settlement of *United States of America* v. *State of Alaska*, Civil Action No. A91–081 CV. This meeting will include: (1) A discussion of the continuing role of the Public Advisory Group in advising the Exxon Valdez Oil Spill Trustee Council; (2) a discussion of the draft Restoration Plan alternatives; and (3) a discussion of the 1994 Work Plan.

Dated: April 22, 1993.

Jonathan P. Deason,

Director, Office of Environmental Affairs.

[FR Doc. 93–9882 Filed 4–27–93; 8:45 am]

BILLING CODE 4310–RG–M

Bureau of Land Management

[OR–135–4191–3; GP3–206; WMP–130–89–019B–3809]

Intent To Prepare an Environmental Impact Statement Supplement to the Kettle River Key Project Expansion FEIS—The Proposed Lamefoot Mine

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of intent to prepare an Environmental Impact Statement Supplement to the Kettle River Key Project Expansion FEIS—The Proposed Lamefoot Mine.

SUMMARY: Pursuant to section 102 (2)(c) of the National Environmental Policy Act of 1969, the Bureau of Land Management Spokane District will be the lead Federal agency and will direct the preparation of an EIS Supplement by a third party contractor. The EIS Supplement will evaluate the impacts of a proposed gold mining and processing operation located on private and public lands in northern Ferry County, Washington. This notice initiates the scoping process for this EIS Supplement.

DATES: Written comments will be accepted until June 7, 1993. A public scoping meeting will be held from 3:30 p.m. to 7:30 p.m. on May 20, 1993, at the Frontier Motel in Republic, Washington. Additional briefing meetings will be considered as appropriate.

ADDRESSES: Comments should be sent to the District Manager, Bureau of Land Management, East 4217 Main Avenue, Spokane, Washington 99202 ATTN: Lamefoot Mine.

FOR FURTHER INFORMATION CONTACT: Ann Aldrich, Border Resource Area Manager, East 4217 Main Avenue, Spokane, Washington 99202 (509) 353–2570.

SUPPLEMENTARY INFORMATION: The Kettle River Project has had a series of environmental reviews. In 1988, a Final Environmental Impact Statement, prepared by the Department of Ecology, was completed for the Overlook and Kettle River underground mines and the Key Mill and tailings storage facilities. This first EIS addressed the total tailings facility, although only one segment has actually been constructed.

In 1992, an Environmental Assessment was completed by the Bureau of Land Management to evaluate the effects of an exploration project on private and public land at the Lamefoot site about four miles northwest of the Overlook and Key Mines. The Lamefoot operations involved surface drilling and development of underground workings for subsurface exploration.

Also in 1992, the Forest Service, BLM, Department of Ecology and Department of Natural Resources completed the Kettle River Key Project Expansion FEIS. This FEIS analyzed the effects of expanding the Project to include development of the two open pit Key Mines. Exploration activities, including the Lamefoot site, were considered in the FEIS as part of the cumulative impacts. The potential for future development of the Lamefoot mine and related mill facilities was addressed as a reasonably foreseeable future action.

However, this speculative future action depended on information that was unknown at the time because exploration was needed to establish the presence and extent of mineralization and the feasibility of mining. Additional environmental review is necessary for an actual mining proposal. Therefore, because the underground Lamefoot Mine would become part of the Kettle River Project mining and processing operations, it was decided to Supplement the existing EIS to address the possible effects.

The mining phase of the Lamefoot Mine would involve excavating ore by a long hole open stoping mining technique, and transporting the ore via State and county roads to the previously permitted Key Mill. About seventy percent of the underground mining would take place on private land and thirty percent would occur on public land administered by the BLM. Total surface disturbance at the Lamefoot Mine would be about 45 acres (38 acres private, 7 acres public). Cumulative disturbance for the Kettle River Project would be about 409 acres (373 acres private (91%), 36 acres Federal (9%)).

The ore would be processed by the conventional carbon in leach method at the Key Mill. After extraction of gold, tailings would be permanently stored in a zero discharge lined tailings facility. The tailings impoundment is located on private land, operating under permits from the State of Washington, and is scheduled for enlargement in 1993 through 1995. Process waters are treated in a cyanide destruction circuit before discharge to the tailings impoundment and recycling for use in the milling circuit.

The Bureau of Land Management's scoping process for the EIS will include: (1) Identification of issues to be addressed; (2) Identification of viable alternatives; and (3) Notifying interested groups, individuals and agencies so that additional information concerning these issues can be obtained.

Joseph Buesing,

District Manager.

[FR Doc. 93–9901 Filed 4–27–93; 8:45 am]

BILLING CODE 4310–33–M

[UT–920–93–4120–01]

Utah and Colorado: Uinta Southwestern Utah Regional Coal Team Meeting

AGENCY: Bureau of Land Management, DOI.

ACTION: Notice of Regional Coal Team Meeting.

SUMMARY: In accordance with responsibilities outlined in the Federal Coal Management Regulations (43 CFR part 3400), the Regional Coal Team (RCT) for the decertified Uinta Southwestern Utah Federal Coal Production Region will hold a meeting to discuss and make recommendations concerning coal leasing and development in the Region. The RCT will review pending coal lease applications under the "Leasing by Application" (LBA) program and discuss any additional coal-related activities appropriate at this time. Members of the public, coal companies and interested agencies are invited to make comments at the meeting.

SUPPLEMENTARY INFORMATION: A total of eight coal lease applications are pending in the region, including seven in Utah and one in Western Colorado. The RCT will be reviewing the applications and where appropriate making recommendations to the BLM concerning processing the applications. Pending applications in the Region include:

State	Applicant	Coal field	Est. acreage
Utah			
	Mining & Energy Res. Inc	Wasatch Plateau	3,431
	Coastal States Energy	Wasatch Plateau	2,020

State	Applicant	Coal field	Est. acreage
Colorado	Sage Point Coal Co	Book Cliffs	1,104
	Sage Point Coal Co	Book Cliffs	2,098
	PacifiCorp Electric Oper	Wasatch Plateau	7,865
	Genwal Coal Co	Wasatch Plateau	3,384
	Genwal Coal Co	Wasatch Plateau	4,052
	Mountain Coal	Paonia/Summerset	1,012

DATES: The Regional Coal Team meeting will be May 27, 1993 at 10 a.m.

ADDRESSES: The meeting will be held at Bureau of Land Management, Utah State Office, BLM Conference Room, No. 302, 324 South State Street, Salt Lake City, Utah.

FOR FURTHER INFORMATION CONTACT: Max Nielson, Uinta Southwestern Utah Coal Project Manager, Utah State Office, P.O. Box 45155, Salt Lake City, Utah, 84145–0155. (Telephone 801–539–4038).

Dated: April 16, 1993.

James M. Parker,

State Director, Utah.

[FR Doc. 93–9851 Filed 4–27–93; 8:45 am]

BILLING CODE 4310–DQ–M

[ID–010–03–4210–05; IDI–28382]

Sale of Public Land in Owyhee County, ID

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of Realty Action—IDI–28382.

SUMMARY: The following described public land has been determined to be suitable for disposal by direct sale pursuant to section 203 of the Federal Land Policy and Management Act (FLPMA) of 1976 (43 U.S.C. 1713) at no less than appraised fair market value. The land will not be offered for sale until at least 60 days after the date of publication of this notice in the **Federal Register.**

Boise Meridian, Idaho

T. 6 S., R. 4 E.
Sec. 4: NE¼SE¼, E½E½NW¼SE¼

Containing 50 acres, more or less, in Owyhee County.

DATES: Interested parties may submit comments to the District Manager, Boise District, Bureau of Land Management, 3948 Development Avenue, Boise, Idaho 83705 on or before June 14, 1993. Objections will be reviewed by the State Director, who may sustain, modify, or vacate this realty action. In the absence of any adverse comments, this realty action will become the final determination of the Department of Interior. Upon publication of this notice in the **Federal Register,** the lands described above will be segregated from appropriation under the public land laws, including the mining laws, except for sale under the provisions of FLPMA. The segregation will end upon issuance of patent or 270 days from the date of publication, whichever occurs first.

FOR FURTHER INFORMATION CONTACT: John Sullivan, Realty Specialist, at the above address or (208) 384–3338.

SUPPLEMENTARY INFORMATION: This land is being offered by direct sale to Owyhee County for construction and use as a refuse transfer station. Acceptance of the sale offer will constitute an application for conveyance of that portion of the mineral estate of no known value. A separate non-returnable fee of $50.00 will be required from the purchaser for conveyance of the mineral interests.

The reservations, terms and conditions of this sale are as follows:

Excepting and Reserving to the United States

1. A right-of-way thereon for ditches or canals constructed by the authority of the United States. Act of August 30, 1890 (43 U.S.C. 945).

2. All oil, gas, and geothermal resources, together with the right to prospect for, mine, and remove the same.

3. A Federal Aid Highway right-of-way granted to the Idaho Transportation Department by right-of-way IDI–03082, under the authority of the Act of November 9, 1921 (42 Stat. 0216).

4. A right-of-way thereon for public access to adjacent public lands.

Subject to

5. Those rights for telephone line purposes granted to Gem State Utilities Corporation, its successors or assigns, by right-of-way no. IDI–15494, under the authority of the Act of October 21, 1976 (43 U.S.C. 1761).

6. Those rights for access road purposes granted to Lincoln C. Mackay, his heirs or assigns, by right-of-way no. IDI–20989, under the authority of the Act of October 21, 1976 (43 U.S.C. 1761).

Dated: April 22, 1993.

Barry C. Cushing,

Acting District Manager.

[FR Doc. 93–9961 Filed 4–27–93; 8:45 am]

BILLING CODE 4310–GG–M

[UT–020–93–4210–05; U–70288]

Realty Action; Application to Purchase Federally Owned Mineral Interests

AGENCY: Bureau of Land Management, Salt Lake District Office, Interior.

ACTION: Application to purchase federally owned mineral interest.

SUMMARY: Notice is hereby given that pursuant to section 209 of the Federal Land Policy and Management Act of 1976 (43 U.S.C. 1719), an application has been filed for the purchase of all federally owned mineral interests, within the following land description:

Salt Lake Meridian, Utah

T. 2 S., R. 4 E.
Section 10, lots 15, 16
Section 11, lot 11
Containing 0.820 acres

The sale is consistent with the Bureau's planning system. It has been determined that there are no known mineral values in the subject lands. The mineral estate will not be offered for sale until 60 days after the date of this notice. The mineral estate is proposed to be offered for sale to the United Park City Mines Company of Park City, Utah.

Publication of this notice in the **Federal Register** segregates the mineral interests owned by the United States from appropriation under the mining and mineral leasing laws. The segregative effect shall terminate 270 days from the publication of this notice or upon final disposition of this action, whichever occurs first.

For a period of 45 days from the date of publication of this notice in the **Federal Register,** interest parties may submit comments to the District Manager, Bureau of Land Management, 2370 South 2300 West, Salt Lake City, Utah 84119. Objections will be reviewed by the State Director who may sustain, vacate, or modify this realty action. In the absence of any objections, this realty action will become the final

determination of the Department of the Interior.

FOR FURTHER INFORMATION CONTACT: Janice MaChipiness, Bear River Resource Area Realty Specialist, 2370 South 2300 West, Salt Lake City, Utah 84119, or call at (801) 977–4300.

Dated: April 20, 1993.

Gary Weiser,

Acting District Manager.

[FR Doc. 93–9939 Filed 4–27–93; 8:45 am]

BILLING CODE 4310–DQ–M

National Park Service

Mississippi River Coordinating Commission; Meeting

AGENCY: National Park Service, Interior.

ACTION: Notice of meeting.

SUMMARY: This notice sets the schedule for a forthcoming meeting of the Mississippi River Coordinating Commission. Notice of this meeting is required under the Federal Advisory Committee Act.

The agenda for the meeting consists of continued Commission review and discussion of the draft comprehensive management plan and draft environmental impact statement for the Mississippi National River and Recreation Area. It is anticipated the commission will vote on a resolution to release the draft plan for public review and comment. Public statements will be heard from 4:00 p.m. to 5:00 p.m., as well as in advance of any commission vote.

DATES: May 22, 1993, 12 p.m. to 5 p.m.

ADDRESSES: Earle Brown Continuing Education Center, University of Minnesota-St. Paul Campus, 1890 Buford Avenue, St. Paul, Minnesota 55108.

FOR FURTHER INFORMATION CONTACT: Superintendent, Mississippi National River and Recreation Area, 175 East Fifth Street, suite 418, St. Paul, MN 55101 (612/290–4160).

SUPPLEMENTARY INFORMATION: The Mississippi River Coordinating Commission was established by Public Law 100–696, November 18, 1988.

Dated: April 16, 1993.

Don H. Castleberry,

Regional Director.

[FR Doc. 93–9853 Filed 4–27–93; 8:45 am]

BILLING CODE 4310–70–P

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 April 17, 1993. 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 May 13, 1993.

Beth L. Savage,

Acting Chief of Registration, National Register.

ALABAMA

Calhoun County

East Anniston Residential Historic District (Anniston MRA), Roughly, along Leighton and Christine Aves. from 11th St. to 22nd Sts. and Woodstock Ave. from 11th St. to Rocky Hollow, Anniston, 93000418

Colbert County

Chambers-Robinson House, 910 Montgomery Ave., Sheffield, 93000419

Mobile County

Cleveland, U.J., House, 551 Charles St., Mobile, 93000420

Wilcox County

Beck, William King, House, AL 28 N side, 3.2 mi. N of jct. with AL 10, Camden vicinity, 93000421

ARKANSAS

Greene County

National Bank of Commerce Building, 200 S. Pruett St., Paragould, 93000423

COLORADO

Custer County

Willows School, Willows Ln. (Co. Rd. 141) between Muddy Ln. (Co. Rd. 155) and Schoolfield Rd. (Co. Rd. 328), Westcliffe vicinity, 93000413

GEORGIA

Banks County

Homer Historic District (Boundary Increase), Off U.S. 41 on E end of existing district adjacent to southern boundary, Homer, 93000422

IOWA

Polk County

Wallace, Henry, House, 756 16th St., Des Moines, 93000412

MINNESOTA

Hennepin County

Healy Block Residential Historic District, 3101–3145 2nd Ave. S. and 3116–3124 3rd Ave. S., Minneapolis, 93000417

UTAH

Grand County

Star Hall, 159 E. Center St., Moab, 93000416

Millard County

Partridge, Edward and Elizabeth, House, 10 S. 200 W., Fillmore, 93000414

Salt Lake County

U.S. Post Office—Sugar House, 2155 S. Highland Dr., Salt Lake City, 93000409

Utah County

Springville High School Mechanical Arts Building, 443 S. 200 E., Springville, 93000415

Washington County

Enterprise Meetinghouse (Mormon Church Buildings in Utah MPS), Approximately 24 S. Center St., Enterprise, 93000410

Wayne County

Torrey Log Church—Schoolhouse (Mormon Church Buildings in Utah MPS), Approximately 49 E. Main St., Torrey, 93000411

WASHINGTON

Clark County

Washington School for the Blind, 2214 E. 13th St., Vancouver, 93000370

[FR Doc. 93–9852 Filed 4–27–93; 8:45 am]

BILLING CODE 4310–70–M

Bureau of Reclamation

Central Valley Project Contracting Program, California

AGENCY: Bureau of Reclamation (Interior).

ACTION: Notice of cancellation of draft environmental impact statements.

SUMMARY: The Bureau of Reclamation (Reclamation) is canceling three draft environmental impact statements (DEIS's) for the Central Valley Project (CVP), California: Sacramento River Service Area (SRSA) Water Contracting Program, American River Service Area (ARSA) Water Contracting Program, and Delta Export Service Area (DESA) Water Contracting Program. These DEIS's were filed with the Environmental Protection Agency (EPA) on December 29, 1988.

FOR FURTHER INFORMATION CONTACT: Mr. Doug Kleinsmith, Bureau of Reclamation, Mid-Pacific Region, 2800 Cottage Way, Sacramento CA 95825–1898; telephone: (916) 978–5121; or Mr. Darrell Cauley, Bureau of Reclamation, Denver Federal Center, Denver CO 80225; telephone: (303) 236–0511.

SUPPLEMENTARY INFORMATION: Reclamation published a notice of intent (NOI) to prepare an environmental impact statement (EIS) for the SRSA Contracting Program in the **Federal Register** (50 FR 19495), dated May 8, 1985. The DEIS for the SRSA was filed with the EPA on December 29, 1988, and the notice of availability (NOA) was published in the **Federal Register** (54 FR 197), dated January 4, 1989.

Reclamation published a NOI to prepare an EIS for the ARSA Water Contracting Program in the **Federal Register** (51 FR 41544), dated November 17, 1987. The DEIS for the ARSA was filed with EPA on December 29, 1988, and the NOA was published in the **Federal Register** (54 FR 195), dated January 4, 1989.

Reclamation published a NOI to prepare an EIS for the DESA Water Contracting Program in the **Federal Register** (52 FR 19599), dated May 26, 1987. The DEIS for the DESA was filed with EPA on December 29, 1988, and the NOA was published in the **Federal Register** (54 FR 196), dated January 4, 1989.

The purpose of the SRSA, ARSA, and DESA Water Contracting Programs was to resume long-term contracting of what was considered at that time to be available and uncommitted water from the CVP. Reclamation is canceling the SRSA, ARSA, and DESA Water Contracting Program DEIS's because the basic assumptions of the amount of available and uncommitted CVP water are no longer valid and because of requirements of Public Law 102–575, the Central Valley Project Improvement Act.

Since the DEIS's were filed, there have been significant changes in the allocation of the water supply from the CVP in California. The most significant change in the allocation was the enactment of Public Law 102–575 in 1992. This law prohibits, with a few exemptions, Reclamation from entering into any new short-term, temporary, or long-term contracts for CVP water for any purpose, except for fish and wildlife, until a series of environmental restoration and enhancement measures are implemented for the Central Valley and Trinity River basins. The law commits 800,000 acre-feet of annual CVP yield for these restoration measures. Public Law 102–575 also requires a programmatic EIS to be prepared within 3 years that will address its implementation.

A more accurate calculation of the yield of the CVP, and expected restrictions on CVP water operations from the State Water Resources Control Board, have reduced the possible amount of water which Reclamation anticipated contracting in 1988.

Dated: April 22, 1993.

J. William McDonald,

Assistant Commissioner Resources Management.

[FR Doc. 93–9895 Filed 4–27–93; 8:45 am]

BILLING CODE 4310–09–M

Proposed Water Service Contract, Sacramento County and San Juan Suburban Water District, Sacramento County, CA

AGENCY: Bureau of Reclamation, Interior.

ACTION: Notice of scoping meeting and notice of intent to prepare a draft environmental impact statement/environmental impact report for proposed water service contracts to Sacramento County Water Agency and San Juan Suburban Water District from the Central Valley Project, California.

SUMMARY: Pursuant to Public Law 101–514 (104 Stat. 2087), and section 102(2)(C) of the National Environmental Policy Act (NEPA) of 1969 (as amended), and section 21002 of the California Environmental Quality Act (CEQA), the Bureau of Reclamation (Reclamation), the Sacramento County Water Agency (Agency), and San Juan Suburban Water District (SJSWD) intend to prepare a joint environmental impact statement/environmental impact report (EIS/EIR) for a water service contract from the Central Valley Project (CVP), California.

The proposed project consists of water supply contracts for agencies within Sacramento County. The Agency, in conjunction with the city of Folsom, and SJSWD have entered into discussions with Reclamation to negotiate long-term water supply contracts from the American River Division, CVP.

DATES: Comments are requested on this notice concerning the scope of analysis of the draft EIS/EIR. Input concerning issues related to the proposed water service contracts should be received by May 28, 1993.

Two public scoping meetings for this project will be held:

May 18, 1993, 7 p.m., Sacramento County Board of Supervisors Hearing Room, 700 H Street, Sacramento, California.

May 19, 1993, 1 p.m., Sacramento County Board of Supervisors Hearing Room, 700 H Street, Sacramento, California.

FOR FURTHER INFORMATION CONTACT: Please address scoping comments or information requests to Donna Dean, Senior Civil Engineer, Sacramento County Water Agency, Sacramento County Public Works Department, 827 7th Street, room 301, Sacramento, CA 95814; telephone: (916) 440–6851. Reclamation's environmental representative is James Frederick, Environmental Specialist, Bureau of Reclamation, Mid-Pacific Region, 2800 Cottage Way, Sacramento, CA 95825–1898; telephone: (916) 978–5134.

SUPPLEMENTARY INFORMATION: The contracts to be negotiated have been authorized and directed by the United States Congress as part of Public Law 101–514. These contracts have been excluded from the prohibition on new contracting found in Public Law 102–575.

Public Law 101–514 directs the Secretary of the Interior to enter into long-term municipal and industrial water supply contracts to meet the immediate water needs of Sacramento and El Dorado Counties. The law directs the Secretary of the Interior to enter into contracts for up to 22,000 acre-feet annually with the Agency, 13,000 acre-feet annually with SJSWD, and 15,000 acre-feet annually with El Dorado County Water Agency. These water service contracts are intended as the first phase of a contracting program to meet the long-term water supply needs of Sacramento and El Dorado Counties.

El Dorado County Water Agency and Reclamation have initiated negotiations on a water service contract under Public Law 101–514 and are preparing NEPA/CEQA environmental documentation under a separate notice of intent. The El Dorado County Water Agency water service contract is not part of the Sacramento County water service contract project.

The Sacramento County Water Agency may enter into a subcontract with the city of Folsom for delivery of up to 7,000 acre-feet annually to the city of Folsom from the water allocated to the Agency. The city of Folsom water supply subcontract, if executed, will be pursuant to the general authority and purposes of the Sacramento County Water Agency.

Public Law 101–514 directs that water taken by SJSWD and the city of Folsom be diverted from the American River at Folsom Dam. The law also requires that water diverted by the Agency be taken at or near the confluence of the American and the Sacramento Rivers.

Sacramento County Water Agency plans on using the acquired surface water in the south county area known as the Near Term Zone 40 Service Area and within areas immediately adjacent to Zone 40 that are under consideration as new development areas in Sacramento County's 1992 draft General Plan. These areas are located 12 miles south of downtown. The surface water will replace groundwater as the primary water source for the Zone 40 Area.

SJSWD plans on using the surface water acquired for municipal and industrial use in the portion of their

service area located within Sacramento County. The SJSWD's major source of water is Folsom Lake.

The city of Folsom plans on using the acquired surface water to serve presently approved developments within the existing city limits. The city of Folsom is primarily residential, with an increasing amount of industry. The existing water supply to the city of Folsom is entirely surface water from Folsom Lake.

The EIS/EIR will focus on impacts to the physical environment from diversion, distribution, and use of the contracted water. The documentation will include analysis of the potential impacts to the natural environment; i.e., aquatic, wetland, and riparian communities including any effect on special status species. Secondary growth impacts associated with the water delivery and secondary impacts associated with the construction of water delivery facilities used to divert, treat, and distribute the contracted water will be investigated. The draft EIS/EIR is expected to be completed and available for review and comment in winter of 1994.

Scoping

One element of the EIS/EIR process is scoping. Scoping activities are initiated early in the process to: Identify reasonable alternatives that should be evaluated in the draft EIS/EIR, identify significant environmental issues related to the proposed projects, determine the depth of analysis for issues addressed in the documentation, and identify resource issues that are not important and that do not require detailed study. Scoping meetings have been scheduled to solicit public input to help identify issues and possible alternative actions within the framework for delivery and use of the contracted water.

Note: Disabled persons requiring special services should contact Reclamation's Equal Employment Office at (916) 978–4911. Please notify this office as far in advance of the meetings as possible and no later than May 11, 1993, to enable Reclamation to secure the needed services. If a request cannot be honored, the requester will be notified. A telephone device for the hearing impaired (TDD) is not available.

Dated: April 22, 1993.

J. William McDonald,

Assistant Commissioner, Resources Management.

[FR Doc. 93–9896 Filed 4–27–93; 8:45 am]

BILLING CODE 4310–09–M

INTERSTATE COMMERCE COMMISSION

[Finance Docket No. 32248]

Hanson Natural Resources Co.; Non-Common Carrier Status; Petition for a Declaratory Order

AGENCY: Interstate Commerce Commission.

ACTION: Extension of comment due date.

SUMMARY: By decision served March 1, 1993 (58 FR 12052, March 2, 1993), the Commission sought public comment by March 22, 1993, on a petition for declaratory order filed by Hanson Natural Resources Company (HNRC), that HNRC will not, upon consummation of certain anticipated transactions, become a common carrier by railroad. By subsequent decisions of which the latest was served April 20, 1993 (58 FR 21595, April 22, 1993), the Commission extended the comment due date to April 23, 1993. By motion filed April 22, 1993, HNRC requests a further extension of the comment due date to April 30, 1993. HNRC states the extension is needed to finalize discussions with Chaco Energy Company (Chaco) and to continue drafting certain documents in order to finalize an agreement. HNRC states that Santa Fe Entities joins in this request. HNRC maintains an extension will prejudice no one. The request will be granted.

DATES: Comments must be filed by April 30, 1993.

ADDRESSES: Send an original and 15 copies of comments, referring to Finance Docket No. 32248 to: Office of the Secretary, Case Control Branch, Interstate Commerce Commission, Washington, DC 20423.

In addition, send one copy to HNRC's representative: C. Michael Loftus, Slover & Loftus, 1224 Seventeenth St., NW., Washington, DC 20036. (202) 374–7170.

FOR FURTHER INFORMATION CONTACT: Joseph H. Dettmar, (202) 927–5660, [TDD for hearing impaired: (202) 927–5721].

Decided: April 23, 1993.

By the Commission, Sidney L. Strickland, Jr., Secretary.

Sidney L. Strickland, Jr.,

Secretary.

[FR Doc. 93–9960 Filed 4–27–93; 8:45 am]

BILLING CODE 7035–01–M

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Manufacturer of Controlled Substances; Application

Pursuant to § 1301.43(a) of title 21 of the Code of Federal Regulations (CFR), this is notice that on March 5, 1993, Johnson Matthey Inc., Custom Pharmaceuticals Department, 2002 Nolte Drive, West Deptford, New Jersey 08066, made written request to the Drug Enforcement Administration (DEA) for registration as a bulk manufacturer of the basic classes of controlled substances listed below:

Drug	Schedule
Hydromorphone (9150)	II
Morphine (9300)	II

Any other such applicant and any person who is presently registered with DEA to manufacture such substances may file comments or objections to the issuance of the above application and may also file a written request for a hearing thereon in accordance with 21 CFR 1301.54 and in the form prescribed by 21 CFR 1316.47.

Any such comments, objections, or requests for a hearing may be addressed to the Director, Office of Diversion Control, Drug Enforcement Administration, United States Department of Justice, Washington, DC 20537, Attention: DEA Federal Register Representative (CCR) and must be filed no later than 30 days from publication.

Dated: April 15, 1993.

Gene R. Haislip,

Director, Office of Diversion Control, Drug Enforcement Administration.

[FR Doc. 93–9947 Filed 4–27–93; 8:45 am]

BILLING CODE 4410–09–M

Importation of Controlled Substances; Application

Pursuant to section 1008 of the Controlled Substances Import and Export Act (21 U.S.C. 958(i)), the Attorney General shall, prior to issuing a registration under this Section to a bulk manufacturer of a controlled substance in Schedule I or II and prior to issuing a regulation under section 1002(a) authorizing the importation of such a substance, provide manufacturers holding registrations for the bulk manufacture of the substance an opportunity for a hearing.

Therefore, in accordance with § 1311.42 of title 21, Code of Federal Regulations (CFR), notice is hereby given that on February 20, 1993, James

Prust, 5900 31st Avenue, Kenosha, Wisconsin 53144, made application to the Drug Enforcement Administration to be registered as an importer of marihuana (7360) a basic class of controlled substance listed Schedule I. This application is exclusively for the importation of marihuana seed which will be rendered non-viable and used as bird seed.

Any manufacturer holding, or applying for, registration as a bulk manufacturer of this basic class of controlled substance may file written comments on or objections to the application described above and may, at the same time, file a written request for a hearing on such application in accordance with 21 CFR 1301.54 in such form as prescribed by 21 CFR 1316.47.

Any such comments, objections, or requests for a hearing may be addressed to the Director, Office of Diversion Control, Drug Enforcement Administration, United States Department of Justice, Washington, DC 20537, Attention: DEA Federal Register Representative (CCR), and must be filed no later than 30 days from publication.

This procedure is to be conducted simultaneously with and independent of the procedures described in 21 CFR 1311.42(b), (c), (d), (e), and (f). As noted in a previous notice at 40 FR 43745–46 (September 23, 1975), all applicants for registration to import a basic class of any controlled substance in Schedule I or II are and will continue to be required to demonstrate to the Director of the Drug Enforcement Administration that the requirements for such registration pursuant to 21 U.S.C. 958(a), 21 U.S.C. 823(a), and 21 CFR 1311.42(a), (b), (c), (d), (e), and (f) are satisfied.

Dated: April 15, 1993.

Gene R. Haislip,

Director, Office of Diversion Control, Drug Enforcement Administration.

[FR Doc. 93–9948 Filed 4–27–93; 8:45 am]

BILLING CODE 4410–09–M

MARTIN LUTHER KING, JR., FEDERAL HOLIDAY COMMISSION

Meeting

AGENCY: Martin Luther King, Jr., Federal Holiday Commission.

ACTION: Notice of meeting.

SUMMARY: In accordance with the Federal Advisory Act, Public Law 92–463, as amended, the Martin Luther King, Jr. Federal Holiday Commission announces a forthcoming meeting of the Commission.

DATES: May 3, 1993.

TIME: 10:30 a.m.–12 noon.

LOCATION: U.S. House of Representatives, Cannon House Office Building, room 311, Washington, DC. The public is invited.

FOR FURTHER INFORMATION CONTACT: Al Boutin, Director of Operations, telephone 404–730–3155 (Atlanta, GA).

Dated: April 21, 1993.

Al Boutin,

Director of Operations.

[FR Doc. 93–9894 Filed 4–27–93; 8:45 am]

BILLING CODE 4210–01–M

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

[Notice 93–032]

Advisory Committee on the Redesign of the Space Station; Meeting

AGENCY: National Aeronautics and Space Administration.

ACTION: Notice of meeting.

SUMMARY: In accordance with the Federal Advisory Committee Act, Public Law 92–463, as amended, the National Aeronautics and Space Administration announces a forthcoming meeting of the Advisory Committee on the Redesign of the Space Station (hereinafter referred to as the "Advisory Committee").

DATES: May 3, 1993, 12:30 p.m. to 6 p.m.

ADDRESSES: Crystal Gateway Marriot, Arlington Ballroom Number 3, 1700 Jefferson Davis Highway, Arlington, VA 22203.

FOR FURTHER INFORMATION CONTACT: Mr. John McCarthy, Code R, National Aeronautics and Space Administration, Washington, DC 20546, 202/358–4599.

SUPPLEMENTARY INFORMATION: The meeting will be open to the public on May 3 up to the seating capacity of the room, which is approximately 430 persons including Advisory Committee members and other participants. The agenda for the meeting is as follows:

—Requirements Assessment Process Update

—Option Development Status and Plans

—Preliminary Schedule and Cost Assessment

—Briefings as Appropriate

It is imperative that the meeting be held on these dates to accommodate the scheduling priorities of the key participants, and in order for the Committee to complete its report by June.

Dated: April 26, 1993.

Danalee Green,

Chief, Management Controls Office, National Aeronautics and Space Administration.

[FR Doc. 93–10094 Filed 4–27–93; 8:45 am]

BILLING CODE 7510–01–M

NUCLEAR REGULATORY COMMISSION

Advisory Committee on Reactor Safeguards (ACRS) and Advisory Committee on Nuclear Waste (ACNW); Notice of Proposed Meetings

In order to provide advance information regarding proposed public meetings of the ACRS Subcommittees and meetings of the ACRS full Committee, of the ACNW, and the ACNW Working Groups the following preliminary schedule is published to reflect the current situation, taking into account additional meetings that have been scheduled and meetings that have been postponed or cancelled since the last list of proposed meetings was published March 25, 1993 (58 FR 16214). Those meetings that are firmly scheduled have had, or will have, an individual notice published in the **Federal Register** approximately 15 days (or more) prior to the meeting. It is expected that sessions of ACRS and ACNW full Committee meetings designated by an asterisk (*) will be closed in whole or in part to the public. The ACRS and ACNW full Committee meetings begin at 8:30 a.m. and ACRS Subcommittee and ACNW Working Group meetings usually begin at 8:30 a.m. The time when items listed on the agenda will be discussed during ACRS and ACNW full Committee meetings, and when ACRS Subcommittee and ACNW Working Group meetings will start will be published prior to each meeting. Information as to whether a meeting has been firmly scheduled, cancelled, or rescheduled, or whether changes have been made in the agenda for the May 1993 ACRS and ACNW full Committee meetings can be obtained by a prepaid telephone call to the Office of the Executive Director of the Committees (telephone: 301/492–4600 (recording) or 301/492–7288, Attn: Barbara Jo White) between 7:30 a.m. and 4:15 p.m., (EDT).

ACRS Subcommittee Meetings

Probabilistic Risk Assessment, May 11, 1993, Bethesda, MD. The Subcommittee will discuss the report of the PRA Working Group that summarizes activities of this Group and provides guidance for the staff regarding the application of PRA.

Joint Thermal Hydraulic Phenomena/Core Performance, May 12, 1993, Bethesda, MD. The Subcommittees will continue their review of the issues pertaining to BWR core power stability. Also, they will discuss the status of issues associated with BWR vessel water level instrumentation.

Planning and Procedures, May 12, 1993, Bethesda, MD (3 p.m.–5:30 p.m.). The Subcommittee will discuss proposed ACRS activities and related matters. Qualifications of candidates nominated for appointment to the ACRS will also be discussed. Portions of this meeting will be closed to discuss information the release of which would represent a clearly unwarranted invasion of personal privacy.

Planning and Procedures, June 9, 1993, Bethesda, MD (3 p.m.–5:30 p.m.). The Subcommittee will discuss proposed ACRS activities and related matters. Qualifications of candidates nominated for appointment to the ACRS will also be discussed. Portions of this meeting will be closed to discuss information the release of which would represent a clearly unwarranted invasion of personal privacy.

Advanced Boiling Water Reactors, June 17, 1993, San Jose, CA. The Subcommittee will review matters related to the General Electric Nuclear Energy Standard Safety Analysis Report related to the ABWR design.

Regulatory Policies and Practices, July 7, 1993, Bethesda, MD (1 p.m.–5 p.m.). The Subcommittee will discuss the report of the NRC Regulatory Review Group.

Planning and Procedures, July 7, 1993, Bethesda, MD (3 p.m.–5:30 p.m.). The Subcommittee will discuss proposed ACRS activities and related matters. Qualifications of candidates nominated for appointment to the ACRS will also be discussed. Portions of this meeting will be closed to discuss information the release of which would represent a clearly unwarranted invasion of personal privacy.

Thermal Hydraulic Phenomena, July 22–23, 1993, Bethesda, MD. The Subcommittee will begin its review of both the Westinghouse analytical and separate effects programs being conducted in support of the AP600 design certification effort.

Advanced Boiling Water Reactors, October 26–27, 1993, Bethesda, MD. The Subcommittee will continue its review of the GE ABWR Standard Safety Analysis Report and the associated NRC staff's Final Safety Evaluation Report.

Advanced Boiling Water Reactors, November 16–17, 1993, Bethesda, MD. The Subcommittee will continue its review of the GE ABWR Standard Safety Analysis Report and the associated NRC staff's Final Safety Evaluation Report.

ACRS Full Committee Meetings

397th ACRS Meeting, May 13–15, 1993, Bethesda, MD. During this meeting, the Committee plans to consider the following:

A. *Proposed Resolution of Generic Issue 105, "Interfacing Systems LOCA in LWRs"*—Review and comment on the NRC staff's proposed resolution of Generic Issue 105. Representatives of the NRC staff and the industry will participate, as appropriate.

B. *PRA Working Groups Activities*—Review and comment on a draft report on the proposed application of PRA prepared by the PRA Working Group. Representatives of the NRC staff and the industry will participate, as appropriate.

C. *Proposed NRC Staff Plan for Comparing Safety Goals with Regulations*—Review and comment on a proposed NRC Staff Plan for using the Safety Goal Policy to judge the effectiveness of the NRC regulations. Representatives of the NRC staff and the industry will participate, as appropriate.

D. *Boiling Water Reactor Core Power Stability*—Review and comment on the NRC staff's review of the approaches proposed by the BWR Owners Group for resolving the issue of BWR core power stability. Representatives of the NRC staff and the industry will participate, as appropriate.

E. *SECY–93–067, Final Policy Statement on Technical Specifications Improvements*—Review and comment on the staff's proposed final policy statement on technical specifications improvements. Representatives of the NRC staff and the industry will participate, as appropriate.

F. *Advanced Reactor Schedules*—Hear a briefing by and hold discussions with representatives of the NRC staff on the schedules for the NRC review of advanced reactor designs.

G. *Form and Content of Combined Operating License*—Hear a briefing by and hold discussions with representatives of the NRC staff regarding requirements for preparation and submittal of documents with regard to a Combined Operating License. Representatives of the industry will participate, as appropriate.

H. *Need for Amending the Backfit Rule (Tentative)*—Discuss the need for the NRC to amend the Backfit Rule. Representatives of the NRC staff and the industry will participate, as appropriate.

I. *Meeting the NRC Commissioners*—Meet with the NRC Commissioners to discuss items of mutual interest.

J. *Meeting with the Director of the Office of Nuclear Reactor Regulation*—Meet with the Director of the Office of Nuclear Reactor Regulation to discuss items of mutual interest.

K. *Future ACRS Activities*—Discuss topics proposed for consideration by the full Committee.

L. *Resolution of ACRS Recommentations*—Discuss responses from the NRC Executive Director for Operations to recent ACRS comments and recommendations.

M. *ACRS Subcommittee Activities*—Hear reports and hold discussions regarding the status of ACRS subcommittee activities, including status of issues associated with the BWR vessel water level instrumentation and use of advanced computer graphics in nuclear power plant design process.

*N. *Appointment of ACRS Members*—Discuss qualifications of candidates proposed for appointment as ACRS members. Portions of this session will be closed to discuss information the release of which would represent a clearly unwarranted invasion of personal privacy.

O. *Miscellaneous*—Discuss miscellaneous matters related to the conduct of Committee activities and complete discussion of topics that were not completed during previous meetings as time and availability of information permit.

398th ACRS Meeting, June 10–12, 1993, Bethesda, MD. Agenda to be announced.

399th ACRS Meeting, July 8–10, 1993, Bethesda, MD. Agenda to be announced.

400th ACRS Meeting, August 5–7, 1993, Bethesda, MD. Agenda to be announced.

401st ACRS Meeting, September 9–11, 1993, Bethesda, MD. Agenda to be announced.

402nd ACRS Meeting, October 7–9, 1993, Bethesda, MD. Agenda to be announced.

403rd ACRS Meeting, November 4–6, 1993, Bethesda, MD. Agenda to be announced.

404th ACRS Meeting, December 9–11, 1993, Bethesda, MD. Agenda to be announced.

ACNW Full Committee and Working Group Meetings

53rd ACNW Meeting, May 19–20, 1993, Bethesda, MD. During this meeting, the Committee plans to consider the following:

A. *Revised Draft HLW Research Program Plan*—Review and comment on the revised Draft HLW Research Program Plan, NUREG–1406, and associated technical assistance. Representatives of the NRC staff will participate.

*Closed

B. *Standard Review Plan for the Review of Remedial Action of Inactive Mill Tailings Sites*—Review and comment on Revision 1 of the Standard Review Plan for use in reviewing the Remedial Action of Inactive Mill Tailings Sites Under Title I of the Uranium Mill Tailings Radiation Control Act. Representatives of the NRC staff will participate.

C. *DOE Site Characterization Progress Reports*—Hear briefings by and hold discussions with representatives of the NRC staff on NRC's responses and follow-up to the DOE Site Characterization Progress Reports for the Proposed Yucca Mountain repository. Also, discuss the revised procedures for evaluating the DOE study plans. Representatives of DOE will participate, as appropriate.

D. *Systematic Regulatory Analysis*—Hear briefings by and hold discussions with representatives of the NRC staff and the Center for Nuclear Waste Regulatory Analyses (CNWRA) on the current status of the Systematic Regulatory Analysis, conducted by CNWRA, and products resulting from this initiative, including technical assistance efforts and the development of the License Application Review Plan.

E. *Standard Review Plan*—Hear a briefing by and hold discussions with representatives of the NRC regarding a proposed NRC staff Standard Review Plan for use in reviewing the DOE Study Plans.

F. *Committee Activities*—Discuss anticipated and proposed Committee activities, future meeting agenda, and organizational matters, as appropriate.

G. *Miscellaneous*—Discuss miscellaneous matters related to the conduct of Committee activities and complete discussion of topics that were not completed during previous meetings as time and availability of information permit.

54th ACNW Meeting July 21–22, 1993, Bethesda, MD. Agenda to be announced.

55th ACNW Meeting August 25–26, 1993, Bethesda, MD. Agenda to be announced.

56th ACNW Meeting September 22–23, 1993, Bethesda, MD. Agenda to be announced.

57th ACNW Meeting October 27–28, 1993, Bethesda, MD. Agenda to be announced.

58th ACNW Meeting November 22–23, 1993, Bethesda, MD. Agenda to be announced.

59th ACNW Meeting December 15–16, 1993, Bethesda, MD. Agenda to be announced.

Dated: April 22, 1993.

John C. Hoyle,

Advisory Committee Management Officer.

[FR Doc. 93–9907 Filed 4–27–93; 8:45 am]

BILLING CODE 7590–01–M

UNITED STATES NUCLEAR REGULATORY COMMISSION

Biweekly Notice

Applications and Amendments to Facility Operating Licenses Involving No Significant Hazards Considerations

I. Background

Pursuant to Public Law 97-415, the U.S. Nuclear Regulatory Commission (the Commission or NRC staff) is publishing this regular biweekly notice. Public Law 97-415 revised section 189 of the Atomic Energy Act of 1954, as amended (the Act), to require the Commission to publish notice of any amendments issued, or proposed to be issued, under a new provision of section 189 of the Act. This provision grants the Commission the authority to issue and make immediately effective any amendment to an operating license upon a determination by the Commission that such amendment involves no significant hazards consideration, notwithstanding the pendency before the Commission of a request for a hearing from any person.

This biweekly notice includes all notices of amendments issued, or proposed to be issued from April 5, 1993, through April 16, 1993. The last biweekly notice was published on April 14, 1993.

Notice of Consideration of Issuance of Amendments to Facility Operating Licenses, Proposed No Significant Hazards Consideration Determination, and Opportunity for a Hearing

The Commission has made a proposed determination that the following amendment requests involve no significant hazards consideration. Under the Commission's regulations in 10 CFR 50.92, this means that operation of the facility in accordance with the proposed amendment would not (1) involve a significant increase in the probability or consequences of an accident previously evaluated; or (2) create the possibility of a new or different kind of accident from any accident previously evaluated; or (3) involve a significant reduction in a margin of safety. The basis for this proposed determination for each amendment request is shown below.

The Commission is seeking public comments on this proposed determination. Any comments received within 30 days after the date of publication of this notice will be considered in making any final determination.

Normally, the Commission will not issue the amendment until the expiration of the 30-day notice period. However, should circumstances change during the notice period such that failure to act in a timely way would result, for example, in derating or shutdown of the facility, the Commission may issue the license amendment before the expiration of the 30-day notice period, provided that its final determination is that the amendment involves no significant hazards consideration. The final determination will consider all public and State comments received before action is taken. Should the Commission take this action, it will publish in the **Federal Register** a notice of issuance and provide for opportunity for a hearing after issuance. The Commission expects that the need to take this action will occur very infrequently.

Written comments may be submitted by mail to the Rules Review and Directives Branch, Division of Freedom of Information and Publications Services, Office of Administration, U.S. Nuclear Regulatory Commission, Washington, DC 20555, and should cite the publication date and page number of this **Federal Register** notice. Written comments may also be delivered to room P-223, Phillips Building, 7920 Norfolk Avenue, Bethesda, Maryland from 7:30 a.m. to 4:15 p.m. Federal workdays. Copies of written comments received may be examined at the NRC Public Document Room, the Gelman Building, 2120 L Street, NW., Washington, DC 20555. The filing of requests for a hearing and petitions for leave to intervene is discussed below.

By May 28, 1993, the licensee may file a request for a hearing with respect to issuance of the amendment to the subject facility operating license and any person whose interest may be affected by this proceeding and who wishes to participate as a party in the proceeding must file a written request for a hearing and a petition for leave to intervene. Requests for a hearing and a petition for leave to intervene shall be filed in accordance with the Commission's "Rules of Practice for Domestic Licensing Proceedings" in 10 CFR part 2. Interested persons should consult a current copy of 10 CFR 2.714 which is available at the Commission's Public Document Room, the Gelman Building, 2120 L Street, NW., Washington, DC 20555 and at the local public document room for the particular

facility involved. If a request for a hearing or petition for leave to intervene is filed by the above date, the Commission or an Atomic Safety and Licensing Board, designated by the Commission or by the Chairman of the Atomic Safety and Licensing Board Panel, will rule on the request and/or petition; and the Secretary or the designated Atomic Safety and Licensing Board will issue a notice of a hearing or an appropriate order.

As required by 10 CFR 2.714, a petition for leave to intervene shall set forth with particularity the interest of the petitioner in the proceeding, and how that interest may be affected by the results of the proceeding. The petition should specifically explain the reasons why intervention should be permitted with particular reference to the following factors: (1) The nature of the petitioner's right under the Act to be made a party to the proceeding; (2) the nature and extent of the petitioner's property, financial, or other interest in the proceeding; and (3) the possible effect of any order which may be entered in the proceeding on the petitioner's interest. The petition should also identify the specific aspect(s) of the subject matter of the proceeding as to which petitioner wishes to intervene. Any person who has filed a petition for leave to intervene or who has been admitted as a party may amend the petition without requesting leave of the Board up to 15 days prior to the first prehearing conference scheduled in the proceeding, but such an amended petition must satisfy the specificity requirements described above.

Not later than 15 days prior to the first prehearing conference scheduled in the proceeding, a petitioner shall file a supplement to the petition to intervene which must include a list of the contentions which are sought to be litigated in the matter. Each contention must consist of a specific statement of the issue of law or fact to be raised or controverted. In addition, the petitioner shall provide a brief explanation of the bases of the contention and a concise statement of the alleged facts or expert opinion which support the contention and on which the petitioner intends to rely in proving the contention at the hearing. The petitioner must also provide references to those specific sources and documents of which the petitioner is aware and on which the petitioner intends to rely to establish those facts or expert opinion. Petitioner must provide sufficient information to show that a genuine dispute exists with the applicant on a material issue of law or fact. Contentions shall be limited to matters within the scope of the amendment under consideration. The contention must be one which, if proven, would entitle the petitioner to relief. A petitioner who fails to file such a supplement which satisfies these requirements with respect to at least one contention will not be permitted to participate as a party.

Those permitted to intervene become parties to the proceeding, subject to any limitations in the order granting leave to intervene, and have the opportunity to participate fully in the conduct of the hearing, including the opportunity to present evidence and cross-examine witnesses.

If a hearing is requested, the Commission will make a final determination on the issue of no significant hazards consideration. The final determination will serve to decide when the hearing is held.

If the final determination is that the amendment request involves no significant hazards consideration, the Commission may issue the amendment and make it immediately effective, notwithstanding the request for a hearing. Any hearing held would take place after issuance of the amendment.

If the final determination is that the amendment request involves a significant hazards consideration, any hearing held would take place before the issuance of any amendment.

A request for a hearing or a petition for leave to intervene must be filed with the Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, DC 20555, Attention: Docketing and Services Branch, or may be delivered to the Commission's Public Document Room, the Gelman Building, 2120 L Street, NW., Washington DC 20555, by the above date. Where petitions are filed during the last 10 days of the notice period, it is requested that the petitioner promptly so inform the Commission by a toll-free telephone call to Western Union at 1-(800) 248-5100 (in Missouri 1-(800) 342-6700). The Western Union operator should be given Datagram Identification Number N1023 and the following message addressed to **(Project Director)**: petitioner's name and telephone number, date petition was mailed, plant name, and publication date and page number of this **Federal Register** notice. A copy of the petition should also be sent to the Office of the General Counsel, U.S. Nuclear Regulatory Commission, Washington, DC 20555, and to the attorney for the licensee.

Nontimely filings of petitions for leave to intervene, amended petitions, supplemental petitions and/or requests for a hearing will not be entertained absent a determination by the Commission, the presiding officer or the Atomic Safety and Licensing Board that the petition and/or request should be granted based upon a balancing of factors specified in 10 CFR 2.714(a)(1)(i)-(v) and 2.714(d).

For further details with respect to this action, see the application for amendment which is available for public inspection at the Commission's Public Document Room, the Gelman Building, 2120 L Street, NW., Washington, DC 20555, and at the local public document room for the particular facility involved.

Baltimore Gas and Electric Company, Docket Nos. 50-317 and 50-318, Calvert Cliffs Nuclear Power Plant, Unit Nos. 1 and 2, Calvert County, Maryland

Date of amendments request: April 1, 1993

Description of amendments request: The proposed amendments would revise Technical Specification (TS) 3/4.1.2 "Boration Systems." The proposed changes will separate the requirements for mitigating small break loss-of-coolant accidents (SBLOCA) from the requirements for providing emergency boration. The requested changes are administrative in nature in that they do not add, revise, or delete any of the existing TS requirements. The changes provide needed clarification to ensure that the appropriate boration lineups are operable during the applicable mode of operation. The TS Bases Section, 3/4.1 "Reactivity Control Systems," will also be revised to support the proposed amendments.

The specific changes and clarification proposed to separate the requirements for mitigating a SBLOCA from the requirements for providing emergency boration are:

TS 3.1.2.6 Boric Acid Pumps - Operating, Limiting Condition for Operation (LCO), will be changed to include a reference to TS 3.1.2.8 Charging Pump Emergency Core Cooling (ECCS) Subsystems:

TS 3.1.2.8 Charging Pump ECCS Subsystems will be changed to only contain the requirements which need to be met to mitigate a SBLOCA. This LCO will continue to be applicable to Mode 1 when greater than 80% of rated thermal power. The previous requirements for providing emergency boration capability are moved to TS 3.1.2.9 Borated Water Sources - Operating.

The footnote on TS 3.1.2.9, Borated Water Sources - Operating, which makes the LCO applicable to Mode 1 when greater than or equal to 80% of rated thermal power is removed. The LCO, as changed, will be applicable in Modes 1

through 4 to assure the requirements needed for emergency boration are available.

Basis for proposed no significant hazards consideration determination: As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

1. Would not involve a significant increase in the probability or consequences of an accident previously evaluated.

The Boration System provides borated water to the Reactor Coolant System to ensure that negative reactivity control is available during each Mode of Operation and during transient conditions. The current Technical Specifications combine the requirements for providing emergency boration and for mitigating a small break loss-of-coolant (SBLOCA). The proposed change will separate the requirements for emergency boration from those for a SBLOCA. The change does not add, revise, or delete any of the existing requirements, nor does it affect the safety function of the Boration System.

Separating the Boration System Technical Specifications to distinguish between the requirements for emergency boration purposes and the requirements to mitigate a SBLOCA will have no effect on the probability of an accident previously evaluated. These changes are administrative in nature and only clarify the existing requirements.

The proposed changes to the Boration System Technical Specifications will have no effect on the consequences of an accident previously evaluated. They will clarify the alignment of systems currently required to be operable. Therefore, this change will not involve a significant increase in the probability or consequences of an accident previously evaluated.

2. Would not create the possibility of a new or different type of accident from any accident previously evaluated.

The proposed changes to the Boration System Technical Specifications are administrative in nature and, therefore, do not represent a significant change in the configuration or operation of the plant. Specifically, no new hardware is being added to the plant as part of the proposed change, no existing equipment is being modified, nor are any different types of operations being introduced. The proposed change will only clarify existing Technical Specifications. Therefore, this change would not create the possibility of a new or different type of accident from any accident previously evaluated.

3. Would not involve a significant reduction in the margin of safety.

The proposed changes to the Boration System Technical Specifications are administrative in nature and, as such, will maintain the existing margin of safety. Clarifying these Technical Specifications will distinguish between what borated water sources and flowpaths are required for emergency boration purposes and which ones are required to mitigate a SBLOCA. Therefore, the proposed change would not involve a significant reduction in the margin of safety.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendments request involves no significant hazards consideration.

Local Public Document Room location: Calvert County Library, Prince Frederick, Maryland 20678.

Attorney for licensee: Jay E. Silbert, Esquire, Shaw, Pittman, Potts and Trowbridge, 2300 N Street, NW., Washington, DC 20037.

NRC Project Director: Robert A. Capra

Commonwealth Edison Company, Docket Nos. 50-295 and 50-304, Zion Nuclear Power Station, Units 1 and 2, Lake County, Illinois

Date of application for amendment: March 11, 1993

Description of amendments request: The proposed amendments would revise the Technical Specifications by relocating the procedural details of the radiological effluent/radiological environmental monitoring program and solid waste program to the Offsite Dose Calculation Manual (ODCM) and the Process Control Program (PCP).

Basis for proposed no significant hazards consideration determination: As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

1. The proposed changes only alter the format and location of procedural details and administrative controls of the radioactive effluents, radiological environmental monitoring and solid radioactive waste programs. The changes are administrative in nature and do not involve any change to the configuration or operation of plant equipment. The Radiological Effluent Technical Specifications (RETS) procedural details are being moved to the Offsite Dose Calculation Manual (ODCM), and the Process Control Program (PCP). However, the contents of the RETS are not being changed. The purpose of the RETS is to assure that the proper controls for the radiological effluent system are in place. The programs containing the procedural details of RETS will continue to perform the same functions. Any future changes to the programs containing the RETS procedural details would require an onsite review and approval. Therefore, the RETS will continue to receive a high level of consideration even though they will no longer be part of the Technical Specifications. All the current provisions of the RETS are being retained, so none of the assumptions used in the accident analysis will be affected. Based on this evaluation, it has been determined that the changes do not affect the probability or consequences of a previously evaluated accident.

2. The procedural requirements of the RETS will be maintained in the ODCM and the PCP. Operation of the plant will not be altered by the changes proposed to the administration of the RETS. This change will not place the plant in any new condition or introduce any mode of operation not previously analyzed. Therefore, this change will not create the possibility of a new or different kind of accident from any accident previously evaluated.

3. The proposed changes relocate the procedural details and bases of RETS from the Technical Specifications to the ODCM or PCP. The RETS procedural details and bases will be maintained by these programs. Changes to these programs will require an onsite review. In addition, new administrative controls have been added to the Technical Specifications which assure the proper control and maintenance of these documents and provide an equivalent level of assurance that activities involving radioactive effluents, solid radioactive waste, and radiological environmental monitoring are conducted in full compliance with regulatory requirements. Therefore, there is no reduction in the margin of safety.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

Local Public Document Room location: Waukegan Public Library, 128 N. County Street, Waukegan, Illinois 60085

Attorney for licensee: Michael I. Miller, Esquire; Sidley and Austin, One First National Plaza, Chicago, Illinois 60690

NRC Project Director: James E. Dyer

Detroit Edison Company, Docket No. 50-341, Fermi-2, Monroe County, Michigan

Date of amendment request: January 29, 1992

Description of amendment request: The proposed amendment would modify the Fermi 2 Technical Specifications for surveillance testing of activated charcoal samples from the Control Room Emergency Filtration System (CREFS) and the Standby Gas Treatment System (SGTS). Specifically, laboratory analysis of a representative charcoal sample from the CREFS and SGTS are required at least every 18 months, after 720 hours of operation, following structural maintenance on filter or charcoal adsorber housings, and following painting, fire or chemical release in any ventilation zone communicating with the CREFS or SGTS. The licensee proposes to update the standards used to evaluate the

surveillances in accordance with previous commitments to the NRC.

Basis for proposed no significant hazards consideration determination: As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

(1) Involve a significant increase in the probability or consequences of an accident previously evaluated.

By providing an improved procedure for charcoal analysis the proposal provides greater assurance that the installed charcoal can perform its design function and, thus, the consequences of evaluated accidents are valid. The method of laboratory analysis has no effect upon how the plant is operated, including the method of sample removal. Therefore, the probability of any evaluated accident is unchanged.

(2) Create the possibility of a new or different kind of accident from any accident previously evaluated.

As described in 1) above, the proposal has no effect on the manner of plant operation. The proposal does not involve any change to the plant design. Therefore, the change creates no new accident modes.

(3) Involve a significant reduction in a margin of safety.

By providing an improved procedure for charcoal analysis the proposal acts to maintain existing safety margins.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

Local Public Document Room location: Monroe County Library System, 3700 South Custer Road, Monroe, Michigan 48161

Attorney for licensee: John Flynn, Esq., Detroit Edison Company, 2000 Second Avenue, Detroit, Michigan 48226

NRC Project Director: L. B. Marsh

Duquesne Light Company, et al., Docket Nos. 50-334 and 50-412, Beaver Valley Power Station, Unit Nos. 1 and 2, Shippingport, Pennsylvania

Date of amendment request: February 19, 1993

Description of amendment request: The proposed amendment would modify Specifications 3.4.9.1, 3.4.9.2 and 4.4.9.2. The changes would specify a 72-hour time limit for an engineering evaluation if an out-of-limit condition is reached, compared to no time limit currently existing. The changes also reformat the action statement into a list of actions. Pressurizer differential spray temperature would be monitored every 30 minutes instead of every 12 hours. In addition, for Unit 2 only, the pressurizer spray water differential temperature limit would be reduced to 320°F (from 625°F), and an auxiliary spray water differential temperature limit of 380°F would be specified.

Basis for proposed no significant hazards consideration determination: As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

1. Does the change involve a significant increase in the probability or consequences of an accident previously evaluated?

The proposed amendment modifies Specifications 3.4.9.1 and 3.4.9.2 by incorporating the STS [Standard Technical Specifications] action requirements in addition to clarification of the limiting condition for operation and surveillance requirements. This change was first initiated to revise the BV-2 pressurizer spray differential temperature limit by replacing the 625°F limit with the 320°F limit. The pressurizer spray differential temperature limit was identified as a concern during investigation into the BV-2 pressurizer surge line thermal stratification issue and the leak-before-break analysis associated with the large bore snubber removal. Additional changes were also included following review of the STS for clarification of the action statements for Specifications 3.4.9.1 and 3.4.9.2.

The current BV-2 auxiliary spray differential temperature limit was incorporated in Specification 3.4.9.2 to provide the maximum value consistent with the pressurizer equipment specification. The fatigue analysis for the pressurizer surge line provides for a limited number of cycles above 320°F, however, the design analysis has been verified to account for auxiliary spray operation with a differential temperature limit of 380°F. Therefore, to ensure the equipment meets the acceptance criteria for the design life of the plant, the normal spray differential temperature limit has been reduced to 320°F and an auxiliary spray differential temperature limit of 380°F has been added. The BV-2 piping adjacent to the pressurizer spray nozzle is equipped with a thermal sleeve which allows the higher limit. BV-1 doesn't have this design, therefore, the 380°F differential temperature doesn't apply for BV-1. The proposed change establishes a more conservative limit and does not affect the [Updated Final Safety Analysis Report] UFSAR, therefore, this change does not involve a significant increase in the probability or consequences of an accident previously evaluated.

The action statements for these specifications have been revised to incorporate the STS requirements in intent, but the format has been changed to separate each of the individual actions and to incorporate a 72 hour action time to perform the engineering evaluation. The current action statements are consistent with the original STS.

Later revisions to the STS modified the wording to more clearly define the type of review required (engineering evaluation) and to ensure the correct subject is evaluated (structural integrity). Reformatting the action statements was done to more clearly present the action requirements and to provide a time period in which to perform the engineering evaluation since none is specified in the STS. The 72 hours is based on typical technical specification action times for performing certain actions prior to beginning a plant shutdown. These are administrative changes that are reasonable, safe and do not affect the UFSAR, therefore, these changes do not involve a significant increase in the probability or consequences of an accident previously evaluated.

The format of Surveillance Requirement 4.4.9.2.2 has been revised for both units into separate surveillance 4.4.9.2.1 and 4.4.9.2.2 to provide the surveillance in a clear format and add surveillance 4.4.9.2.3 for auxiliary spray water differential temperature. Normal pressurizer spray is supplied from the RCS and is not expected to exceed the maximum spray water differential temperature limit during power operation, but during heatup and cooldown operations the differential temperature may approach the limit at low RCS temperatures. Therefore, Surveillance Requirement 4.4.9.2.2 is applied to normal spray and requires verifying the differential temperature is within the limit at least once per 30 minutes during heatup and cooldown operations. This frequency is consistent with 4.4.9.2.1 for verification of the pressurizer temperature also required during heatup and cooldown operations. Surveillance Requirement 4.4.9.2.3 is applied to auxiliary spray operation with verification of the differential temperature at least once per 30 minutes when auxiliary spray is used. Since auxiliary spray may be used at times other than during heatup and cooldown operations, it has been separated from normal spray. These changes reflect the analysis assumptions and are consistent with the operation of the pressurizer sprays, therefore, these changes do not involve a significant increase in the probability or consequences of an accident previously evaluated.

2. Does the change create the possibility of a new or different kind of accident from any accident previously evaluated?

The requirements of BV-2 Specification 3.4.9.2 will continue to govern the operability of the pressurizer and incorporates more conservative spray water differential temperature limits that are consistent with the analysis. The proposed change does not introduce any new mode of plant operation or require any physical modification to the plant, therefore, this change will not create the possibility of a new or different kind of accident from any accident previously evaluated.

The revised action statement for Specifications 3.4.9.1 and 3.4.9.2 is consistent with the intent of the STS and will ensure an engineering evaluation is performed when required to ensure the structural integrity of the RCS and the pressurizer is acceptable for continued plant operation. Changing the format separates the individual action requirements into individual actions. Adding the 72 hour action time to perform the engineering

evaluation is consistent with other action requirements which provide a typical action time to perform an action function prior to plant shutdown. These changes do not reduce the limiting condition for operation or action requirements, therefore, these changes will not create the possibility of a new or different kind of accident from any accident previously evaluated in the UFSAR.

Surveillance Requirement 4.4.9.2 for both units has been separated into individual surveillances 4.4.9.2.1 and 4.4.9.2.2. Surveillance Requirement 4.4.9.2.1 requires verification of the pressurizer temperatures at least once per 30 minutes during system heatup and cooldown operations. This is consistent with the current surveillance requirement. Surveillance Requirement 4.4.9.2.2 requires verification of the normal spray water temperature differential at least once per 30 minutes during system heatup and cooldown operations. This includes changing the surveillance requirement to apply to normal spray, replaces the 12 hour frequency with 30 minutes, and changes the application of this surveillance requirement to system heatup or cooldown operations. Surveillance Requirement 4.4.9.2.3 has been added for verification of the auxiliary spray water temperature differential at least once per 30 minutes during auxiliary spray operation. These changes specify frequency and application requirements similar to Specification 4.4.9.2.1 where a parameter is verified under the conditions when that parameter may approach the limit. These changes provide for reasonable verification of the required parameters at a consistent frequency and are applied when required to verify system operability, therefore, these changes will not create the possibility of a new or different kind of accident from any accident previously evaluated.

3. Does the change involve a significant reduction in a margin of safety?

The BV-2 625°F auxiliary spray differential temperature limit was incorporated in Specification 3.4.9.2 to provide the maximum value consistent with the pressurizer equipment specification, however, this only provided for a limited number of cycles. By incorporating a conservative reduction in the limit to 320°F for normal spray and 380°F for auxiliary spray the analysis assumptions are satisfied and the equipment meets the acceptance criteria for the design life of the plant. Therefore, overall plant safety is enhanced and the margin of safety is not reduced.

Changing the action statements to specify an engineering evaluation in lieu of an analysis is acceptable since the engineering evaluation can be performed in a reasonable period of time to ensure those parameters that may be affected are consistent with the analysis assumptions. The engineering evaluation provides adequate assurance that the structural integrity of the RCS and pressurizer are acceptable for continued operation and is consistent with the STS, therefore, these changes will not reduce the margin of safety.

Normal pressurizer spray during heatup and cooldown operations and auxiliary spray operation when using auxiliary spray are the limiting conditions for the use of these systems, therefore, the changes to Surveillance Requirement 4.4.9.2 emphasize verification of the differential temperature when these conditions apply. Reducing the frequency to once per 30 minutes provides additional assurance that the differential temperature is adequately monitored and maintained within the specified limits. These changes ensure the required parameters are verified during the applicable conditions and on a consistent frequency, therefore, these changes will not reduce the margin of safety.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

Local Public Document Room location: B. F. Jones Memorial Library, 663 Franklin Avenue, Aliquippa, Pennsylvania 15001.

Attorney for licensee: Gerald Charnoff, Esquire, Jay E. Silberg, Esquire, Shaw, Pittman, Potts & Trowbridge, 2300 N Street, NW., Washington, DC 20037.

NRC Project Director: Walter R. Butler

Florida Power and Light Company, et al., Docket No. 50-335 St. Lucie Plant, Unit No. 1, St. Lucie County, Florida

Date of amendment request: March 19, 1993

Description of amendment request: The proposed amendment allows a reduction in Reactor Coolant System (RDS) design flowrate from the current value of 370,000 gpm to 355,000 gpm in Technical Specifications (TS) Figure 2.1-1, and Tables 2.2-1 and 3.2-1.

The purpose of the proposed change is to accommodate future steam generator tube plugging (SGTP) up to 25% (average). Though not expected, it is possible that SGTP performed during the upcoming refueling outages may eliminate any remaining margin between the actual number of plugged tubes and that used in existing safety analyses assumptions.

Basis for proposed no significant hazards consideration determination: As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

Pursuant to 10 CFR 50.92, a determination may be made that a proposed license amendment involves no significant hazards consideration if operation of the facility in accordance with the proposed amendment would not: (1) involve a significant increase in the probability or consequences of an accident previously evaluated; or (2) create the possibility of a new or different kind of accident from any accident previously evaluated; or (3) involve a significant reduction in a margin of safety. Each standard is discussed as follows:

(1) Operation of the facility in accordance with the proposed amendment would not involve a significant increase in the probability or consequences of an accident previously evaluated.

The proposed amendment would permit full power operation of St. Lucie Unit 1 with a decreased value of design reactor coolant flow. It is postulated that this steady state RCS flow decrease would occur as a result of an increased level of steam generator tube plugging. No increase in the probability of any accident previously analyzed is likely to occur because no changes are being made to the plant's required mode of operation or to any active plant component. By their nature, steam generator tube plugs are passive components and this amendment does not change the nature or type of plugs which may be used.

Florida Power and Light Company (FPL) has submitted the results of a safety evaluation which concludes that potential radiological consequences of previously analyzed accidents remain within their established acceptance criteria when including the values of increased steam generator tube plugging or reduced RCS flow consistent with this proposed amendment. This conclusion is supported by reanalysis of relevant limiting events in several accident categories, as appropriate.

Therefore, operation of the facility in accordance with this amendment would not involve a signficant increase in the probability or consequences of any accident previously evaluated.

(2) Operation of the facility in accordance with the proposed amendment would not create the possibility of a new or different kind of accident from any accident previously evaluated.

This amendment does not result in a change to any active plant component or in the mode of operation of the plant. The design function of the Reactor Coolant System, Steam Generators, Emergency Core Cooling System and other systems will not change. The designed excess capacity of the steam generators can accommodate the potential reduction in primary to secondary heat transfer area caused by increased tube plugging without significantly impacting the plant's dynamic behavior. The presence of plugged steam generator tubes is not changed by this proposed amendment. Therefore, operation of the facility in accordance with the proposed amendment will not create the possibility of a new or different kind of accident from any accident previously evaluated.

(3) Operation of the facility in accordance with the proposed amendment would not involve a significant reduction in a margin of safety.

The impact of the proposed change on available margin to the acceptance criteria for Specified Acceptable Fuel Design Limits (SAFDL), primary and secondary overpressurization transients, 10 CFR 50.46(b) criteria, peak containment pressure, potential radioactive dose releases and to existing Limiting Conditions for Operation has been examined as part of the safety

evaluation submitted by FPL in support of this amendment. After considering the proposed steam generator tube plugging level and resultant RCS flow, a comparison of limiting events to the acceptance criteria listed above shows that a conservative safety margin to the acceptable limits remains available. For this reason, FPL has concluded that there is no significant reduction in a margin of safety as a result of this proposed license amendment.

Based on the discussions presented above and on the supporting technical justifications, FPL has concluded that this proposed license amendment involves no significant hazards consideration.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

Local Public Document Room location: Indian River Junior College Library, 3209 Virginia Avenue, Fort Pierce, Florida 34954-9003

Attorney for licensee: Harold F. Reis, Esquire, Newman and Holtzinger, 1615 L Street, NW., Washington, DC 20036

NRC Project Director: Herbert N. Berkow

Georgia Power Company, Oglethorpe Power Corporation, Municipal Electric Authority of Georgia, City of Dalton, Georgia, Docket Nos. 50-424 and 50-425, Vogtle Electric Generating Plant, Units 1 and 2, Burke County, Georgia

Date of amendment request: April 8, 1993

Description of amendment request: The proposed amendments would revise the Technical Specifications (TSs) to change the value of the peak containment pressure (P_a) calculated for design basis accidents. The value would be changed from 45 psig to 37 psig in TSs 4.6.1.1.c, 3.6.1.2.a, 3.6.1.2.b, 4.6.1.2.a, 4.6.1.2.d, 3.6.1.3.b, 4.6.1.3.a, and 4.6.1.3.b.

Basis for proposed no significant hazards consideration determination: On March 22, 1993, the NRC issued Amendments 60 (Unit 1) and 39 (Unit 2) which modified the Vogtle Licenses and TSs by increasing maximum core power level from 3411 megawatts thermal to 3565 megawatts thermal. To support these previous amendments, the licensee provided revised analyses of design basis loss-of-coolant accidents (LOCAs) and main steam line break (MSLB) accidents. The revised analyses benefited from several changes, including a more accurate accounting of heat sinks inside containment, an improved mass and energy evaluation model (WCAP-10325-P-A), credit for the full number of containment coolers required to be available by TSs (4 of 8), and an initial containment pressure of 3.0 psig required by TSs rather than 0.3 psig. The results showed that the highest P_a would occur for a LOCA rather than a MSLB and reach a maximum value of 36.5 psig. The NRC staff found the revised analyses acceptable in the Safety Evaluation accompanying Amendments 60 and 39.

The calculated peak containment pressure is used for leak testing the containment, containment isolation valves, and containment penetrations, including the containment airlock, in accordance with 10 CFR 50 Appendix J. The proposed amendments would recognize the revised, accepted value of 36.5 psig, rounded up to 37 psig, as the basis for these tests.

As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

1. The revision of pressure for containment leak testing does not involve a significant increase in the probability or consequences of an accident previously evaluated. Utilization of the revised pressure will not cause any design or analysis acceptance criteria to be exceeded because the containment will continue to be tested at a pressure greater than or equal to the highest pressure associated with any design basis accident. The structural and functional integrity of plant systems is unaffected. Furthermore, this change does not affect the initiators for any transient. Therefore, the probability of occurrence is not affected.

The change to the pressure for containment leak testing does not affect the integrity of the fission product barriers utilized for mitigation of radiological dose consequences as a result of an accident. In addition, the offsite mass releases used as input to the dose calculations are unchanged from those previously assumed. Therefore, the offsite dose predictions remain within the acceptance criteria for each of the transients affected. Since it has been determined that the transient results are unaffected by the change in pressure for containment leak testing it is concluded that the consequences of an accident previously evaluated are not increased.

2. The change in pressure for containment leak testing does not create the possibility of a new or different kind of accident from any accident previously evaluated. The change in pressure does not affect accident initiation sequences. No new operating configuration is being imposed by the reduction in pressure that would create a new failure scenario. In addition, no new failure modes are being created for any plant equipment. Therefore, the types of accidents defined in the Final Safety Analysis Report (FSAR) continue to represent the credible spectrum of events to be analyzed which determine safe plant operation.

3. The margin of safety associated with the change in the pressure for containment leak testing has been demonstrated by the results of the accident analyses. The analyses confirm that the peak containment pressure calculated as a result of LOCA and steam line break does not challenge the containment design pressure of 52 psig. The relationship of the test pressure to the peak calculated pressure remains the same; therefore, the required margin of safety regulated for each affected safety analysis is maintained. Since the revised Technical Specification value continues to be less than the containment design pressure and greater than or equal to the peak calculated containment pressure, the change does not involve a significant reduction in a margin of safety.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

Local Public Document Room location: Burke County Public Library, 412 Fourth Street, Waynesboro, Georgia 30830.

Attorney for licensee: Mr. Arthur H. Domby, Troutman Sanders, NationsBank Plaza, Suite 5200, 600 Peachtree Street, NE., Atlanta, Georgia 30308

NRC Project Director: David B. Matthews

Illinois Power Company and Soyland Power Cooperative, Inc., Docket No. 50-461, Clinton Power Station, Unit No. 1, DeWitt County, Illinois

Date of amendment request: April 16, 1992

Description of amendment request: The proposed amendment would change Clinton Power Station Technical Specification Figure 3.1.5-1, "Weight Percent Sodium Pentaborate Solution as a Function of Net Tank Volume," to show the reduction in net tank volume that results from raising the Standby Liquid Control System storage tank level instrument zero to prevent potential air entrainment in the pump suction piping due to vortexing. Additionally the Technical Specification Bases which describe this curve would be revised to reflect the changes.

Basis for proposed no significant hazards consideration determination: As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration which is presented below:

(1) As discussed previously, increasing the instrument zero elevation reduces the total available volume of sodium pentaborate solution above the revised instrument zero. However, the low-level and high-level alarm setpoints were also revised to account for the

revised instrument zero such that the net volume of sodium pentaborate solution corresponding to each of these setpoints does not change. As a result, sufficient sodium pentaborate solution will continue to be available to shut down the reactor in the event of an ATWS event. In addition, revisions have been made to the figure to provide additional understanding and less confusion in the use of the figure. Since these changes do not impact the ability of the system to perform its function, this request does not result in a significant increase in the consequences of any accident previously evaluated. With respect to the probability of occurrence of any accident previously evaluated, the [standby liquid control] SLC system is designed to mitigate the consequences of transients/accidents in the event of a failure to scram. Operation of the SLC system and the impact of the proposed changes on the SLC system have no impact on the probability of occurrence of those transients/accidents.

(2) This request does not result in any change to the plant design or operation beyond the change to the instrument zero for the SLC storage tank level instrumentation. The proposed change does not involve any changes to the plant design other than that specifically described and impacts no other systems or components. In fact, the proposed changes ensure the design requirements of the system are achieved. As a result, no new failure modes are introduced, and the request will not create the possibility of a new or different kind of accident from any accident previously evaluated.

(3) The proposed request does not adversely impact the reliability of the SLC system as the reliability of the SLC system operation is in fact increased by preventing potential air entrainment in the pump suction piping due to vortexing. Since this request does not involve an adverse impact to system operation or reliability, and since SLC system reactivity control capability is not affected by the proposed change, this request does not involve a significant reduction in a margin of safety.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

Local Public Document Room location: Vespasian Warner Public Library, 120 West Johnson Street, Clinton, Illinois 61727

Attorney for licensee: Sheldon Zabel, Esq., Schiff, Hardin and Waite, 7200 Sears Tower, 233 Wacker Drive, Chicago, Illinois 60606

NRC Project Director: James E. Dyer

Maine Yankee Atomic Power Company, Docket No. 50-309, Maine Yankee Atomic Power Station, Lincoln County, Maine

Date of amendment request: February 17, 1993

Description of amendment request: The proposed amendment would 1) increase the minimum fuel storage requirements for the emergency diesel generators, 2) revise alternate train testing requirements for the emergency diesel generators, 3) revise the monthly emergency diesel generator load testing requirement, 4) add a requirement to perform a semi-annual demonstration of the emergency load capability test of the emergency diesel generators, 5) revise the Remedial Actions to be taken if more than one of the required electrical sources becomes unavailable when the reactor is critical, 6) remove a restriction placed on 115 kV power to the station by a previous Amendment, 7) revise or add the Basis associated with each item, 1 through 6, above, and 8) make minor editorial changes.

Basis for proposed no significant hazards consideration determination: As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration. The NRC staff has reviewed the licensee's analysis against the standards of 10 CFR 50.92(c). The staff's review is presented below:

1. The proposed amendment does not involve a significant increase in the probability or consequences of an accident previously evaluated.

The proposed changes to Technical Specifications (TS) 3.12.A and B neither alter plant systems or components, nor directly affect system or component maintenance. The proposed changes would improve safe operation of the plant.

Increasing minimum diesel fuel storage requirements ensures compliance with American National Standards Institute (ANSI) N195-1976, which specifies that stored fuel oil be sufficient to supply the emergency diesel generators for 7 continuous days of operation.

Removing the operational restriction on the 115 kV Surowiec line reflects the increased reliability of this source due to the operability of the associated capacitor bank.

Remedial Action 2 to TS 3.12.B is revised to prevent loss of the second (alternate train) emergency diesel generator during testing, when one train becomes inoperable and the cause of the inoperabililty is not due to a common mode failure.

Remedial Action 3 to TS 3.12.B provides a reasonable time to restore the required 115 kV incoming line and an inoperable emergency diesel generator--including the emergency buses and dc distribution cabinets associated with the emergency diesel generator--should these sources become inoperable.

The change to TS 4.5.A revises the monthly surveillance requirement for the emergency diesel generators by specifying the loading range and power factor to be used during the test. (An editorial change makes it clear that during the test, operation of the fuel oil transfer pump for the running emergency diesel generator must be verified). In addition, a new, semi-annual test of the emergency diesel generators will demonstrate their ability to start and deliver power at the maximum expected emergency loading.

Technical Specification 4.5.B, Station Batteries, is revised by dividing it into three separate requirements, based on frequency of performance. The change is editorial. There is no change to technical requirements.

2. The proposed amendment does not create the possibility of a new or different kind of accident from any previously evaluated.

The proposed amendment makes no hardware modifications or creates any unique operating conditions. Technical Specification 3.12 wouldincrease the diesel fuel oil storage requirement, remove a now unnecessary restriction on use of the 115 kV Surowiec supply line, prevent the loss of both emergency diesel generators through unnecessary testing when only one is operable, and provide a reasonable time to restore the required 115 kV incoming line and an inoperable emergency diesel generator--including the emergency buses and dc distribution cabinets associated with the emergency diesel generator.

Technical Specification 4.5.A would specify the load range and power factor to be used during the monthly emergency diesel generator surveillance test; establish a new, semi-annual emergency diesel generator surveillance test; and make two clarifying editorial changes. The change to TS 4.5.B reorganizes battery testing requirements; no technical changes are made.

3. The proposed change does not involve a significant reduction in a margin of safety.

The proposed change to TS 3.12 would make this specification consistent with current administrative controls, which are more restrictive than the present requirements of TS 3.12. The proposed monthly surveillance requirement of TS 4.5.A.1 would clearly specify the load to which the emergency diesel generators are to be tested (90 to 100% of their continuous rating), while TS 4.5.A.3 adds a semi-annual load test at the maximum expected emergency loading values. The change to TS 4.5.B is editorial only; no technical changes are made.

Based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

Local Public Document Room location: Wiscasset Public Library, High Street, P.O. Box 367, Wiscasset, Maine 04578.

Attorney for licensee: Mary Ann Lynch, Esquire, Maine Yankee Atomic Power Company, 83 Edison Drive, Augusta, Maine 04336

NRC Project Director: Walter R. Butler

Niagara Mohawk Power Corporation, Docket No. 50-410, Nine Mile Point Nuclear Station, Unit 2, Oswego County, New York

Date of amendment request: April 7, 1993

Description of amendment request: The proposed Technical Specification (TS) changes would revise TS Section 3/4.1.3.5, "Control Rod Scram Accumulators." Action a.2.a for Limiting Condition for Operation 3.1.3.5 would be revised to allow the reactor operator 20 minutes to restart at least one control rod drive pump if more than one accumulator is inoperable, the control rod associated with any inoperable accumulator is withdrawn, and reactor pressure is greater than or equal to 900 psig. If reactor pressure is less than 900 psig, the operator would be required to place the reactor mode switch in the shutdown position. The proposed changes would also delete the surveillance requirement of TS 4.1.3.5.b.2, which requires scram accumulator check valve testing at least once per 18 months. Testing of the scram accumulator check valves would continue to be demonstrated during each refueling outage in accordance with TS 4.0.5, which requires inservice testing of ASME Code Class 1, 2, and 3 components.

Basis for proposed no significant hazards consideration determination: As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

The operation of Nine Mile Point Unit 2, in accordance with the proposed amendment, will not involve a significant increase in the probability or consequences of an accident previously evaluated.

The proposed changes to Action a.2.a of LCO [Limiting Condition for Operation] 3.1.3.5 provide additional operating flexibility where plant safety is not an immediate concern and prevent plant operation in a condition when the accumulators are required to support the scram function. Removal of the 18 month leak test specified by SR [Surveillance Requirement] 4.1.3.5.b.2 does not affect the reliability of the check valves because operability of the scram accumulator check valves is assured by TS Section 4.0.5 which requires that inservice testing of the check valves comply with ASME Code, Section XI. In addition, the proposed changes will not affect nor change any plant hardware, plant design or plant system operation from that already described in the USAR [Updated Safety Analysis Report]. Therefore, the proposed changes do not modify or add any initiating parameters that would significantly increase the probability or consequences of any accident previously analyzed.

The operation of Nine Mile Point Unit 2, in accordance with the proposed amendment, will not create the possibility of a new or different kind of accident from any accident previously evaluated.

The safety function of the scram accumulator is to assist in control rod insertion when reactor pressure alone is insufficient. Prompt operator action is still required to prevent circumstances where more than one scram accumulator is inoperable and reactor pressure might be insufficient to scram the plant. The capability of the control rods to perform their safety function and provide proper reactivity insertion within the required time will not be affected by the proposed changes.

The proposed additions to the LCO 3.1.3.5 action statement will assure the scram capability of all control rods and reduce the probability of unnecessary forced shutdowns and the associated demands on safety systems. The additional LCO Action proposed (i.e., shutdown if reactor pressure is less than 900 psig) provides for prompt operator action to prevent reactor operation in a condition where the accumulators are required to support the scram function. Removal of SR 4.1.3.5.b.2 does not eliminate testing and maintenance of the scram accumulator check valves. Testing and operation of the scram accumulator check valves will continue to be demonstrated by the TS required IST [Inservice Testing] Program.

In addition, the proposed changes do not represent a change in the plant or the design bases as described in the NMP2 [Nine Mile Point Nuclear Station, Unit 2] USAR. The proposed changes do not modify any equipment nor do they create any potential initiating events that would create any new or different kind of accident. As such, the plant initial conditions utilized for the design basis accident analyses are still valid. The current USAR will remain accurate with respect to its discussion of the licensing basis events and its analysis of plant response and consequences. Therefore, the proposed changes do not create the possibility of a new or different kind of accident from any accident previously evaluated.

The operation of Nine Mile Point Unit 2, in accordance with the proposed amendment, will not involve a significant reduction in a margin of safety.

At normal reactor pressure (i.e., greater than 900 psig), reactor pressure alone is sufficient to scram the control rods. The proposed TS changes allow the plant operator 20 minutes to restart at least one CRD [Control Rod Drive] pump if there is more than one inoperable scram accumulator and reactor pressure is equal to or greater than 900 psig. Control rod scram accumulators and accumulator check valves are required to support the scram function only at reactor pressures less than 600 psig. To prevent approaching the 600 psig limit, the proposed TS requires plant operators to immediately scram the reactor if there is more than one inoperable scram accumulator and there is not a CRD pump operating when reactor pressure is less than 900 psig. The proposed removal of SR 4.1.3.5.b.2 does not affect the reliability of the scram accumulator check valves because operability of these valves is assured by TS 4.0.5 which requires inservice testing per Section XI of the ASME Code.

The control rod system is designed to bring the reactor subcritical at a rate fast enough to prevent fuel thermal parameters from exceeding their respective safety limits during limiting plant events. The safety function of the scram accumulators is to assist in control rod insertion when reactor pressure alone is insufficient. The proposed changes do not affect the capability of the control rods to perform their safety function and provide proper reactivity insertion within the required time. Therefore, the fuel cladding integrity safety limit will not be affected as the MCPR [Minimum Critical Power Ratio] limit will continue to be met.

For the reasons stated above, the proposed changes do not involve a significant reduction in a margin of safety.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 50.92(c) are satisfied.

Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

Local Public Document Room location: Reference and Documents Department, Penfield Library, State University of New York, Oswego, New York 13126.

Attorney for licensee: Mark J. Wetterhahn, Esquire, Winston & Strawn, 1400 L Street, NW., Washington, DC 20005-3502.

NRC Project Director: Robert A. Capra

Niagara Mohawk Power Corporation, Docket No. 50-410, Nine Mile Point Nuclear Station, Unit 2, Oswego County, New York

Date of amendment request: March 22, 1993

Description of amendment request: The proposed amendment would revise Section 6.9.1.9, "Core Operating Limits Report," of the Technical Specifications (TS) to permit use of the SAFER/GESTR-LOCA methodology which has been approved by the NRC staff for accident analyses. TS Bases Section 3/4.2 would also be revised to reflect the addition of the SAFER/GESTR-LOCA

methodology as well as several editorial changes.

Basis for proposed no significant hazards consideration determination: As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

The operation of Nine Mile Point Unit 2, in accordance with the proposed amendment, will not involve a significant increase in the probability or consequences of an accident previously evaluated.

SAFER/GESTR-LOCA uses a realistic approach to calculate peak cladding temperatures with margin substantiated by statistical considerations. The use of SAFER/GESTR-LOCA methodology was approved by the Staff in their Safety Evaluation on Amendment 13 to GESTAR II. In the Safety Evaluation, the Staff concluded that SAFER/GESTR-LOCA satisfies the requirements of 10CFR 50.46 and Appendix K. The Staff stated that SAFER/GESTR-LOCA is acceptable as a basis for and reference in license applications so long as the material contained in SAFER/GESTR-LOCA is applicable to the specific plant involved. Niagara Mohawk has confirmed the applicability of SAFER/GESTR-LOCA to NMP2 [Nine Mile Point Nuclear Station, Unit 2]. The SAFER/GESTR-LOCA methodology conservatively calculates peak cladding temperatures such that USAR [Updated Safety Analysis Report] accident analyses remain bounding for the new methodology. Therefore, operation of Nine Mile Point Unit 2, in accordance with this proposed change, will not involve a significant increase in the probability or consequences of any accident previously evaluated.

The operation of Nine Mile Point Unit 2, in accordance with the proposed amendment, will not create the possibility of a new or different kind of accident from any accident previously evaluated.

SAFER/GESTR-LOCA uses a realistic application approach to calculate peak cladding temperatures with margin substantiated by statistical considerations. The peak cladding temperatures calculated with SAFER/GESTR-LOCA are in accordance with Appendix K and remain bounding for all operating conditions and evolutions. The use of SAFER/GESTR-LOCA methodology was approved by the Staff in their Safety Evaluation on Amendment 13 to GESTAR II. Incorporation of SAFER/GESTR-LOCA is only a change to analytical techniques and does not affect plant operating modes or any system operation. Thus, the proposed change does not adversely affect the response of any component or system to previously analyzed accidents. The response to previously evaluated accidents remains within previously assessed limits of temperature and pressure. Further, all safety-related systems and components remain within their applicable design limits. Thus, system and component performance is not adversely affected by this change, thereby assuring that the design capabilities of those systems and components are not challenged in a manner not previously assessed so as to create the possibility of a new or different kind of accident.

Therefore, operation of Nine Mile Point Unit 2, in accordance with the proposed change, will not create the possibility of a new or different kind of accident from any previously assessed.

The operation of Nine Mile Point Unit 2, in accordance with the proposed amendment, will not involve a significant reduction in a margin of safety.

SAFER/GESTR-LOCA is an improved ECCS [emergency core cooling system] evaluation methodology which uses a realistic approach to calculate peak cladding temperatures. LOCA events are analyzed with nominal values for inputs and correlations. The Staff has previously determined that SAFER/GESTR-LOCA methodology conforms to 10CFR 50.46 and Appendix K and may be used in lieu of the currently referenced SAFE/REFLOOD methodology. Therefore, the peak cladding temperatures calculated with SAFER/GESTR-LOCA are applicable. The Staff stated that SAFER/GESTR-LOCA is acceptable so long as the material contained in SAFER/GESTR-LOCA is applicable to the specific plant involved.

Niagara Mohawk has reviewed GESTAR II and confirmed the applicability of SAFER/GESTR-LOCA to NMP2. Thus, the proposed changes do not affect the basis for any Technical Specification and previously established safety limits remain valid. Therefore, the operation of Nine Mile Point Unit 2, in accordance with the proposed change, will not involve a significant reduction in any margin of safety.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

Local Public Document Room location: Reference and Documents Department, Penfield Library, State University of New York, Oswego, New York 13126.

Attorney for licensee: Mark J. Wetterhahn, Esquire, Winston & Strawn, 1400 L Street, NW., Washington, DC 20005-3502.

NRC Project Director: Robert A. Capra

Niagara Mohawk Power Corporation, Docket No. 50-410, Nine Mile Point Nuclear Station, Unit 2, Oswego County, New York

Date of amendment request: April 7, 1993

Description of amendment request: The proposed Technical Specification (TS) changes would revise TS Section 3.1.5, "Standby Liquid Control System," to remove the requirement for the Standby Liquid Control System to be operable in Operational Condition 5 (Refueling) with any control rod withdrawn. The proposed TS changes are consistent with the requirements of NUREG-1434, "Standard Technical Specifications - General Electric Plants, BWR/6."

Basis for proposed no significant hazards consideration determination: As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

The operation of Nine Mile Point Unit 2, in accordance with the proposed amendment, will not involve a significant increase in the probability or consequences of an accident previously evaluated.

The purpose of the SLC [Standby Liquid Control] System is to bring the reactor to and maintain it in a cold shutdown condition from normal power operations following failure to scram with the control rods event. Initiation of the SLC System is not a precursor to any accident. Therefore, inoperability of the SLC System cannot increase the probability of an accident previously evaluated. The SLC System was not designed to provide shutdown capability during OPERATIONAL CONDITION 5. Since the SLC System's purpose is to shut the reactor down following a failure to scram during power operation, the USAR [Updated Safety Analysis Report] takes no credit for the operability of the SLC System in OPERATIONAL CONDITION 5. Therefore, the SLC System not being operable in OPERATIONAL CONDITION 5 will not involve a significant increase in the consequences of an accident previously evaluated.

The operation of Nine Mile Point Unit 2, in accordance with the proposed amendment, will not create the possibility of a new or different kind of accident from any accident previously evaluated.

This request does not involve a physical change in any system's configuration and no new modes of operation are introduced. The SLC System's only purpose is to mitigate the consequences of a failure to scram during power operation; it neither causes nor prevents an accident from occurring. Furthermore, in OPERATIONAL CONDITION 5 the SLC System has no analyzed function. Therefore, this change will not create the possibility of a new or different kind of accident from any previously evaluated.

The operation of Nine Mile Point Unit 2, in accordance with the proposed amendment, will not involve a significant reduction in a margin of safety.

The purpose of the SLC System is to bring the reactor to and maintain it in a cold shutdown condition from normal power operations following a failure to scram during power operations. Initiation of the SLC System is not designed to terminate an inadvertent criticality during OPERATIONAL CONDITION 5. SDM [Shutdown Margin], either demonstrated or analytically determined, in conjunction with Technical Specifications and procedural controls, will assure that an inadvertent criticality event will not occur during refueling operations. In addition, the RPS [Reactor Protection

System] and Control Rod System, which are extremely reliable, will provide protection in the unlikely event that an inadvertent criticality does occur. Therefore, this change will not involve a significant reduction in a margin of safety.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

Local Public Document Room location: Reference and Documents Department, Penfield Library, State University of New York, Oswego, New York 13126.

Attorney for licensee: Mark J. Wetterhahn, Esquire, Winston & Strawn, 1400 L Street, NW., Washington, DC 20005-3502.

NRC Project Director: Robert A. Capra

Niagara Mohawk Power Corporation, Docket No. 50-410, Nine Mile Point Nuclear Station, Unit 2, Oswego County, New York

Date of amendment request: March 30, 1993

Description of amendment request: The proposed Technical Specifications (TS) changes would revise TS 4.8.1.1.2.e.4 and 4.8.1.1.2.e.8, "AC Sources - Operating." The current TS require that a simulated loss of offsite power (LOOP) test be performed within 5 minutes of completing a 24-hour full load emergency diesel generator test run. The proposed TS changes would separate the requirements for the 24-hour run from the LOOP test.

Basis for proposed no significant hazards consideration determination: As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

The operation of Nine Mile Point Unit 2, in accordance with the proposed amendment, will not involve a significant increase in the probability or consequences of an accident previously evaluated.

As stated in Regulatory Guide 1.108, the performance of the LOOP test of Technical Specification 4.8.1.1.2.e.4.a) and .b) immediately following the 24-hour load test demonstrates that the diesel generator can start and accept the required loads in the prescribed time when the diesel generator is at its full load operating temperature. This provides assurance that the diesel generator is capable of responding to a Loss-of-Off-Site Power as assumed in the accident analysis. Because the purpose of performing the LOOP test immediately following the 24-hour run is to demonstrate the functional capability of the diesel generator at full load temperature conditions, establishing full load temperature conditions with other than a 24-hour run provides the necessary initial conditions for the LOOP testing. Diesel generator design and function remain as previously analyzed. Diesel generator response during accident conditions are not affected by these changes. Therefore, no significant increase in the probability or consequences of an accident previously evaluated results from these changes.

The operation of Nine Mile Point Unit 2, in accordance with the proposed amendment, will not create the possibility of a new or different kind of accident from any accident previously evaluated.

This request does not involve a physical change in any system's configuration and no new modes of operation are introduced. These changes will not reduce any required testing and will not affect diesel generator reliability. Additionally, the surveillances proposed will establish the same initial conditions as those required by the current Technical Specification. Testing of the diesel generators in accordance with these changes will assure that diesel generator responses remain as previously analyzed for all required conditions. Therefore, these changes do not create the possibility of a new or different kind of accident from any previously evaluated.

The operation of Nine Mile Point Unit 2, in accordance with the proposed amendment, will not involve a significant reduction in a margin of safety.

Allowing the diesel generators to reach full temperature conditions by other than the 24-hour load test required by Technical Specification 4.8.1.1.2.e.8.a and .b will satisfy the intent of conducting the test following the 24-hour load test. These changes will not result in any reduction in testing and will not affect diesel generator reliability. As proposed, the changes will adequately demonstrate the diesel generator's functional capability at full load temperature conditions, thus ensuring the design margin of safety in the diesel generator's ability to start and accept the required loads in the prescribed time. Therefore, these changes will not involve a significant reduction in a margin of safety.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

Local Public Document Room location: Reference and Documents Department, Penfield Library, State University of New York, Oswego, New York 13126.

Attorney for licensee: Mark J. Wetterhahn, Esquire, Winston & Strawn, 1400 L Street, NW., Washington, DC 20005-3502.

NRC Project Director: Robert A. Capra

North Atlantic Energy Service Corporation, Docket No. 50-443, Seabrook Station, Unit No. 1, Rockingham County, New Hampshire

Date of amendment request: February 26, 1993

Description of amendment request: The proposed amendment would modify Technical Specification (TS) 3/4 7.3 applicable to the primary component cooling water system. Limiting Condition for Operation (LCO) 3/4.7.3 would be revised to require one operable pump in each primary component cooling water (PCCW) loop vice two pumps. The amendment also would delete Actions b. and c., and Surveillance Requirement 4.7.3 b.2 which would no longer be applicable with the requirement for one operable pump per loop.

Basis for proposed no significant hazards consideration determination: As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration. The NRC staff has reviewed the licensee's analysis against the standards of 10 CFR 50.92(c). The NRC staff's review is presented below.

A. The changes do not involve a significant increase in the probability or consequences of an accident previously evaluated (10 CFR 50.92(c)(1)) because even with the proposed LCO change, two operable PCCW loops would be required and the single failure criterion still would be met. The PCCW system is designed to perform its safety functions assuming a single failure of any component. This is accomplished with two independent redundant loops. Each of the PCCW loops contains two 100% capacity pumps. The required safety functions can be accomplished with one pump operating in one PCCW loop. The second operable loop with at least one operable pump provides the redundancy necessary to meet the single failure criterion. The proposed changes to the action statement and the surveillance requirements merely reflect the proposed change to the LCO.

B. The changes do not create the possibility of a new or different kind of accident from any accident previously evaluated (10 CFR 50.92(c)(2)) because the PCCW system would continue to meet the single failure criterion. The proposed changes do not affect the manner by which the facility is operated or involve equipment or features which affect the operational characteristics of the facility.

C. The changes do not involve a significant reduction in a margin of safety (10 CFR 50.92(c)(3)) because the proposed changes do not affect the

manner by which the facility is operated or involve equipment or features which affect the operational characteristics of the facility. Based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

Local Public Document Room location: Exeter Public Library, 47 Front Street, Exeter, New Hampshire 03833.

Attorney for licensee: Thomas Dignan, Esquire, Ropes & Grey, One International Place, Boston Massachusetts 02110-2624.

NRC Project Director: John F. Stolz

Northeast Nuclear Energy Company, et al., Docket No. 50-423, Millstone Nuclear Power Station, Unit No. 3, New London County, Connecticut

Date of amendment request: April 1, 1993

Description of amendment request: The licensee has requested that technical specifications be changed to permit prelubrication and warmup of emergency diesel generators before surveillance testing.

Basis for proposed no significant hazards consideration determination: As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

The proposed changes do not involve a significant hazards consideration based on the following:

1. The relocation of the footnote to encompass all aspects of diesel surveillance requirements will not increase the probability or consequences of an accident previously evaluated.

Each diesel's primary function is to provide power to mitigate the consequences of an accident when offsite power is lost. Therefore, the probability of an accident is not affected. Prelubing is performed to decrease engine wear which will extend diesel life. Ultimately, prelubing reduces the number of maintenance intervals, thereby increasing the availability of the diesels.

2. The proposed changes do not create the possibility of a new or different kind of accident from any previously evaluated.

There are no new failure modes associated with the proposed change. Since the plant will continue to operate as designed, the proposed changes will not modify the plant response and is not considered a new accident.

3. The proposed changes do not involve a significant reduction in the margin of safety.

The proposed changes do not have any adverse impact on the margin of safety afforded the diesel generators. This change will prevent engine wear and ultimately extend the life of the diesels. The operability of the diesels is not dependent upon the prelube system and therefore, the margin of safety is not affected.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

Local Public Document Room location: Learning Resources Center, Thames Valley State Technical College, 574 New London Turnpike, Norwich, Connecticut 06360.

Attorney for licensee: Gerald Garfield, Esquire, Day, Berry & Howard, City Place, Hartford, Connecticut 06103-3499.

NRC Project Director: John F. Stolz

Northern States Power Company, Docket No. 50-263, Monticello Nuclear Generating Plant, Wright County, Minnesota

Date of amendment request: December 31, 1992

Description of amendment request: The proposed amendment would revise Surveillance Requirement 4.13.B.1.e, "Fire Suppression Water System," by changing the American Society for Testing and Materials (ASTM) specification which is followed when performing required sampling of the diesel fire pump fuel oil supply.

Basis for proposed no significant hazards consideration determination: As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

a. The proposed amendment will not involve a significant increase in the probability or consequences of an accident previously evaluated.

The diesel fire pump sampling specification to be used is not a factor in any accident analysis and this change is primarily administrative in nature. Use of the proposed ASTM specifications will provide the same level of assurance of diesel fire pump fuel oil quality as the old ASTM specifications. Diesel fire pump reliability and operability will not be degraded. Therefore, this amendment does not involve an increase in the probability or consequences of any previously analyzed accident.

b. The proposed amendment will not create the possibility of a new or different kind of accident from any accident previously analyzed.

No safety-related equipment, safety function, or plant operations (other than the methodology for drawing the fuel oil sample) will be altered as a result of the proposed amendment. Therefore, the proposed amendment does not in any way create the possibility of a new or different kind of accident from any accident previously evaluated.

c. The proposed amendment will not involve a significant reduction in the margin of safety.

Use of the proposed ASTM specifications will provide the same level of assurance of diesel fire pump fuel oil quality as the old ASTM specifications. Diesel fire pump reliability and operability will not be degraded. Therefore, the proposed amendment does not involve any reduction in the margin of safety.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

Local Public Document Room location: Minneapolis Public Library, Technology and Science Department, 300 Nicollet Mall, Minneapolis, Minnesota 55401

Attorney for licensee: Gerald Charnoff, Esq., Shaw, Pittman, Potts and Trowbridge, 2300 N Street, NW, Washington, DC 20037

NRC Project Director: L. B. Marsh

Northern States Power Company, Docket No. 50-263, Monticello Nuclear Generating Plant, Wright County, Minnesota

Date of amendment request: December 31, 1992

Description of amendment request: The proposed amendment would revise Surveillance Requirement 4.13.B.1.e, "Fire Suppression Water System," by changing the American Society for Testing and Materials (ASTM) specification which is followed when performing required sampling of the diesel fire pump fuel oil supply.

Basis for proposed no significant hazards consideration determination: As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

a. The proposed amendment will not involve a significant increase in the probability or consequences of an accident previously evaluated.

The diesel fire pump sampling specification to be used is not a factor in any accident analysis and this change is primarily administrative in nature. Use of the proposed ASTM specifications will provide the same level of assurance of diesel fire pump fuel oil quality as the old ASTM specifications. Diesel fire pump reliability and operability will not be degraded. Therefore, this amendment does not involve an increase in the probability or consequences of any previously analyzed accident.

b. The proposed amendment will not create the possibility of a new or different kind of accident from any accident previously analyzed.

No safety-related equipment, safety function, or plant operations (other than the methodology for drawing the fuel oil sample) will be altered as a result of the proposed amendment. Therefore, the proposed amendment does not in any way create the possibility of a new or different kind of accident from any accident previously evaluated.

c. The proposed amendment will not involve a significant reduction in the margin of safety.

Use of the proposed ASTM specifications will provide the same level of assurance of diesel fire pump fuel oil quality as the old ASTM specifications. Diesel fire pump reliability and operability will not be degraded. Therefore, the proposed amendment does not involve any reduction in the margin of safety.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

Local Public Document Room location: Minneapolis Public Library, Technology and Science Department, 300 Nicollet Mall, Minneapolis, Minnesota 55401

Attorney for licensee: Gerald Charnoff, Esq., Shaw, Pittman, Potts and Trowbridge, 2300 N Street, NW, Washington, DC 20037

NRC Project Director: L. B. Marsh

Pennsylvania Power and Light Company, Docket No. 50-388, Susquehanna Steam Electric Station, Unit 2, Luzerne County, Pennsylvania

Date of amendment request: April 5, 1993

Description of amendment request: The proposed amendment would revise the Susquehanna Steam Electric Station (SSES), Unit 1, Technical Specifications to change the isolation signal for suppression pool cleanup line valves HV-15766 and HV-15768 from reactor vessel low water level 3 (+13") or high drywell pressure to reactor vessel low water level 2 (-38") or high drywell pressure. The same change was approved for SSES, Unit 2, by Amendment No. 92, issued on October 29, 1992.

Basis for proposed no significant hazards consideration determination: As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

The proposed change does not:

1. Involve an increase in the probability of occurrence or the consequences of an accident or malfunction of equipment important to safety as previously evaluated.

This conclusion is based on the consideration that the isolation signal change from level 3 to 2 does not degrade the operation of any equipment or system. Furthermore, the Agastat relays and level switches to be used for the level 2 isolation signals are identical in design, material, and construction to those currently used for level 3.

The modification does not alter or degrade the ability of the two cleanup line valves to isolate the cleanup line following those LOCAs inside containment that require isolation. The isolation system design will always result in its actuation at level 2. The design requirement for isolation at level 2 remains satisfied, and in compliance with NUREG-0800 (Standard Review Plan) and NUREG-0776 (Safety Evaluation Report, SSES).

During transients that result in reactor vessel water levels between 2 & 3, the modification will permit the cleanup line to be used, if necessary, to lower the suppression pool water level. Manual control the filter pump has not been changed. Operation of the cleanup line following these transients is permissible because a LOCA inside containment has not occurred.

Since the cleanup line isolation signal remains in compliance with the design requirements established by General Electric, it is concluded that the consequences of an accident have not been increased.

The probability of a malfunction of equipment important to safety has not been increased by the modification. The relay room panels, where both the level 2 & 3 relays are located, will have minor changes to the internal wiring. Seismic qualification of the equipment will be unaltered. Valve operation remains unchanged, except for the level of reactor vessel water that initiates a containment isolation signal.

The loading on the suppression pool structure, and submerged components in the pool, following safety/relief valve operation, has not been increased. Since higher water levels result in higher loads, the loading following the modification would either be less than or equal to the existing loading depending on whether the filter pump is operating.

The modification does not result in an increase in consequences assuming a malfunction of equipment important to safety. The consequences of failing to isolate containment following a LOCA inside containment or preventing the suppression pool from performing its function are not influenced by the modification.

2. Create the possibility of a new or different kind of accident from any previously evaluated.

The modification uses spare terminals on existing relays to receive an input from a level 2 switch. These relays are identical to those used to receive the level 3 input signal. The actuation logic remains single failure proof. A new possibility has not been created for those LOCAs inside containment that require isolation to occur without isolation of the cleanup line.

The modification does not create the possibility of a malfunction of the suppression pool structure and submerged components in the pool. The use of the cleanup line serves to lower the pool water level which decreases the loading during a LOCA or safety/relief valve operation.

3. Involve a reduction in the margin of safety.

The NRC provided their review of containment isolation signals in Section 6.2.4 of the Safety Evaluation Report (NUREG-0776). Reactor vessel water level 2 was found to be acceptable and therefore defines the basis for the margin of safety.

It is therefore concluded that since the proposed modification changes a containment isolation setpoint to a previously accepted value, a reduction in the margin of safety will not occur.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

Local Public Document Room location: Osterhout Free Library, Reference Department, 71 South Franklin Street, Wilkes-Barre, Pennsylvania 18701

Attorney for licensee: Jay Silberg, Esquire, Shaw, Pittman, Potts and Trowbridge, 2300 N Street NW., Washington, D.C. 20037

NRC Project Director: Charles L. Miller

Power Authority of The State of New York, Docket No. 50-286, Indian Point Nuclear Generating Unit No. 3, Westchester County, New York

Date of amendment request: March 12, 1993

Description of amendment request: The licensee commenced operating on a 24-month fuel cycle, instead of the previous 18-month fuel cycle, with fuel cycle 9. Fuel cycle 9 started in August 1992. In order to accommodate operation on a 24-month cycle, the licensee requested a Technical Specifications (TS) amendment to incorporate the changes listed below:

(1) The licensee proposed changing the frequency of high pressure water fire protection system testing (specified in TS Section 4.12.A.1) to accommodate operation on a 24-month cycle.

(2) The licensee proposed changing the frequency of fire pump diesel engine testing (specified in TS Section 4.12.A.2) to accommodate operation on a 24-month cycle.

(3) The licensee proposed changing the frequency of electrical tunnel, diesel generator building, and containment fan cooler fire protection spray and/or sprinkler system testing (specified in TS Section 4.12.B.1) to accommodate operation on a 24-month cycle.

(4) The licensee proposed changing the frequency of fire detection system testing (specified in TS Section 4.12.D.1) to accommodate operation on a 24month cycle.

(5) The licensee proposed changing the frequency of fire hose station testing (specified in TS Section 4.12.E.1) to accommodate operation on a 24-month cycle.

(6) The licensee proposed changing the frequency of CO_2 fire protection system testing (specified in TS Section 4.12.G.1) to accommodate operation on a 24-month cycle.

(7) The licensee proposed changing the frequency of fire barrier penetration seal inspection (specified in TS Section 4.12.C.1) to accommodate operation on a 24-month cycle.

These proposed changes follow the guidance provided in Generic Letter 91-04, "Changes in Technical Specification Surveillance Intervals to Accommodate a 24-Month Fuel Cycle," as applicable.

In addition, the licensee proposed reformatting TS Section 4.12 in its entirety and proposed several administrative changes for clarity.

Basis for proposed no significant hazards consideration determination: As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

Consistent with the criteria of 10 CFR 50.92, the enclosed application is judged to involve no significant hazards based on the following information:

(1) Does the proposed license amendment involve a significant increase in the probability or consequences of any accident previously evaluated?

Response:

Since the proposed change to extend the surveillance test intervals for High Pressure Water Fire Protection System, Fire Pump Diesel Engine, Electrical Tunnel, Diesel Generator Building and Fan Cooler Fire Protection Spray and/or Sprinkler System, Fire Detection System, Fire Hose Station, CO_2 Fire Protection System and Fire Barrier Penetration Seal inspection does not involve changes in equipment/system functions and does not adversely affect system operability, the proposed change does not involve a significant increase in the probability or consequences of any accident previously evaluated.

(2) Does the proposed license amendment create the possibility of a new or different kind of accident from any previously evaluated?

Response:

Since the proposed changes [to extend the surveillance test intervals for High Pressure Water Fire Protection System, Fire Pump Diesel Engine, Electrical Tunnel, Diesel Generator Building and Fan Cooler Fire Protection Spray and/or Sprinkler System, Fire Detection System, Fire Hose Station, CO_2 Fire Protection System and Fire Barrier Penetration Seal inspection] only increase the surveillance interval to be consistent with the operating cycle and do not involve changes in equipment/system functions or adversely affect system operability, the proposed changes do not create the possibility of a new or different kind of accident from any previously analyzed.

(3) Does the proposed amendment involve a significant reduction in the margin of safety?

Response:

The proposed changes [to extend the surveillance test intervals for High Pressure Water Fire Protection System, Fire Pump Diesel Engine, Electrical Tunnel, Diesel Generator Building and Fan Cooler Fire Protection Spray and/or Sprinkler System, Fire Detection System, Fire Hose Station, CO_2 Fire Protection System and Fire Barrier Penetration Seal inspection] only extend the surveillance interval. Evaluation of the past performance of the equipment indicates that the effects of extending the surveillance test intervals would not involve a significant reduction in the margin of safety. Therefore, the proposed changes do not involve a significant reduction in the margin of safety.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

Local Public Document Room location: White Plains Public Library, 100 Martine Avenue, White Plains, New York 10601.

Attorney for licensee: Mr. Charles M. Pratt, 10 Columbus Circle, New York, New York 10019.

NRC Project Director: Robert A. Capra

Power Authority of The State of New York, Docket No. 50-286, Indian Point Nuclear Generating Unit No. 3, Westchester County, New York

Date of amendment request: April 5, 1993

Description of amendment request: The licensee has requested an amendment to the Technical Specifications (TS) to revise Section 6.0 (Administrative Controls). Specifically, the plant staff requirement (specified in TS 6.2.2.i) would be revised to remove the condition that the operations manager must hold a senior reactor operator (SRO) license and replace it with the requirements that the assistant operations manager must hold an SRO license and that the operations manager must hold or have held an SRO license at the facility. In addition, the plant staff qualifications requirement (specified in TS 6.3.1) would be modified to reflect that the operations manager shall meet or exceed the qualification requirements of ANSI N18.1-1971 (Selection and Training of Nuclear Plant Personnel) except for the SRO license requirement.

Basis for proposed no significant hazards consideration determination: As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

Consistent with the criteria of 10 CFR 50.92, the enclosed application is judged to involve no significant hazards based on the following information:

(1) Does the proposed license amendment involve a significant increase in the probability or consequences of an accident previously evaluated?

Response:

The proposed changes do not involve an increase in the probability or consequences of a previously analyzed accident because Shift Supervisors and Reactor Operators will still be required to maintain a current SRO [senior reactor operator] license. This ensures that shift activities are directed by persons holding SRO licenses. The Shift Supervisors will report directly to an individual with an SRO license and qualifications of an "Operations Manager" per ANSI N18.1-1971. The Operations Manager will continue to be a knowledgeable and qualified individual.

(2) Does the proposed license amendment create the possibility of a new or different kind of accident from any accident previously evaluated?

Response:

The proposed changes do not create the possibility of a new or different kind of accident from any accident previously evaluated because they do not affect plant configuration or plant design. Senior Reactor Operators and Shift Supervisors are still required to maintain a knowledge of current plant configuration and operation through SRO license requalification training. This ensures that shift activities will be directed by persons holding SRO licenses. Additionally, the Shift Supervisors will report directly to an individual with an SRO license and qualifications of an "Operations Manager" per ANSI N18.1-1971 and the Operations Manager will continue to be a knowledgeable and qualified individual.

(3) Does the proposed amendment involve a significant reduction in a margin of safety?

Response:

The proposed amendment does not involve a significant reduction in a margin of safety because Shift Supervisors and Senior Reactor Operators will still be required to maintain a current SRO license. This ensures that shift activities are directed by persons holding SRO licenses. Additionally, the Shift Supervisors will report directly to an individual with an SRO license and qualifications of an "Operations Manager" per ANSI N18.1-1971 and the Operations Manager will continue to be a knowledgeable and qualified individual. These changes are expected to enhance the Operations Manager's ability to effectively carry out the primary responsibilities of that position, and to have an overall positive effect on the safe and efficient operation of Indian Point 3.

The NRC staff has reviewed the licensee's analysis and, based on this

review, it appears that the three standards of 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

Local Public Document Room location: White Plains Public Library, 100 Martine Avenue, White Plains, New York 10601.

Attorney for licensee: Mr. Charles M. Pratt, 10 Columbus Circle, New York, New York 10019.

NRC Project Director: Robert A. Capra

Public Service Electric & Gas Company, Docket Nos. 50-272 and 50-311, Salem Nuclear Generating Station, Unit Nos. 1 and 2, Salem County, New Jersey

Date of amendment request: February 5, 1993

Description of amendment request: The proposed amendment revises Salem Nuclear Generating Station, Units 1 and 2 Technical Specifications 2.2 Limiting Safety System settings and 3/4.1.1 Reactor Trip System Instrumentation. The proposed changes eliminates the Steam/Feedwater Flow Mismatch and Low Steam Generator Water Level Reactor Trip due to the installation of the digital feedwater control system incorporating a median signal selector.

Basis for proposed no significant hazards consideration determination: As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration. The NRC staff has reviewed the licensee's analysis against the standards of 10 CFR 50.92(c). The NRC staff's review is presented below:

1. Involve a significant increase in the probability or consequences of an accident previously evaluated.

Removing the steam flow/feed flow mismatch and low steam generator level reactor trip does not increase the probability of an accident previously evaluated because the trip does not cause an accident: therefore, the trip can not effect the probability of an accident. The consequences are not effected because no credit is taken for the trip when the accidents are evaluated. Therefore, the proposed amendment will not increase the probability or consequences of any accident.

2. Create the possibility of a new or different kind of accident from any accident previously evaluated.

Removal of the steam flow/feed flow mismatch and low steam generator level trip does not create the possibility of a new or different kind of accident than previously evaluated because the trip cannot create an accident. Therefore, the proposed amendment cannot create the possibility of any accident.

3. Involve a significant reduction in a margin of safety.

The circuitry can only create an inadvertent trip which is bounded by a required trip or failure to trip which is acceptable because no credit is taken for the trip in accident evaluation. Therefore, the proposed amendment will not reduce the margin of safety.

Based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

Local Public Document Room location: Salem Free Public library, 112 West Broadway, Salem, New Jersey 08079

Attorney for licensee: Mark J. Wetterhahn, Esquire, Winston and Strawn, 1400 L Street, N.W., Washington, D.C., 20005-3502

NRC Project Director: Charles L. Miller

Public Service Electric & Gas Company, Docket No. 50-354, Hope Creek Generating Station, Salem County, New Jersey

Date of amendment request: April 1, 1993

Description of amendment request: The licensee's proposed amendment would extend the surveillance test intervals and allowed out-of-service times for the emergency core cooling system (ECCS) and reactor core isolation cooling (RCIC) system actuation instrumentation. This change is based on the technical information contained in the General Electric Company (GE) Licensing Topical Report (LTR) NEDC-30936P-A, Parts 1 and 2 (December, 1988) and GE LTR GENE-770-06-2-A (December 1992).

Basis for proposed no significant hazards consideration determination: As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

PSE&G has, pursuant to 10 CFR 50.92, reviewed the proposed amendment to determine whether the request involves a significant hazards consideration. We have determined that operation of the Hope Creek Generating Station in accordance with the proposed changes:

1. Will not involve a significant increase in the probability or consequences of an accident previously evaluated.

The proposed changes to the ECCS and RCIC actuation instrumentation were judged to potentially affect core damage frequency through their impact on the water injection function (WIF) failure frequency. The generic analyses contained in Licensing Topical Report (LTR) NEDC-30936P-A and LTR GENE-770-06-2-A assessed the impact of changing ECCS and RCIC surveillance test intervals (STIs) and allowed out-of-service times (AOTs) on the WIF failure frequency. The analyses contained in these LTRs demonstrate that the proposed changes have an insignificant effect on the WIF failure frequency, and when all contributing factors are considered, the net impact of the proposed changes is to improve plant safety. These generic analyses have been shown to be applicable to the HCGS as indicated in Section III [of the licensee's April 1, 1993 submittal]. Since the proposed changes do not significantly affect the WIF failure frequency and have a beneficial impact on plant safety when all factors are considered, the proposed changes will not significantly increase the probability or consequences of a previously analyzed accident.

2. Will not create the possibility of a new or different kind of accident from any accident previously evaluated.

Increasing the AOTs and STIs for the ECCS and RCIC instrumentation does not alter the function of the emergency core cooling system (ECCS) or reactor core isolation cooling system (RCIC) nor involve any type of plant modification. Additionally, no new modes of plant operation are involved with these changes. The proposed changes therefore will not create the possibility of a new or different kind of accident from any accident previously evaluated.

3. Will not involve a significant reduction in a margin of safety.

The proposed changes to the ECCS and RCIC actuation instrumentation were judged to potentially affect core damage frequency through their impact on the WIF failure frequency. As requested by the BWR Owners' Group, GE performed analyses to evaluate the effect of the proposed changes on the WIF failure frequency. The NRC staff has reviewed and approved the generic study contained in LTRs NEDC-30936P-A and GENE-770-06-2-A and has concurred with the BWR Owners' Group that the proposed changes do not significantly affect the WIF failure frequency. Furthermore, the overall level of plant safety will be improved by the proposed changes as indicated in Section II [of the licensee's April 1, 1993 submittal]. A plant specific evaluation was conducted for HCGS, as indicated in Section III [of the licensee's April 1, 1993 submittal] which demonstrated applicability of the generic conclusions to HCGS. It can therefore be concluded that the proposed changes will not significantly reduce a margin of safety.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

Local Public Document Room location: Pennsville Public Library, 190 S. Broadway, Pennsville, New Jersey 08070

Attorney for licensee: M. J. Wetterhahn, Esquire, Winston and

Strawn, 1400 L Street, NW., Washington, DC 20005-3502

NRC Project Director: Charles L. Miller

Southern California Edison Company, et al., Docket Nos. 50-361 and 50-362, San Onofre Nuclear Generating Station, Unit Nos. 2 and 3, San Diego County, California

Date of amendment requests: April 13, 1993

Description of amendment requests: The licensee proposes to revise Technical Specification (TS) 3/4.8.1, "A. C. Sources." This proposed change will provide a one-time exception to TS 4.8.1.1.1.a to allow replacement of the 480V transformers B04X and B06X during the Units 2 and 3 Cycle 7 refueling outages.

Basis for proposed no significant hazards consideration determination: As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

1. Will operation of the facility in accordance with this proposed change involve a significant increase in the probability or consequences of an accident previously evaluated?

Response: No

The purpose of maintaining redundant offsite power sources is to prevent a loss of offsite power. This proposed change allows a one-time exception to Technical Specification 4.8.1.1.1.a to allow the tie-breakers to the opposite unit cross-tie to be OPERABLE while the associated load centers B04 and B06 are INOPERABLE. This will allow replacement of the 480V transformers. While the replacement is performed, a charger will be attached to the associated battery bank and will be connected to the temporary non-class 1E power sources. The associated battery bank will be maintained OPERABLE by performance of TS 3/4.8.2.2 ACTION b. The cross-tie will remain OPERABLE and able to perform its function of providing a second source of A. C. power to the companion Unit. Therefore, there is no increase in probability or consequences of a loss of offsite power or any other accident previously evaluated.

2. Will operation of the facility in accordance with this proposed change create the possibility of a new or different type of accident from any previously evaluated?

Response: No

This proposed change allows a one-time exception to Technical Specification 4.8.1.1.1.a to allow the tie breakers to the opposite unit cross-tie to be OPERABLE while the associated load centers B04 and B06 are INOPERABLE. This will allow replacement of the 480V transformers. While the replacement is performed, a charger will be attached to the associated battery bank and will be connected to the temporary non-class 1E power sources. The associated battery bank will be maintained OPERABLE by performance of TS 3/4.8.2.2 ACTION b. The cross-tie will remain OPERABLE and able to perform its function of providing a second source of A. C. power to the companion unit. Therefore, there is no possibility of a new or different type of accident than any previously evaluated.

3. Will operation of the facility according to this proposed change involve a significant reduction in a margin of safety?

Response: No

This proposed change allows a one-time exception to Technical Specification 4.8.1.1.1.a to allow the tie breakers to the opposite unit cross-tie to be OPERABLE while the associated load centers B04 and B06 are INOPERABLE. This will allow replacement of the 480V transformers. While the replacement is performed, a charger will be attached to the associated battery bank and will be connected to the temporary non-class 1E power sources. The associated battery bank will be maintained OPERABLE by performance of TS 3/4.8.2.2 ACTION b. The cross-tie will remain OPERABLE and able to perform its function of providing a second source of A. C. power to the companion Unit. Therefore, there is no significant reduction in a margin of safety.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment requests involve no significant hazards consideration.

Local Public Document Room location: Main Library, University of California, P.O. Box 19557, Irvine, California 92713

Attorney for licensee: James A. Beoletto, Esquire, Southern California Edison Company, P. O. Box 800, Rosemead, California 91770

NRC Project Director: Theodore R. Quay

TU Electric Company, Docket Nos. 50-445 and 50-446, Comanche Peak Steam Electric Station, Unit Nos. 1 and 2, Somervell County, Texas

Date of amendment request: October 19, 1992, as supplemented by letter dated March 17, 1993.

Description of amendment request: The proposed amendment would revise Technical Specification 3/4.1.2.5, 3/4.1.2.6, 3/4.5.1, and 3/4.5.4 by increasing the boron concentrations for the refueling water storage tank (RWST) and the emergency core cooling system (ECCS) accumulators. These changes enable the use of extended reload cycles.

Basis for proposed no significant hazards consideration determination: As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration. The NRC staff has reviewed the licensee's analysis against the standards of 10 CFR 50.92(c). The NRC staff's review is presented below:

1. The proposed change would not increase the probability or consequences of a previously evaluated accident.

The proposed changes are related to the boron concentration in the RWST and ECCS accumulators. This increased concentration does not constitute a change expected to increase the probability of a previously evaluated accident. The means by which the proposed changes might result in increased radiological consequences of various accidents are discussed below.

The higher boron concentrations may result in increased probability of equipment failure due to in-containment or in-process equipment being exposed to an environment more severe than that to which it is qualified. A review of the general chemistry properties of the slightly higher boron concentration fluid indicates no mechanism that would result in an appreciable increase in the in-line component failure rate. While the corrosive nature of the fluid will increase, this increase will be only minimal. Thus, there is no significant increase in the consequences of any accident due to an increase in the probability of equipment failure.

The changes in containment spray and sump solution pH may change the radioisotope removal and partition characteristics. A review indicates that while the relevant characteristics are affected, the resulting limiting coefficient values associated with the pH changes are bounded by the values used in Comanche Peak design calculations. Thus, no adverse impact on the radiological consequences arising from this mechanism has been identified.

The impact of the containment spray, with a lower pH, upon the combustible gas production rate was also evaluated. No mechanism for increased combustible gas production was identified.

The higher boron concentration could have an adverse impact on the inadvertent actuation of the ECCS event. Although the timing of the sequence of events may be affected, the departure from nucleate boiling ratio continues to increase from its initial value throughout the event. Based on a review of this event, no changes in the event probability or consequences are anticipated; however, the continued validity of this conclusion will be reconfirmed on a cycle-specific basis.

2. The proposed change would not create the possibility of a new or different kind of accident from any previously evaluated.

The proposed change is a passive change associated with fluid boron concentration. No new or different accident sequences have been identified. Furthermore, a review of heat tracing requirements indicates that there are no additional requirements resulting from the boron concentration increase. There are no previously unconsidered failure mechanisms.

3. The proposed change would not involve a significant reduction in the margin of safety.

The decrease in the containment spray and sump solution pH could be expected to result in higher airborne iodine concentrations. The accident source terms could be impacted by variations in the iodine spray removal and partition factors. A comparison of the coefficients for the minimum equilibrium containment sump solution pH to those used in the CPSES design analyses, indicated that the expected coefficient values would remain bounded by the values in the previous analyses. Thus, no significant reduction in the margin of safety has been identified as associated with this phenomena.

Based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

Local Public Document Room location: University of Texas at Arlington Library, Government Publications/Maps, 701 South Cooper, P. O. Box 19497, Arlington, Texas 76019

Attorney for licensee: George L. Edgar, Esq., Newman and Holtzinger, 1615 L Street, N.W., Suite 1000, Washington, D.C. 20036

NRC Project Director: Suzanne C. Black

Vermont Yankee Nuclear Power Corporation, Docket No. 50-271, Vermont Yankee Nuclear Power Station, Vernon, Vermont

Date of amendment request: March 26, 1993

Description of amendment request: The proposed amendment would update Technical Specification (TS) Section 6.0 to add and revise NRC-approved methodologies which will be used to generate the cycle-specific limits in the Vermont Yankee Core Operating Limits Report (COLR) for Cycle 17.

Basis for proposed no significant hazards consideration determination: As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

1. The proposed change will not involve any significant increase in the probability or consequences of an accident because the change only updates a table in the Technical Specifications to include previously approved methods and, therefore, is administrative in nature. It also does not affect plant operation and will not weaken or degrade the facility.

2. The proposed change will not create the possibility of a new or different kind of accident because the change is administrative in nature and no physical alterations of any plant configuration, changes to setpoints, or operating parameters are proposed.

3. The proposed change will not involve a significant reduction in a margin of safety because the change involves an update to Section 6.0, "Administrative Controls," of the Technical Specifications and does not affect any operating practices, limits, or safety-related equipment, and, therefore, is administrative. The NRC-approved [Yankee Atomic Electric Company] YAEC methodologies will be used to perform a [Loss of Coolant Accident] LOCA analysis for Vermont Yankee in accordance with 10 CFR [Part] 50, Appendix K and to demonstrate compliance with the [Emergency Core Cooling Systems] ECCS limits specified in 10 CFR 50.46.

The NRC staff has reviewed the licensee's analysis, and based on this review, it appears that the three standards of 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

Local Public Document Room location: Brooks Memorial Library, 224 Main Street, Brattleboro, Vermont 05301

Attorney for licensee: John A. Ritsher, Esquire, Ropes and Gray, One International Place, Boston, Massachusetts 02110-2624

NRC Project Director: Walter R. Butler

Washington Public Power Supply System, Docket No. 50-397, Nuclear Project No. 2, Benton County, Washington

Date of amendment request: March 10, 1993

Description of amendment request: The proposed amendment would modify the Technical Specifications (TS) to implement replacement of the existing grab sampler and noble gas monitor for Reactor Building post-accident sampling with an on-line monitor that would sample stack effluents directly. In addition, the proposed change would include a one time exclusion from TS 3.0.4 that would allow startup from the 1993 refueling outage with the on-line monitor inoperable to allow calibration of the monitor.

Basis for proposed no significant hazards consideration determination: As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration. The staff's evaluation of the licensee's analysis for the change to the effluent grab sample and noble gas monitoring capability is presented below:

1. Does the amendment involve a significant increase in the probability or consequences of an accident previously evaluated?

The proposed amendment would replace the current grab sample and noble gas radiation monitor with a single system capable of continuous monitoring and analysis of all currently analyzed radioactive iodines and particulates in plant gaseous effluents following an accident. The intent of the monitoring and analysis functions is to evaluate the radioactive releases following an accident to guide mitigative and emergency response actions. The accident is assumed to have already occurred before the samples affected by this TS change request are required. As such, the monitor is not an accident initiator and is not likely to contribute to the probability of an accident previously evaluated. The in-line, continuous monitor provides at least equivalent, and in the case of the grab sample, enhanced analysis capability, and will provide a more immediate indication of the release of effluents following an accident through the reactor building elevated release. Further, it will provide a more timely indication of a release impact over a period of time. More timely input of such data will allow a more deliberate and accurate response to plant events. Mitigation actions can then be based on a better knowledge of the release. A better knowledge base from which to direct accident mitigation and emergency response efforts should lead to more effective response to accidents, which should lead to a decrease in the consequences of an accident.

The one time exception to TS 3.0.4., which would allow startup with the new effluent monitoring system inoperable, provides the means to align and calibrate the system under actual operating conditions. During this maximum of a 30 day period during which the new effluent monitoring system will be considered inoperable until the calibration is complete, the licensee will use a pre-planned alternative method of monitoring off-site releases that uses in-containment

monitors and off-site dose assessment procedures. This alternate method is currently used during emergency conditions to determine mitigative and emergency response actions, since the grab sampler would be inaccessable post-accident. This alternate method is intended for use post-accident, and does not affect the probability of any accidents previously evaluated, since the accident is assumed to have already occurred before the samples are required. There will be no impact on the consequences of an accident, since the alternate method is the method currently used under emergency conditions.

Based on this analysis, the staff concludes that the changes proposed by the licensee will not significantly increase the probability or consequences of an accident previously evaluated.

2. Does the amendment create the possibility of a new or different kind of accident from any accident previously evaluated?

The monitor performs a passive function that follows and monitors plant events after an accident is assumed to have occurred. The requested exception to TS 3.0.4. would use the existing pre-planned alternate method of determining effluents, again after an accident is assumed to have occurred. These proposed changes have no automatic control function, and thus do not affect accident initiation. The proposed amendment does not, therefore, create the possibility of a new or different kind of accident from any accident previously evaluated.

3. Does the amendment involve a significant reduction in a margin of safety?

The existing grab-sample method provided time-delayed results that identified specific isotopes off-line. The current noble gas monitor only provides indication of gross gamma radiation. The new monitor provides information on actual concentrations of specific isotopes in the reactor building effluent on a real time basis, which will provide more timely information from which to base mitigative and emergency response actions on than that presently provided by the grab sample system. Therefore, the margin of safety created by the existence and use of the grab sample system is increased by the proposed replacement with the in-line system. Therefore, the in-line system does not reduce any margins of safety.

The NRC staff has determined based on its analysis that it appears that the three standards of 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

Local Public Document Room location: Richland Public Library, 955 Northgate Street, Richland, Washington 99352

Attorney for licensee: Nicholas S. Reynolds, Esq., Winston & Strawn, 1400 L Street, N.W., Washington, D.C. 20005-3502

NRC Project Director: Theodore R. Quay

Previously Published Notices of Consideration of Issuance of Amendments to Facility Operating Licenses, Proposed No Significant Hazards Consideration Determination, and Opportunity for a Hearing

The following notices were previously published as separate individual notices. The notice content was the same as above. They were published as individual notices either because time did not allow the Commission to wait for this biweekly notice or because the action involved exigent circumstances. They are repeated here because the biweekly notice lists all amendments issued or proposed to be issued involving no significant hazards consideration.

For details, see the individual notice in the **Federal Register** on the day and page cited. This notice does not extend the notice period of the original notice.

Duquesne Light Company, et al., Docket No. 50-334, Beaver Valley Power Station, Unit No. 1, Shippingport, Pennsylvania

Date of amendment request: November 2, 1992

Description of amendment request: The proposed amendment would modify the Appendix A Technical Specifications (TSs) to allow for increasing the number of spent fuel assemblies that may be stored in the spent-fuel pool. The changes would allow for the storage of fuel with U-235 enrichment up to 5.0% (weight). The proposed amendment would affect TS sections 3/4 9.14, 5.6.1, and 5.6.3, and Table 3.9-1.

Date of publication of individual notice in **Federal Register:** February 2, 1993 (58 FR 7161).

Expiration date of individual notice: March 8, 1993

Local Public Document Room location: B. F. Jones Memorial Library, 663 Franklin Avenue, Aliquippa, Pennsylvania 15001.

Florida Power and Light Company, Docket No. 50-335, St. Lucie Plant, Unit No. 1, St. Lucie County, Florida

Date of application for amendment: November 30, 1992

Brief description of amendment: This amendment revises Technical Specifications Tables 3.3-3, 3.3-4, and 4.3-2 where they apply to the Emergency Bus Undervoltage Protection Devices and will permit improvements to be made in the undervoltage protective relaying scheme.

Date of issuance: April 12, 1993

Effective date: April 12, 1993

Amendment No.: 121

Facility Operating License No. DPR-67: Amendment revised the Technical Specifications.

Date of initial notice in **Federal Register:** January 21, 1993 (58 FR 5431). The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated April 12, 1993. No significant hazards consideration comments received: No.

Local Public Document Room location: Indian River Junior College Library, 3209 Virginia Avenue, Fort Pierce, Florida 34954-9003

GPU Nuclear Corporation, et al., Docket No. 50-289, Three Mile Island Nuclear Station, Unit 1, Dauphin County, Pennsylvania

Date of application for amendment: May 19, 1992, as supplemented November 30, 1992, January 29, and February 12, 1993.

Brief description of amendment: The amendment deletes portions of the TMI-1 Radiological Environmental Technical Specifications (RETS) and relocates them to controlled programs in accordance with the guidance contained in NRC Generic Letter 89-01, dated January 31, 1989.

Date of issuance: April 5, 1993

Effective date: April 5, 1993

Amendment No.: 173

Facility Operating License No. DPR-50. Amendment revised the Technical Specifications.

Date of initial notice in **Federal Register:** December 23, 1992 (57 FR 61112) The January 29, and February 12, 1993 letters provided errata pages that did not change the initial no significant hazards consideration determination. The Commission's related evaluation of this amendment is contained in a Safety Evaluation dated April 5, 1993.

No significant hazards consideration comments received: No.

Local Public Document Room location: Government Publications Section, State Library of Pennsylvania,

Walnut Street and Commonwealth Avenue, Box 1601, Harrisburg, Pennsylvania 17105.

Illinois Power Company and Soyland Power Cooperative, Inc., Docket No. 50-451, Clinton Power Station, Unit No. 1, DeWitt County, Illinois

Date of application for amendment: September 20, 1991 and supplemented by letters dated August 17, 1992, and February 17, 1993

Description of amendment request: The amendment revised both surveillance test intervals and allowed out-of-service times for Reactor Protection System, Emergency Core Cooling System, Control Rod Block System, and Containment and Reactor Vessel Isolation Control System Instrumentation contained in the Clinton Power Station Technical Specifications (TS). In addition, several administrative changes to the TS are contained in this TS change.

Date of issuance: April 9, 1993

Effective date: Immediately, to be implemented within 30 days.

Amendment No.: 71

Facility Operating License No. NPF-62. The amendment revised the Technical Specifications.

Date of initial notice in **Federal Register:** December 26, 1991 (56 FR 66921) The August 17, 1992, and February 17, 1993, submittals consisted of revisions/clarifications which did not change the staff's initial proposed no significant hazards consideration determination.

The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated April 9, 1993.

No significant hazards consideration comments received: No

Local Public Document Room location: The Vespasian Warner Public Library, 120 West Johnson Street, Clinton, Illinois 61727.

Illinois Power Company and Soyland Power Cooperative, Inc., Docket No. 50-461, Clinton Power Station, Unit No. 1, DeWitt County, Illinois

Date of application for amendment: December 15, 1992

Brief description of amendment: The amendment modifies Technical Specifications 3/4.7.1.1, "Shutdown Service Water System (Loops A, B, C)," and 3/4.7.2, "Control Room Ventilation System," to add exceptions to Technical Specification 3.0.4 to permit tensioning and detensioning of the reactor pressure vessel head with one of the required divisions of the systems addressed by these Technical Specifications inoperable.

Date of issuance: April 9, 1993

Effective date: April 9, 1993

Amendment Nos.: 72

Facility Operating License No. NPF-62. The amendment revised the Technical Specifications.

Date of initial notice in **Federal Register:** February 3, 1993 (58 FR 6999)

The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated April 9, 1993.

No significant hazards consideration comments received: No

Local Public Document Room location: The Vespasian Warner Public Library, 120 West Johnson Street, Clinton, Illinois 61727.

Iowa Electric Light and Power Company, Docket No. 50-331, Duane Arnold Energy, Center, Linn County, Iowa

Date of application for amendment: December 19, 1991 and supplemented by additional information on August 25, October 8, and November 24, 1992.

Brief description of amendment: The amendment revised the Technical Specifications by incorporating extended allowable out-of-service times and surveillance test intervals for reactor protection system, isolation actuation system, emergency core cooling system and control rod block function instrumentation. Additional changes for clarity and consistency were also made.

Date of issuance: April 14, 1993

Effective date: April 14, 1993

Amendment No.: 193

Facility Operating License No. DPR-49. Amendment revised the Technical Specifications.

Date of initial notice in **Federal Register:** July 22, 1992 (57 FR32573) The August 25, October 8, and November 24, 1992 letters provided clarifying information only and did not affect the NRC's origianl determination of no significant hazards consideration.

The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated April 14, 1993.

No significant hazards consideration comments received: No.

Local Public Document Room location: Cedar Rapids Public Library, 500 First Street, S. E., Cedar Rapids, Iowa 52401.

Indiana Michigan Power Company, Docket Nos. 50-315 and 50-316, Donald C. Cook Nuclear Plant, Unit Nos. 1 and 2, Berrien County, Michigan

Date of application for amendments: May 1, 1992

Brief description of amendments: The amendments change the number of containment thermistor fire detectors listed in Table 3.3-10 (Unit 1) and Table 3.3-11 (Unit 2) to reflect as-built conditions.

Date of issuance: April 8, 1993

Effective date: April 8, 1993

Amendment Nos.: 172 and 155

Facility Operating License Nos. DPR-58 and DPR-74. Amendments revised the Technical Specifications.

Date of initial notice in **Federal Register:** July 8, 1992 (57 FR 30250)

The Commission's related evaluation of the amendments is contained in a Safety Evaluation dated April 8, 1993.

No significant hazards consideration comments received: No.

Local Public Document Room location: Maude Preston Palenske Memorial Library, 500 Market Street, St. Joseph, Michigan 49085.

Nebraska Public Power District, Docket No. 50-298, Cooper Nuclear Station, Nemaha County, Nebraska

Date of amendment request: February 1, 1993

Brief description of amendment: The amendment revised the Technical Specifications (TS) to (1) incorporate the NRC Staff position on leak detection per the guidance of Generic Letter (GL) 88-01 and its supplement, (2) incorporate the NRC Staff position on inservice inspection schedules, methods, personnel, and sample expansion per the guidance of GL 88-01 and its supplement, and (3) make administrative changes wherein certain system names are replaced by system names which are more consistent with those used in other portions of the TS.

Date of issuance: April 14, 1993

Effective date: April 14, 1993

Amendment No.: 161

Facility Operating License No. DPR-46. Amendment revised the Technical Specifications.

Date of initial notice in **Federal Register:** March 3, 1993 (58 FR 12264)

The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated April 14, 1993.

No significant hazards consideration comments received: No.

Local Public Document Room location: Auburn Public Library, 118 15th Street, Auburn, Nebraska 68305.

Niagara Mohawk Power Corporation, Docket No. 50-220, Nine Mile Point Nuclear Station Unit No. 1, Oswego County, New York

Date of application for amendment: November 20, 1990, as superseded February 7, 1992, as supplemented June 22, 1992, January 29, 1993, February 18, 1993, and March 29, 1993.

Brief description of amendment: The amendment revises Technical Specifications (TSs) 3.2.7.1, 3.3.3, 4.3.3,

and 3.3.4 and associated Bases to update these TSs to conform to the requirements of 10 CFR Part 50, Appendix J, and NRC Safety Evaluations, dated May 6, 1988, and November 9, 1988.

Date of issuance: April 12, 1993
Effective date: April 12, 1993
Amendment No.: 140
Facility Operating License No. DPR-63: Amendment revises the Technical Specifications.
Date of initial notice in **Federal Register:** February 6, 1991 (56 FR 4866) and renoticed April 1, 1992 (57 FR 11111)

The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated April 12, 1993.

No significant hazards consideration comments received: No.

Local Public Document Room location: Reference and Documents Department, Penfield Library, State University of New York, Oswego, New York 13126.

North Atlantic Energy Service Corporation, Docket No. 50-443, Seabrook Station, Unit No. 1, Seabrook, New Hampshire

Date of amendment request: August 17, 1992.

Description of amendment request: The amendment revises the Appendix A Technical Specifications relating to Reactor Coolant System heatup and cooldown limitations. Specifically, Figures 3.4-2 and 3.4-3 are modified to show applicability of the curves up to 11.1 equavalent full-power years (EFPY), to provide revised RT_{NDT} values at 11.1 EFPY at 1/4 and 3/4 thickness, and to indicate the copper content of the controlling material.

Date of issuance: April 7, 1993
Effective date: April 7, 1993
Amendment No.: 19
Facility Operating License No. NPF-86. Amendment revised the Technical Specifications.
Date of initial notice in **Federal Register:** December 9, 1992 (57 FR 58247).

The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated April 7, 1993.

No significant hazards consideration comments received: No.

Local Public Document Room location: Exeter Public Library, 47 Front Street, Exeter, New Hampshire 03833.

Power Authority of The State of New York, Docket No. 50-286, Indian Point Nuclear Generating Unit No. 3, Westchester County, New York

Date of application for amendment: July 17, 1992, as supplemented December 23, 1992

Brief description of amendment: The amendment revised the Technical Specifications to incorporate the following changes:

(1) The containment isolation system automatic actuation testing frequency (specified in TS Table 4.1-3) was revised to accommodate operation on a 24-month fuel cycle.

(2) The containment isolation valve testing frequency (specified in TS Section 4.4.E.1) was revised and the acceptance criteria for the combined containment leakage rate (specified in TS Section 4.4.E.2) was reduced to 0.5 L_a to accommodate operation on a 24-month fuel cycle.

(3) The containment spray system testing frequency (specified in TS Section 4.5.A.2.a) was revised to accommodate operation on a 24-month fuel cycle.

(4) The spray additive valves testing frequency (specified in TS Section 4.5.B.2.a) was revised to accommodate operation on a 24-month fuel cycle.

(5) The sensitive leakage rate testing frequency (specified in TS Section 4.4.C.3) was revised to clarify that the maximum test interval is 3 years.

(6) The Basis of TS Section 4.1 (Operational Safety Review) was revised to specify that the phrase "at least," when referring to surveillance periodicity, does not negate the 25% extension time allowed by TS Definition 1.12.

These changes followed the guidance provided in Generic Letter 91-04, "Changes in Technical Specification Surveillance Intervals to Accommodate a 24-Month Fuel Cycle."

Date of issuance: April 9, 1993
Effective date: April 9, 1993
Amendment No.: 129
Facility Operating License No. DPR-64: Amendment revised the Technical Specifications.
Date of initial notice in **Federal Register:** September 2, 1992 (57 FR 40219)

The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated April 9, 1993.

No significant hazards consideration comments received: No

Local Public Document Room location: White Plains Public Library, 100 Martine Avenue, White Plains, New York 10610.

Rochester Gas and Electric Corporation, Docket No. 50-244, R. E. Ginna Nuclear Power Plant, Wayne County, New York

Date of application for amendment: October 8, 1992

Brief description of amendment: Updates the auxiliary electrical systems Technical Specifications with instrument bus operability provisions by adding Specifications, Action Statements, Surveillance Requirements and Basis sections relative to the operation of the vital instrument buses.

Date of issuance: April 13, 1993
Effective date: April 13, 1993
Amendment No.: 51
Facility Operating License No. DPR-18: Amendment revised the Appendix A Technical Specifications.
Date of initial notice in **Federal Register:** December 9, 1992 (57 FR 58251)

The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated April 13, 1993.

No significant hazards consideration comments received: No

Local Public Document Room location: Rochester Public Library, 115 South Avenue, Rochester, New York 14610.

Southern California Edison Company, et al., Docket Nos. 50-361 and 50-362, San Onofre Nuclear Generating Station, Unit Nos. 2 and 3, San Diego County, California

Date of application for amendments: October 2, 1992

Brief description of amendments: The licensee proposes to revise License Condition 2.C.(19)i for San Onofre Unit 2 and License Condition 2.C.(17)d for San Onofre Unit 3, "Post-Accident Sampling System (NUREG-0737 Item II.B.3)," to remove conditions already complied with, and to revise four Post-Accident Sampling System requirements.

Date of issuance: April 6, 1993
Effective date: April 6, 1993
Amendment Nos.: 103 and 92
Facility Operating License Nos. NPF-10 and NPF-15: The amendments revised the Operating Licenses.
Date of initial notice in **Federal Register:** February 17, 1993 (58 FR 8782)

The Commission's related evaluation of the amendments is contained in a Safety Evaluation dated April 6, 1993.

No significant hazards consideration comments received: No.

Local Public Document Room location: Main Library, University of California, P. O. Box 19557, Irvine, California 92713

Tennessee Valley Authority, Docket Nos. 50-259, 50-260 and 50-296, Browns Ferry Nuclear Plant, Units 1, 2 and 3, Limestone County, Alabama

Date of application for amendments: September 10, 1992 (TS 323)

Brief description of amendment: These license amendments revise the

Browns Ferry Nuclear Plant Technical Specifications by restoring the operability requirements of the Control Room Emergency Ventilation System that were temporarily modified by previous license amendments issued on September 18, 1989. These license amendments also remove a list of dampers in accordance with Generic Letter 91-08, "Removal of Component Lists From Technical Specifications," and revises associated Bases.

Date of issuance: April 9, 1993

Effective date: April 9, 1993

Amendment Nos.: 193, 208, and 165

Facility Operating License Nos. DPR-33, DPR-52 and DPR-68: Amendments revise the Technical Specifications.

Date of initial notice in **Federal Register:** October 28, 1992 (57 FR 48829)

The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated April 9, 1993.

No significant hazards consideration comments received: No

Local Public Document Room location: Athens Public Library, South Street, Athens, Alabama 35611

Tennessee Valley Authority, Docket Nos. 50-259, 50-260, and 50-296, Browns Ferry Nuclear Plant, Units 1, 2, and 3, Limestone County, Alabama

Date of application for amendments: October 9, 1992, as supplemented March 31, 1993 (TS 324)

Brief description of amendments: The amendments provide a revised definition of core alterations for refueling operations, revise surveillance requirements for infrequently used refueling equipment, revise refueling core reactivity monitoring requirements, and revise administrative requirements for supervision of refueling operations.

Date of issuance: April 9, 1993

Effective date: April 9, 1993Amendment Nos. 194, 209, and 166

Facility Operating License Nos. DPR-33, DPR-52 and DPR-68:

Date of initial notice in **Federal Register:** November 25, 1992 (57 FR 55592)

The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated April 9, 1993.

No significant hazards consideration comments received: None

Local Public Document Room location: Athens Public Library, South Street, Athens, Alabama 35611

Toledo Edison Company, Centerior Service Company, and The Cleveland Electric Illuminating Company, Docket No. 50-346, Davis-Besse Nuclear Power Station, Unit No. 1, Ottawa County, Ohio

Date of application for amendment: October 29, 1992 supplemented February 17, 1993.

Brief description of amendment: The amendment revised Technical Specification (TS) 5.3.1, "Fuel Assemblies," to be consistent with the model TS wording included in Supplement 1 to Generic Letter 90-02, "Alternative Requirements for Fuel Assemblies in the Design Features Section of Technical Specifications."

Date of issuance: April 7, 1993

Effective date: April 7, 1993

Amendment No. 179

Facility Operating License No. NPF-3. Amendment revised the Technical Specifications.

Date of initial notice in **Federal Register:** November 25, 1992 (57 FR 55594) The supplemental letter of February 17, 1993 withdrew the phrase "zirconium alloy," reverting to the term "zircaloy" for describing fuel rod cladding. This change did not significantly change the request or affect the staff's notice of the request.

The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated April 7, 1993.

No significant hazards consideration comments received:

Local Public Document Room location: University of Toledo Library, Documents Department, 2801 Bancroft Avenue, Toledo, Ohio 43606.

Washington Public Power Supply System, Docket No. 50-397, Washington Nuclear Project No. 2, Benton County, Washington

Date of application for amendment: April 1, 1993

Brief description of amendment: The amendment adds a footnote to TS 3.7.3, "Reactor Core Isolation Cooling System," that allows plant operation to continue with the Reactor Core Isolation Cooling (RCIC) automatic transfer of the suction path to the suppression pool disabled until May 17, 1993, or the beginning of the 1993 refueling outage, whichever comes first.

Date of issuance: April 9, 1993

Effective date: April 9, 1993

Amendment No.: 114

Facility Operating License No. NPF-21: The amendment revised the Technical Specifications.

The Commission's related evaluation of the amendment, finding of emergency circumstances, and final determination of no significant hazards consideration are contained in a Safety Evaluation dated April 9, 1993.Public comments on proposed no significant hazards consideration comments received: No.

Attorney for licensee: Nicholas S. Reynolds, Esq., Winston & Strawn, 1400 L Street, N.W., Washington, D.C. 20005-3502

Local Public Document Room location: Richland Public Library, 955 Northgate Street, Richland, Washington 99352 NRC

Project Director: Theodore R. Quay

Wisconsin Electric Power Company, Docket Nos. 50-266 and 50-301, Point Beach Nuclear Plant, Unit Nos. 1 and 2, Town of Two Creeks, Manitowoc County, Wisconsin

Date of application for amendments: December 7, 1989

Brief description of amendments: The amendments eliminated the requirements for testing components in the opposite train when certain components in a train are out of service. These components are safety injection pumps, residual heat removal pumps, containment spray pumps, and containment accident pumps. The change also eliminates testing redundant valves in safety injection, residual heat removal, and containment spray systems when a valve is inoperable.

Date of issuance: April 16, 1993

Effective date: April 16, 1993

Amendment Nos.: 138 and 142

Facility Operating License Nos. DPR-24 and DPR-27. Amendments revised the Technical Specifications.

Date of initial notice in **Federal Register:** July 10, 1991 (56 FR 31415)

The Commission's related evaluation of the amendments is contained in a Safety Evaluation dated April 16, 1993.

No significant hazards consideration comments received: No.

Local Public Document Room location: Joseph P. Mann Library, 1516 Sixteenth Street, Two Rivers, Wisconsin.

Wolf Creek Nuclear Operating Corporation, Docket No. 50-482, Wolf Creek Generating Station, Coffey County, Kansas

Date of amendment request: December 22, 1992

Brief description of amendment: The amendment consists of a revision to Technical Specification Table 4.8-1, Diesel Generator Test Schedule, which eliminates the requirement to increase the testing frequency upon experiencing five or more failures in the last 100 valid tests. The provision for increased testing based upon the last 20 valid tests has been retained.

Date of issuance: April 6, 1993
Effective date: April 6, 1993, to be implemented within 30 days of issuance.
Amendment No.:
Amendment No. 62
Facility Operating License No. NPF-42. Amendment revised the Technical Specifications.
Date of initial notice in **Federal Register:** February 3, 1993 (58 FR 7008).
The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated April 6, 1992.
No significant hazards consideration comments received: No.
Local Public Document Room Locations: Emporia State University, William Allen White Library, 1200 Commercial Street, Emporia, Kansas 66801 and Washburn University School of Law Library, Topeka, Kansas 66621

Notice of Issuance of Amendments to Facility Operating Licenses and Final Determination of No Significant Hazards Consideration and Opportunity for a Hearing (Exigent, Public Announcement or Emergency Circumstances)

During the period since publication of the last biweekly notice, the Commission has issued the following amendments. The Commission has determined for each of these amendments that the application for the amendment complies with the standards and requirements of the Atomic Energy Act of 1954, as amended (the Act), and the Commission's rules and regulations. The Commission has made appropriate findings as required by the Act and the Commission's rules and regulations in 10 CFR Chapter I, which are set forth in the license amendment.

Because of exigent or emergency circumstances associated with the date the amendment was needed, there was not time for the Commission to publish, for public comment before issuance, its usual 30-day Notice of Consideration of Issuance of Amendment, Proposed No Significant Hazards Consideration Determination, and Opportunity for a Hearing.

For exigent circumstances, the Commission has either issued a **Federal Register** notice providing opportunity for public comment or has used local media to provide notice to the public in the area surrounding a licensee's facility of the licensee's application and of the Commission's proposed determination of no significant hazards consideration. The Commission has provided a reasonable opportunity for the public to comment, using its best efforts to make available to the public means of communication for the public to respond quickly, and in the case of telephone comments, the comments have been recorded or transcribed as appropriate and the licensee has been informed of the public comments.

In circumstances where failure to act in a timely way would have resulted, for example, in derating or shutdown of a nuclear power plant or in prevention of either resumption of operation or of increase in power output up to the plant's licensed power level, the Commission may not have had an opportunity to provide for public comment on its no significant hazards consideration determination. In such case, the license amendment has been issued without opportunity for comment. If there has been some time for public comment but less than 30 days, the Commission may provide an opportunity for public comment. If comments have been requested, it is so stated. In either event, the State has been consulted by telephone whenever possible.

Under its regulations, the Commission may issue and make an amendment immediately effective, notwithstanding the pendency before it of a request for a hearing from any person, in advance of the holding and completion of any required hearing, where it has determined that no significant hazards consideration is involved.

The Commission has applied the standards of 10 CFR 50.92 and has made a final determination that the amendment involves no significant hazards consideration. The basis for this determination is contained in the documents related to this action. Accordingly, the amendments have been issued and made effective as indicated.

Unless otherwise indicated, the Commission has determined that these amendments satisfy the criteria for categorical exclusion in accordance with 10 CFR 51.22. Therefore, pursuant to 10 CFR 51.22(b), no environmental impact statement or environmental assessment need be prepared for these amendments. If the Commission has prepared an environmental assessment under the special circumstances provision in 10 CFR 51.12(b) and has made a determination based on that assessment, it is so indicated.

For further details with respect to the action see (1) the application for amendment, (2) the amendment to Facility Operating License, and (3) the Commission's related letter, Safety Evaluation and/or Environmental Assessment, as indicated. All of these items are available for public inspection at the Commission's Public Document Room, the Gelman Building, 2120 L Street, NW., Washington, DC 20555, and at the local public document room for the particular facility involved.

The Commission is also offering an opportunity for a hearing with respect to the issuance of the amendment. By May 28, 1993, the licensee may file a request for a hearing with respect to issuance of the amendment to the subject facility operating license and any person whose interest may be affected by this proceeding and who wishes to participate as a party in the proceeding must file a written request for a hearing and a petition for leave to intervene. Requests for a hearing and a petition for leave to intervene shall be filed in accordance with the Commission's "Rules of Practice for Domestic Licensing Proceedings" in 10 CFR Part 2. Interested persons should consult a current copy of 10 CFR 2.714 which is available at the Commission's Public Document Room, the Gelman Building, 2120 L Street, NW., Washington, DC 20555 and at the local public document room for the particular facility involved. If a request for a hearing or petition for leave to intervene is filed by the above date, the Commission or an Atomic Safety and Licensing Board, designated by the Commission or by the Chairman of the Atomic Safety and Licensing Board Panel, will rule on the request and/or petition; and the Secretary or the designated Atomic Safety and Licensing Board will issue a notice of a hearing or an appropriate order.

As required by 10 CFR 2.714, a petition for leave to intervene shall set forth with particularity the interest of the petitioner in the proceeding, and how that interest may be affected by the results of the proceeding. The petition should specifically explain the reasons why intervention should be permitted with particular reference to the following factors: (1) the nature of the petitioner's right under the Act to be made a party to the proceeding; (2) the nature and extent of the petitioner's property, financial, or other interest in the proceeding; and (3) the possible effect of any order which may be entered in the proceeding on the petitioner's interest. The petition should also identify the specific aspect(s) of the subject matter of the proceeding as to which petitioner wishes to intervene. Any person who has filed a petition for leave to intervene or who has been admitted as a party may amend the petition without requesting leave of the Board up to 15 days prior to the first prehearing conference scheduled in the proceeding, but such an amended petition must satisfy the specificity requirements described above.

Not later than 15 days prior to the first prehearing conference scheduled in the proceeding, a petitioner shall file a supplement to the petition to intervene which must include a list of the contentions which are sought to be litigated in the matter. Each contention must consist of a specific statement of the issue of law or fact to be raised or controverted. In addition, the petitioner shall provide a brief explanation of the bases of the contention and a concise statement of the alleged facts or expert opinion which support the contention and on which the petitioner intends to rely in proving the contention at the hearing. The petitioner must also provide references to those specific sources and documents of which the petitioner is aware and on which the petitioner intends to rely to establish those facts or expert opinion. Petitioner must provide sufficient information to show that a genuine dispute exists with the applicant on a material issue of law or fact. Contentions shall be limited to matters within the scope of the amendment under consideration. The contention must be one which, if proven, would entitle the petitioner to relief. A petitioner who fails to file such a supplement which satisfies these requirements with respect to at least one contention will not be permitted to participate as a party.

Those permitted to intervene become parties to the proceeding, subject to any limitations in the order granting leave to intervene, and have the opportunity to participate fully in the conduct of the hearing, including the opportunity to present evidence and cross-examine witnesses. Since the Commission has made a final determination that the amendment involves no significant hazards consideration, if a hearing is requested, it will not stay the effectiveness of the amendment. Any hearing held would take place while the amendment is in effect.

A request for a hearing or a petition for leave to intervene must be filed with the Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, DC 20555, Attention: Docketing and Services Branch, or may be delivered to the Commission's Public Document Room, the Gelman Building, 2120 L Street, NW., Washington, DC 20555, by the above date. Where petitions are filed during the last 10 days of the notice period, it is requested that the petitioner promptly so inform the Commission by a toll-free telephone call to Western Union at 1-(800) 248-5100 (in Missouri 1-(800) 342-6700). The Western Union operator should be given Datagram Identification Number N1023 and the following message addressed to **(Project Director)**: petitioner's name and telephone number, date petition was mailed, plant name, and publication date and page number of this **Federal Register** notice. A copy of the petition should also be sent to the Office of the General Counsel, U.S. Nuclear Regulatory Commission, Washington, DC 20555, and to the attorney for the licensee.

Nontimely filings of petitions for leave to intervene, amended petitions, supplemental petitions and/or requests for a hearing will not be entertained absent a determination by the Commission, the presiding officer or the Atomic Safety and Licensing Board that the petition and/or request should be granted based upon a balancing of the factors specified in 10 CFR 2.714(a)(1)(i)-(v) and 2.714(d).

Consolidated Edison Company of New York, Inc., Docket No. 50-247, Indian Point Nuclear Generating Unit No. 2, Westchester County, New York

Date of application for amendment: April 8, 1993, as supplemented on April 12, 1993, and April 14, 1993.

Brief description of amendment: The amendment revises (Technical Specifications (TS) Section 3.3.D (Weld Channel and Penetration Pressurization System) to permit disconnecting a portion of the weld channel system if that portion became inoperable and repairs to that portion of the system were determined to be not practicable. The amendment also revises the associated TS Bases.

Date of issuance: April 14, 1993

Effective date: April 14, 1993

Amendment No.: 162

Facility Operating License No. DPR-26: Amendment revised the Technical Specifications.Public comments requested as to proposed no significant hazards consideration: No. The Commission's related evaluation of the amendment and final no significant hazards consideration determination are contained in a Safety Evaluation dated April 14, 1993.

Local Public Document Room location: White Plains Public Library, 100 Martine Avenue, White Plains, New York 10610.

Attorney for licensee: Mr. Brent L. Brandenburg, Assistant General Counsel, Consolidated Edison Company of New York, Inc., 4 Irving Place - 1822, New York, New York 10003.

NRR Project Director: Robert A. Capra, Director

Virginia Electric and Power Company, et al., Docket No. 50-339, North Anna Power Station, Unit No. 2, Louisa County, Virginia

Date of application for amendment: March 31, 1993

Brief description of amendment: The amendment suspends the manual engineered safety features functional test of safety injection input to the reactor trip breakers for the remainder of the NA-2 operating Cycle 9.

Date of issuance: April 12, 1993

Effective date: April 12, 1993

Amendment No.: 150

Facility Operating License No. NPF-7: Amendment revised the Technical Specifications.

Public comments requested as to proposed no significant hazards consideration: No. On March 26, 1993, the staff granted an enforcement discretion to be in effect until the amendment was issued.

The Commission's related evaluation of the amendments, consultation with the State of Virginia and final no significant hazards determination are contained in a safety evaluation dated April 12, 1993.

Attorney for licensee: Michael W. Maupin, Esq., Hunton and Williams, Riverfront Plaza, East Tower, 951 E. Byrd Street, Richmond, Virginia 23219.

Local Public Document Room location: The Alderman Library, Special Collections Department, University of Virginia, Charlottesville, Virginia 22903-2498.

Duquesne Light Company, et al., Docket Nos. 50-334 and 50-412, Beaver Valley Power Station, Unit Nos. 1 and 2, Shippingport, Pennsylvania

Date of amendment request: December 30, 1992

Description of amendment request: The proposed amendments would modify the Technical Specifications and Bases to allow sleeving at the steam generator tube support plate and tubesheet regions in accordance with processes performed by the vendors, Babcock & Wilcox and Westinghouse.Date of publication of individual notice in **Federal Register**: April 6, 1993 (58 FR 17912).

Expiration date of individual notice: May 6, 1993

Local Public Document Room location: B. F. Jones Memorial Library, 663 Franklin Avenue, Aliquippa, Pennsylvania 15001.

Tennessee Valley Authority, Docket Nos. 50-327 and 50-328, Sequoyah Nuclear Plant, Units 1 and 2, Hamilton County, Tennessee

Date of amendment request: March 27, 1992, as supplemented May 11, May 28, September 8 and October 8, 1992; February 18 and April 1, 1993.

Description of amendment request: The proposed amendment would increase the storage capacity of the spent fuel pool from its present 1386 storage cells to 2091 storage cells. This would be accomplished by replacing the present medium density fuel racks with 12 free-standing, self-supporting, high density rack modules constructed of stainless steel and a neutron absorber material (boron carbide and aluminum-composite sandwich, product name "boral"). In addition, the proposed amendments would add controls affecting the fuel arrangement and spacing of fuel in the spent fuel pool, revise related surveillance requirements, address controls for fuel movement over the cask loading area of the spent fuel pool, revise the operability requirements of the crane interlocks and physical stops, address additional fuel storage capacity in the cask loading area, and incorporate other related information.

Date of publication of individual notice in **Federal Register:** June 24, 1992 (57 FR 28217)

Expiration date of individual notice: July 24, 1992

Local Public Document Room location: Chattanooga-Hamilton County Library, 1101 Broad Street, Chattanooga, Tennessee 37402

Notice of Issuance of Amendments to Facility Operating Licenses

During the period since publication of the last biweekly notice, the Commission has issued the following amendments. The Commission has determined for each of these amendments that the application complies with the standards and requirements of the Atomic Energy Act of 1954, as amended (the Act), and the Commission's rules and regulations. The Commission has made appropriate findings as required by the Act and the Commission's rules and regulations in 10 CFR Chapter I, which are set forth in the license amendment.

Notice of Consideration of Issuance of Amendment to Facility Operating License, Proposed No Significant Hazards Consideration Determination, and Opportunity for A Hearing in connection with these actions was published in the **Federal Register** as indicated.

Unless otherwise indicated, the Commission has determined that these amendments satisfy the criteria for categorical exclusion in accordance with 10 CFR 51.22. Therefore, pursuant to 10 CFR 51.22(b), no environmental impact statement or environmental assessment need be prepared for these amendments. If the Commission has prepared an environmental assessment under the special circumstances provision in 10 CFR 51.12(b) and has made a determination based on that assessment, it is so indicated.

For further details with respect to the action see (1) the applications for amendment, (2) the amendment, and (3) the Commission's related letter, Safety Evaluation and/or Environmental Assessment as indicated. All of these items are available for public inspection at the Commission's Public Document Room, the Gelman Building, 2120 L Street, NW., Washington, DC 20555, and at the local public document rooms for the particular facilities involved.

Commonwealth Edison Company, Docket Nos. STN 50-454 and STN 50-455, Byron Station, Unit Nos. 1 and 2, Ogle County, IllinoisDocket Nos. STN 50-456 and STN 50-457, Braidwood Station, Unit Nos. 1 and 2, Will County, Illinois

Date of application for amendments: April 15, 1992, as supplemented November 23, 1992.

Brief description of amendments: The amendments revise the Technical Specifications to incorporate the results of the Setpoint Reconcilation Program.

Date of issuance: April 13, 1993

Effective date: April 13, 1993

Amendment Nos.: 53, 53, 42, and 42

Facility Operating License Nos. NPF-37, NPF-66, NPF-72 and NPF-77: The amendments revised the Technical Specifications.

Date of initial notice in **Federal Register:** June 10, 1992 (57 FR 24666) The November 23, 1992, submittal provided additional clarifying information that did not change the initial proposed no significant hazards consideration determination.

The Commission's related evaluation of the amendments is contained in a Safety Evaluation dated April 13, 1993.

No significant hazards consideration comments received: No

Local Public Document Room location: For Byron, the Byron Public Library, 109 N. Franklin, P.O. Box 434, Byron, Illinois 61010; for Braidwood, the Wilmington Township Public Library, 201 S. Kankakee Street, Wilmington, Illinois 60481.

Commonwealth Edison Company, Docket Nos. 50-295 and 50-304, Zion Nuclear Power Station Units 1 and 2, Lake County, Illinois

Date of application for amendments: November 5, 1992

Brief description of amendments: The amendments revise the Technical Specifications by deleting the requirements to perform additional surveillance testing when the associated redundant components and/or subsystems have been found to be inoperable.

Date of issuance: April 7, 1993

Effective date: Immediately, to be implemented within 30 days.

Amendment Nos.: 144 and 133

Facility Operating License Nos. DPR-39 and DPR-48. The amendments revised the Technical Specifications.

Date of initial notice in **Federal Register:** March 3, 1993 (58 FR 12258)

The Commission's related evaluation of the amendments is contained in a Safety Evaluation dated April 7, 1993.

No significant hazards consideration comments received: No

Local Public Document Room location: Waukegan Public Library, 128 N. County Street, Waukegan, Illinois 60085.

Duke Power Company, Docket Nos. 50-269, 50-270 and 50-287, Oconee Nuclear Station, Units 1, 2 and 3, Oconee County, South Carolina

Date of application for amendments: December 8, 1992

Brief description of amendments: The amendments (1) extend the time interval between Reactor Protection System (RPS) instrument channel tests from a month to 45 days on a staggered time basis, (2) define "staggered time basis," and (3) remove the time limitation on placing one RPS channel in bypass and one channel in the tripped condition.

Date of issuance: April 8, 1993

Effective date: April 8, 1993

Amendment Nos.: 199, 199, and 196

Facility Operating License Nos. DPR-38, DPR-47 and DPR-55. Amendments revised the Technical Specifications.

Date of initial notice in **Federal Register:** March 3, 1992 (58 FR 12259)

The Commission's related evaluation of the amendments is contained in a Safety Evaluation dated April 8, 1993.

No significant hazards consideration comments received: No.

Local Public Document Room location: Oconee County Library, 501 West South Broad Street, Walhalla, South Carolina 29691

Duquesne Light Company, et al., Docket Nos. 50-334 and 50-412, Beaver Valley Power Station, Unit Nos. 1 and 2, Shippingport, Pennsylvania

Date of application for amendments: November 2, 1992

Brief description of amendments: The amendments revise the Appendix A Technical Specifications (TSs) relating to reactor containment building penetrations. The amendments permit containment penetrations to be closed using a device that is functionally equivalent to an isolation valve, blind flange, or manual valve during core alterations or movement of irradiated fuel within containment.

Date of issuance: April 6, 1993

Effective date: As of date of issuance and to be implemented within 60 days of issuance

Amendment Nos.: 170 for Unit 1 - 50 for Unit 2

Facility Operating License Nos. DPR-66 and NPF-73. Amendments revised the Technical Specifications.

Date of initial notice in Federal Register: January 21, 1993 (58 FR 5429).

The Commission's related evaluation of the amendments is contained in a Safety Evaluation dated April 6, 1993.

No significant hazards consideration comments received: No.

Local Public Document Room location: B. F. Jones Memorial Library, 663 Franklin Avenue, Aliquippa, Pennsylvania 15001.

Dated at Rockville, Maryland, this 20th day of April 1993.

For the Nuclear Regulatory Commission

Steven A. Varga,

Director, Division of Reactor Projects - I/II Office of Nuclear Reactor Regulation

[FR Doc. 93-9767 Filed 4-27-93; 8:45 am]

BILLING CODE 7590-01-F

NUCLEAR REGULATORY COMMISSION

[Docket No. 50-335]

Florida Power and Light Co.; Withdrawal of Application for Amendment to Facility Operating License

The United States Nuclear Regulatory Commission (the Commission) has granted the request of Florida Power & Light Company (the licensee) to withdraw its December 17, 1992 application for proposed amendment to Facility Operating License No. DPR-67 for St. Lucie, Unit 1, located in St. Lucie County, Florida.

The proposed amendment would have revised the Technical Specifications to allow certain monitoring functions to be performed with a reduced number of operable incore detector locations.

The Commission had previously issued a Notice of Consideration of Issuance of Amendment published in the Federal Register on January 21, 1993 (58 FR 5432). However, by letter dated March 31, 1993, the licensee withdrew the proposed change.

For further details with respect to this action, see the application for amendment dated December 17, 1992, and the licensee's letter dated March 31, 1993, which withdrew the application for licensee amendment. The above documents are available for public inspection at the Commission's Public Document Room, the Gelman Building, 2120 L Street, NW., Washington, DC, and at the local public document room located at the Indian River Junior College Library, 3209 Virginia Avenue, Fort Pierce, Florida 34954-9003.

Dated at Rockville, Maryland this 20th day of April, 1993.

For the Nuclear Regulatory Commission.

Jan A. Norris,

Project Manager, Project Directorate II-2, Division of Reactor Projects—I/II, Office of Nuclear Reactor Regulation.

[FR Doc. 93-9906 Filed 4-27-93; 8:45 am]

BILLING CODE 7590-01-M

PHYSICIAN PAYMENT REVIEW COMMISSION

Commission Meeting

AGENCY: Physician Payment Review Commission.

ACTION: Notice of public meeting.

SUMMARY: The Commission will hold its next public meeting on May 6, 1993 at the Embassy Suites Hotel—Chevy Chase Pavilion, 4300 Military Road NW., Washington, DC, 202-362-9300, in the Tenley Town Meeting Room (third level). The meeting will begin at 9:30 a.m. The Commission will review its budget recommendations presented to the Congress, its upcoming report and recommendations on setting volume performance standards, and its reports on access and beneficiary financial liability. The Commission may also discuss further work on health system reform.

ADDRESSES: The Commission is located at 2120 L Street, NW., in Suite 510, Washington, DC The telephone number is 202/653-7220.

FOR FURTHER INFORMATION, CONTACT: Annette Hennessey, Executive Assistant or Lauren LeRoy, Deputy Director at 202/653-7220.

SUPPLEMENTARY INFORMATION: Information on the exact agenda for the public meetings can be obtained on Friday, April 30, 1993. Copies of the agenda will be mailed at that time. Please direct all requests for the agenda to the Commission's receptionist.

Paul B. Ginsburg,

Executive Director.

[FR Doc. 93-9859 Filed 4-27-93; 8:45 am]

BILLING CODE 6820-SE-M

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-32190; International Series No. 537 File No. S7-8-90]

Options Price Reporting Authority; Filing of Amendment to the National Market System Plan

April 21, 1993.

Pursuant to Rule 11Aa3-2 under the Securities Exchange Act of 1934 ("Act"), notice is hereby given that on March 18, 1993, the Options Price Reporting authority ("OPRA")[1] submitted to the Securities and Exchange Commission ("Commission") an amendment to its National Market System Plan for the purpose of providing separate "unbundled" last sale and quotation services for foreign currency and index options.[2] The Commission is publishing this notice to solicit comments from interested persons on the amendment.

I. Description and Purpose of the Amendment

The OPRA Plan is being amended to provide for the separation of the OPRA system into three services covering equity options, index options and foreign currency options. As the variety and number of option products traded has increased, so too has the desire of the individual exchanges to exercise

[1] OPRA is a National Market System Plan approved by the Commission pursuant to Section 11A of the Act and Rule 11Aa3-2. Securities Exchange Act Release No. 17638 (Mar. 18, 1981).

OPRA is a plan for the collection and dissemination of last sale and quotation information on options that are traded on the five member exchanges. The five exchanges which agreed to the OPRA Plan are the Philadelphia Stock Exchange ("PHLX), the Chicago Board Options Exchange ("CBOE"), the American Stock Exchange ("AMEX"), the Pacific Stock Exchange ("PSE"), and the New York Stock Exchange ("NYSE").

The OPRA plan was agreed to in response to directives of the SEC that provision be made for the consolidated reporting of transactions in eligible options contracts listed and traded on national securities exchanges.

[2] The proposed amendment was approved by OPRA in accordance with the OPRA Plan at a meeting held by conference telephone on March 17, 1993.

more control over the products in which they specialize. To this end, the parties negotiated an agreement which forms the substance of this proposed amendment. The amendment was approved by the parties in accordance with the OPRA Plan at a meeting held by telephone conference on March 17, 1993.

Revenues

The amendment includes revisions to OPRA's fee schedule that provide for separate fees for access to each of these separate services. Foreign currency option fees would be set by those exchanges that trade foreign currency options. Fees for the index option service would be set by those exchanges offering that product but could not be raised above a level equal to two-thirds of the fee for equity options as set by those exchanges trading equity options. For all three services a weighted majority of those exchanges offering the service will be required to approve any changes in fees. The revenues derived from the fees for each service shall be allocated to each exchange that offers that service according to the relative number of compared trades submitted.

Costs

The amendment also provides for the allocation among the three separate services of costs and expenses associated with the receipt, processing and distribution of information relating to the options included in each service, as well as the costs of developing, operating and administering each service.

Specifically, costs directly attributable solely to the development, operation or administration of a single service shall be allocated entirely to that service. Costs and expenses of OPRA's processor, the Securities Industry Automation Corporation ("SIAC"), attributable to more than one service shall be allocated among such services in the same proportion as the processor's line output capacity is available to each such service. Incremental costs associated with the operation of one or more services outside of regular trading hours will also be allocated on the basis of OPRA's line output capacity available to each service at that time. Costs and expenses directly related to billing and collection of OPRA fees (exclusive of bad debt expense, which shall be allocated to the service to which the bad debt is attributed) shall be allocated among all three services in proportion to the relative number of accounts maintained by OPRA in respect of each service. The amendment provides for the further allocation of such costs and expenses according to the relative number of compared trades handled by each exchange offering that service.

Other

Finally, the amendment includes a few nonsubstantive editorial changes to clarify the language of the Plan. In all other respects, action taken by OPRA would continue to be voted upon by all of the parties to the OPRA plan.

II. Implementation of the Plan

These changes will require certain systems modifications by SIAC. It also requires advance notice to OPRA's vendors and subscribers of the changes to OPRA's fees and specifications in accordance with OPRA's agreements with those persons. OPRA will also have to modify its various agreements with vendors and end-users of options information to reflect the unbundling of OPRA's services. Amendments to these agreements will be the subject of one or more separate filings under Rule 11Aa3–2.

In light of the time needed to implement the changes described above, OPRA is planning to implement the proposed amendment in two phases. Separate reporting of foreign currency information will begin on September 1, 1993. Equity and index options will continue to be offered only on a bundled basis until January 1, 1994, after which separate reporting of index and equity options will commence. However, a previously negotiated fee for both services is not due to expire until January 1, 1996. In order to permit the separation of services to go forward on January 1, 1994, the parties have agreed to separate rate structures that will not result in any overall increase in fees during the two year period. After that time, the parties will be free to set their own rates subject only to the two-thirds limitation mentioned above.

III. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing. Commentators are asked to address whether they believe the proposed amendment is necessary or appropriate in the public interest, for the protection of investors and the maintenance of fair and orderly markets, to remove impediments to, and perfect the mechanisms of a national market system, or otherwise in furtherance of the purposes of the Act.

Persons making written submissions should file six copies thereof with the Secretary, Securities and Exchange Commission, 450 Fifth Street, NW., Washington, DC 20549. Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying in the Commission's Public Reference Room. Copies of the filing also will be available at the offices of OPRA. All submissions should refer to File No. S7–8–90 and should be submitted by May 19, 1993.

For the Commission by the Division of Market Regulation, by delegated authority.

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 93–9886 Filed 4–27–93; 8:45 am]

BILLING CODE 8010–01–M

Self-Regulatory Organizations; Application for Unlisted Trading Privileges and of Opportunity for Hearing; Pacific Stock Exchange, Inc.

April 22, 1993.

The above-named national securities exchange has filed an application with the Securities and Exchange Commission ("Commission") pursuant to section 12(f)(1)(B) of the Securities Exchange Act of 1934 and Rule 12f–1 thereunder for unlisted trading privileges in the following security:

TIG Holding Inc.
Common Stock, $.01 Par Value (File No. 10507)

This security is listed and registered on one or more other national securities exchange and is reported in the consolidated transaction reporting system.

Interested persons are invited to submit on or before May 17, 1993, written data, views and arguments concerning the above-referenced application. Persons desiring to make written comments should file three copies thereof with the Secretary of the Securities and Exchange Commission, 450 5th Street, NW., Washington, DC 20549. Following this opportunity for hearing, the Commission will approve the application if it finds, based upon all the information available to it, that the extension of unlisted trading privileges pursuant to such application is consistent with the maintenance of fair and orderly markets and the protection of investors.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.

Jonathan G. Katz,

Secretary.

[FR Doc. 93–9887 Filed 4–27–93; 8:45 am]

BILLING CODE 8010–01–M

[Release No. 34–32176; File Nos. SR–PHLX–90–23 and 91–07]

Self-Regulatory Organizations; Philadelphia Stock Exchange, Inc.; Order Approving Proposed Rule Changes Relating to Dual Affiliations of Floor Members and Other Market Participants

On July 31, 1990 and March 20, 1991, the Philadelphia Stock Exchange, Inc. ("PHLX" or "Exchange") submitted to the Securities and Exchange Commission ("Commission" or "SEC"), pursuant to section 19(b)(1) of the Securities Exchange Act of 1934 ("Act")[1] and Rule 19b–4 thereunder,[2] proposed rule changes relating to dual affiliations. Specifically, as discussed in more detail below, in File No. SR–PHLX–90–23, the PHLX proposes to adopt Options Floor Procedure Advice ("OFPA") F–9 ("Advice"), entitled "Dual Affiliations," which relates to the practice of dual or multiple affiliations between Registered Options Traders ("ROTs") and floor brokerage firms. The Exchange is also proposing to add a fine schedule for OFPA F–9 and allow violations to be sanctioned pursuant to the PHLX's Minor Infraction Rule Plan.[3] In addition, in File No. SR–PHLX–91–07, the Exchange proposes an amendment to PHLX Rule 793 which would add dual affiliations of associated persons of PHLX members/participant organizations to the list of dual affiliations that must be disclosed to the Office of the Secretary of the Exchange. In general, the proposed rule changes recognize the practice of ROTs and floor brokers having multiple and/or dual affiliations, thereby requiring compliance with existing PHLX Rules 793, 1014, 1020 and 1064(c). The proposals set forth specific requirements and trading restrictions that must be followed by floor members and other market participants who have dual affiliations.

The proposed rule changes were published for comment in Securities Exchange Act Release Nos. 28838 (January 30, 1991), 56 FR 5044 and 29071 (April 12, 1991), 56 FR 16146, respectively. No comments were received on the proposed rule changes. This order approves the proposals.

Proposed OFPA F–9 contains three parts. First, Part (i) reiterates the requirement contained in PHLX Rule 793 that dual affiliations must be filed in writing with the Exchange's Office of the Secretary.[4] In addition, Part (i) to OFPA F–9 provides that submissions made pursuant to Rule 793 must also disclose all agreed upon forms of compensation between either dual affiliate firm and the individual floor member/participant and between the two firms. In the case of "soft dollar" compensation, the Exchange proposes that a good faith dollar value be estimated. The PHLX has indicated that it will make every effort to determine whether a particular "soft dollar" arrangement constitutes an improper application of the exempt credit treatment for specialists under Regulation T to an off-floor trading entity.[5] Second, Part (ii) of OFPA F–9 prohibits an ROT from receiving communications about trading interests or orders from an affiliated floor broker's customers prior to the respective trading crowd receiving the same information. Part (ii) also prohibits an ROT from answering telephones at an affiliate's post, except an ROT may access a telephone at his affiliate's post to communicate with associates of his ROT firm.[6]

Lastly, Part (iii) of OFPA F–9 provides that the respective trading crowd must be informed of any exchange of interests to trade between an ROT and an affiliated floor brokerage unit. In particular, the proposed OFPA would require the application of PHLX Rule 1064(c) when an exchange of trading interest between an ROT and an affiliated floor brokerage unit occurs.[7] Therefore, the same information that is exchanged between the two participants must also be communicated to the trading crowd. In addition, OFPA F–9 contains a fine schedule for violations of the provisions of the OFPA and will be added to the list of rules that can be sanctioned under Phlx's Minor Infraction Rule Plan.[8] Specifically, a fine of $250 will be assessed for the first occurrence of a violation; $500 for the second occurrence; and a sanction within the discretion of the Exchange's Business Conduct Committee ("BCC") for the third occurrence and any occurrence thereafter.

Finally, the PHLX proposes to amend PHLX Rule 793 to broaden the categories of dual affiliations that must be disclosed and approved by the Exchange to include dual affiliations of associated persons of members/participant organizations. Currently, Rule 793 only requires disclosure of dual affiliations involving general/limited partners, officers, directors and stockholders of members/participant organizations.

The Commission finds that the proposed rule changes are consistent with the requirements of the Act and the rules and regulations thereunder applicable to a national securities exchange, and, in particular, the requirements of section 6(b)(5). More specifically, the Commission believes that providing the PHLX with the authority to require associated persons of members/participant organizations to disclose their dual affiliation arrangements will protect investors and the public interest, as well as remove impediments to and perfect the mechanism of a free and open market. Moreover, the Commission believes that this expansion of the scope of Rule 793

---

[1] 15 U.S.C. 78s(b)(1) (1982).

[2] 17 CFR 240.19b–4 (1991).

[3] See note 8, *infra*.

[4] Specifically, Part (i) of proposed OFPA F–9 is based on PHLX Rule 793. Commentary .01 to Rule 793 requires a member or participant organization to file with the Office of the Secretary of the Exchange notice of a multiple affiliation detailing the business purpose of this arrangement, the person at each organization who will supervise the conduct of the dually affiliated member/participant for compliance with PHLX by-laws and rules, and sufficient information for the Exchange to determine whether one person has registered with more than one organization. This notice must also contain each organization's written approval of the affiliation.

[5] See letter from Gerald D. O'Connell, Vice President, Market Surveillance, PHLX, to Thomas Gira, Branch Chief, Division of Market Regulation, SEC, dated April 21, 1992.

[6] PHLX Rule 1014(e) prohibits an ROT from initiating an options transaction while on the floor of the Exchange in any account in which he has an interest and at the same time executing as a floor broker an off-floor order in the same option during the same trading session.

[7] PHLX Rule 1064(c) provides that when an order is presented to the trading crowd which arose out of an expression of trading interest between two broker-dealers away from the crowd, the solicited order must be shown to the crowd along with any information given to the solicited member. In addition, participants in the trading crowd must be given a reasonable opportunity to respond to the order.

[8] Phone conversation between Richard Zack, Branch Chief, Options Regulation, SEC, and Edith Hallahan, Market Surveillance, Phlx, on April 16, 1993. Pursuant to paragraph (c)(1) of Rule 19d–1, an SRO is required to file promptly with the Commission notice of any "final" disciplinary action taken by the SRO. Pursuant to paragraph (c)(2) of Rule 19d–1, any disciplinary action taken by the SRO for violation of an SRO rule that has been designated a minor rule violation pursuant to the plan shall not be considered "final" for purposes of section 19(d)(1) of the Act if the sanction imposed consists of a fine not exceeding $2500 and the sanctioned person has not sought an adjudication, including a hearing, or otherwise exhausted his or her administrative remedies. By deeming unadjudicated minor violations as not final, the Commission permits the SRO to report violations on a periodic (quarterly), as opposed to immediate, basis.

will more realistically address the types of dual affiliations that typically occur on the Exchange floor. By requiring disclosure and approval of these types of arrangements, the Commission believes the Exchange will be in a better position to detect collusive trading and minimize potential conflicts of interest, thereby protecting investors in furtherance of the Act.

The Commission further believes that requiring the disclosure of all agreed upon forms of compensation involved in a dual affiliation arrangement, including all "soft dollar" compensation, will enable the Exchange to determine better whether an affiliation is consistent with Exchange standards enumerated in Rule 793.[9] In addition, through the disclosure of all compensation arrangements, the Exchange will be able to determine and detect whether the specialist exempt credit treatment under Regulation T is being improperly applied to an off-floor trading entity and, thereby, will be better able to prevent such improper use of good faith margin.

The Commission also believes that prohibiting ROTs from receiving communications about trading interests or orders from an affiliated floor broker's customers prior to the respective crowd receiving the same information and providing that respective trading crowds must be informed of any exchange of interests to trade between an ROT and an affiliated floor brokerage unit promotes just and equitable principles of trade on the PHLX trading floor. In this regard, the Commission also believes that these restrictions, in addition to the restrictions that an ROT cannot answer the telephone at an affiliated floor broker's post except to contact associates of his ROT firm, will serve as reasonable means to prevent the misuse by ROTs of information concerning orders and trading interests of customers of affiliated floor brokerage units.

Moreover, the Commission believes that it is appropriate for the Exchange to establish a fine schedule consistent with its Minor Infraction Rule Plan for infractions of OFPA F–9.[10] Specifically, the Commission believes that the use of the fine schedule will enable Exchange officials to impose sanctions for minor infractions of the Advice. The Commission also believes that this streamlined disciplinary process will help the Exchange to ensure that PHLX members/participant organizations abide by the Exchange's rule governing dual affiliations. In addition, the Commission further finds that the fine schedule provides for suitable sanctions for violations of the Advice, and is consistent with sections 6(b)(6) and 6(b)(7) of the Act, which requires exchanges to have appropriate sanctions and procedures for the fair disciplining of members for violations of the rules of an exchange.

It is therefore ordered, Pursuant to section 19(b)(2) of the Act,[11] that the proposed rule changes (SR–PHLX–90–23 and 91–07) are approved.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[12]

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 93–9885 Filed 4–27–93; 8:45 am]

BILLING CODE 8010–01–M

[9] Pursuant to PHLX 793, the Exchange may disapprove dual or multiple affiliations which are inconsistent with Exchange standards of financial responsibility, operational capability, or compliance responsibility.

[10] Even though the Exchange intends that violations of the dual affiliation provisions be sanctioned according to the PHLX's Minor Infraction Rule Plan, violations of the Advice do not necessarily have to be subject to the Minor Infraction Rule Plan. For instance, for egregious violations, the Commission would expect that these matters will be handled directly by the Exchange's BCC.

[11] 15 U.S.C. 78s(b)(2) (1982).

[12] 17 CFR 200.30–3(a)(12) (1991).

[Rel. No. IC–19426; 812–8318]

Equitable Capital Partners, L.P., et al.; Application

April 22, 1993.

AGENCY: Securities and Exchange Commission ("SEC").

ACTION: Notice of Application for Exemption under the Investment Company Act of 1940 (the "Act").

APPLICANTS: Equitable Capital Partners, L.P., Equitable Capital Partners (Retirement Fund), L.P. (each a "Partnership," and together the "Partnerships"), Equitable Capital Management Corporation ("Equitable Capital"), and Alliance Corporate Finance Group Incorporated ("Alliance Incorporated").

RELEVANT ACT SECTIONS: Order requested to amend (1) an order under section 6(c) that granted an exemption from sections 2(a)(19) and 2(a)(3)(D) of the Act, and (2) an order under section 57(i) of the Act and rule 17d–1 thereunder that permitted certain joint transactions.

SUMMARY OF APPLICATION: Applicants seek an order that would amend two prior orders. When the prior orders were issued, Equitable Capital served as investment adviser to and managing general partner of the Partnerships. The order would permit the Partnerships to continue to operate under the terms of the prior orders following a corporate reorganization in which Alliance Incorporated would replace Equitable Capital as investment adviser to and managing general partner of the Partnerships.

FILING DATE: The application was filed on March 18, 1993, and amended on April 12, 1993.

HEARING OR NOTIFICATION OF HEARING: An order granting the application will be issued unless the SEC orders a hearing. Interested persons may request a hearing by writing to the SEC's Secretary and serving applicants with a copy of the request, personally or by mail. Hearing requests should be received by the SEC by 5:30 p.m. on May 17, 1993, and should be accompanied by proof of service on applicants, in the form of an affidavit or, for lawyers, a certificate of service. Hearing requests should state the nature of the writer's interest, the reason for the request, and the issues contested. Persons who wish to be notified of a hearing may request notification by writing to the SEC's Secretary.

ADDRESSES: Secretary, SEC, 450 Fifth Street, NW., Washington, DC 20549. Applicants (except for Alliance Incorporated), 1285 Avenue of the Americas, New York, New York 10019; and Alliance Incorporated, 1345 Avenue of the Americas, New York, New York 10105.

FOR FURTHER INFORMATION CONTACT: Robert A. Robertson, Staff Attorney, at (202) 504–2283, or C. David Messman, Branch Chief, at (202) 272–3018 (Division of Investment Management, Office of Investment Company Regulation).

SUPPLEMENTARY INFORMATION: The following is a summary of the application. The complete application may be obtained for a fee at the SEC's Public Reference Branch.

Applicants' Representations

1. Each Partnership is a Delaware limited partnership that has elected to operate as a business development company under the Act. The Partnerships primarily invest in subordinated debt and related equity securities issued in conjunction with the "mezzanine financing" of privately-structured leveraged buyouts. Equitable Capital, a wholly-owned subsidiary of The Equitable Life Assurance Society of the United States ("Equitable Life"), is the managing general partner of and the

investment adviser to each of the Partnerships.

2. In 1988, the Partnerships and Equitable Capital received an order (the "2(a)(19) Order") under section 6(c) of the Act determining that (i) the independent general partners of a Partnership are not "interested persons" (as defined in section 2(a)(19) of the Act) of the Partnership or Equitable Capital by virtue of being general partners of the Partnerships and co-partners of Equitable Capital, and (ii) limited partners who own a less than a 5% limited partnership interest in a Partnership are not "affiliated persons" (as defined in section 2(a)(3) of the Act) of the Partnership or its partners solely by reason of their status as limited partners.[1]

3. In 1990, the Partnerships and Equitable Capital received an exemptive order (the "17d–1 Order") under section 57(i) of the Act and rule 17d–1 thereunder amending a previous order and (i) permitting purchases of securities by the Partnerships in joint transactions with each other or in transactions in which an affiliate of Equitable Capital is a participant; (ii) permitting certain affiliated persons of Equitable Life or any of its subsidiaries to serve as directors of Equitable Capital notwithstanding a condition to the prior order; (iii) permitting Equitable Life and certain other affiliated persons of Equitable Capital to invest as limited partners in certain limited partnerships that invest in entities in which the partnerships also invest; and (iv) amending and restating the conditions and undertakings contained in the previous order.[2] The 2(a)(19) Order and the 17d–1 Order are referred to as the Existing Orders.

4. Alliance Capital Management L.P. ("Alliance") is a Delaware limited partnership that is registered as an investment adviser. Alliance's sole general partner is Alliance Capital Management Corporation, an indirect wholly-owned subsidiary of Equitable Life. Alliance's partnership interests are represented by units, which are publicly-traded on the New York Stock Exchange. Currently, a wholly-owned subsidiary of Equitable Life owns approximately 54.7% of Alliance's units, public shareholders own approximately 33.8%, and employees of Alliance own approximately 11.5%.

5. On February 23, 1993, Equitable Capital, Alliance and Equitable Investment Corporation[3] entered into a transfer agreement providing for the transfer of substantially all of the assets and liabilities comprising Equitable Capital's business to Alliance and its subsidiaries in exchange for newly issued units representing limited partnership interests in Alliance (the "Combination"). Under the transfer agreement, Equitable Capital may receive additional units as incentive fees. Upon completion of the Combination, Equitable Life will own directly and indirectly up to approximately 63% of the units of Alliance.

6. In connection with the Combination, applicants anticipate that key personnel in Equitable Capital's corporate finance department will become employees of Alliance Incorporated, a registered investment adviser that is an indirect wholly-owned subsidiary of Alliance. The corporate finance department of Equitable Capital has had primary responsibility for providing investment management and other services to the Partnerships.

7. Upon completion of the Combination, which is subject to a number of closing conditions, the Partnerships' existing investment advisory agreements with Equitable Capital will terminate by operation of law. Applicants expect that, subject to approval by each Partnership's independent general partners and limited partners, Alliance Incorporated will become the investment adviser to the Partnerships without any substantive change in the terms and conditions under which Equitable Capital now serves as adviser. Applicants also expect that Equitable Capital will withdraw from the Partnerships and assign its interest as general partner of each Partnership to Alliance Incorporated, and, subject to approval by each Partnership's limited partners, that Alliance Incorporated will succeed Equitable Capital as managing general partner.

8. Applicants request that the Existing Orders be amended to permit the Partnerships to operate under the terms of such orders in the event that Alliance Incorporated replaces Equitable Capital as investment adviser to and managing general partner of the Partnerships. If the transfer agreement is terminated prior to the completion of the Combination, the Combination will not take place, the Equitable Capital personnel that advise the Partnerships will not become employees of Alliance Incorporated and Equitable Capital will remain as investment adviser to and managing general partner of the Partnerships.

9. A joint special meeting of limited partners has been scheduled to consider (i) a proposal to approve as to each Partnership a new investment advisory agreement between the Partnership and Alliance Incorporated; and (ii) a proposal to admit Alliance Incorporated as successor managing general partner of each Partnership. Approval of each proposal is a precondition to the approval of the other. Accordingly, if either proposal is not approved by the limited partners, neither proposal will have been approved. The independent general partners of the Partnership then will make such arrangements for the management of the Partnership and its investments as they believe appropriate and in the best interests of the limited partners.

Applicants' Legal Analysis

1. Applicants believe that the relief requested is reasonable, necessary and appropriate in the public interest and consistent with the protection of investors and the purposes fairly intended by the policies and provisions of the Act. Alliance Incorporated will comply with the conditions and undertakings in the Existing Orders Currently applicable to Equitable Capital as the investment adviser to and managing general partner of the Partnerships.

2. In particular, the 17d–1 Order is subject to several conditions relating to the operations of the Partnerships and to coinvestments by the Partnerships with each other and with "Equitable Affiliates," which is defined to include Equitable Life (and its subsidiaries other than Equitable Capital); funds with investment objectives similar to the Partnerships that may be sponsored by Equitable Capital; and Equitable Capital advisory accounts that have similar investment objectives. Alliance Incorporated will comply with all such conditions as they currently apply to Equitable Capital. In addition, the proposed amendment provides that, upon consummation of the Combination, the term "Equitable Affiliate" also will include funds with investment objectives similar to the Partnerships that may be sponsored by Alliance Incorporated or Alliance as well as Alliance Incorporated or Alliance advisory accounts that have similar investment objectives, but will not include Alliance Incorporated or Alliance.[4]

[1] Investment Company Act Rel. Nos. 16404 (May 18, 1988) (notice) and 16444 (June 21, 1988) (order).

[2] Investment Company Act Rel. Nos. 17894 (Dec. 5, 1990) (notice) and 17925 (Dec. 31, 1990) (order).

[3] Equitable Investment Corporation is an indirect wholly-owned subsidiary of Equitable Life.

[4] The 17d–1 Order permits the Partnerships to purchase certain securities in joint transactions

3. The replacement of Equitable Capital with Alliance Incorporated as investment adviser and managing general partner, if approved by the limited partners of the Partnerships, is not expected to result in any significant change in the operations of the Partnerships or in the services provided to the Partnerships.

4. With respect to the 2(a)(19) Order, applicants note that, as a practical matter, the order applies to the independent general partners rather than Equitable Capital and that the individuals presently serving as independent general partners will continue to serve in these roles. Accordingly, the terms of the 2(a)(19) Order will not be affected by the Combination.

5. Applicants believe that it is appropriate to seek amendments to the Existing Orders to ensure that the Existing Orders remain in effect after the consummation of the Combination.

For the Commission, by the Division of Investment Management, under delegated authority.

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 93–9920 Filed 4–27–93; 8:45 am]

BILLING CODE 8010–01–M

[Investment Company Act Rel. No. 19427; 812–8282]

Overland Express Funds, Inc., et al.; Application for Exemption

April 22, 1993.

AGENCY: Securities and Exchange Commission ("SEC").

ACTION: Notice of application for exemption under the Investment Company Act of 1940 (the "Act").

APPLICANTS: Overland Express Funds, Inc. ("Overland"), Stagecoach Funds, Inc. ("Stagecoach"), Cash Investment Trust ("CIT"), WellsFunds Inc. ("WellsFunds"), and all existing and future series thereof (other than the Overland Sweep Fund series of Overland or any other series hereafter established that seeks to accomplish its investment objective by investing all of its assets in the shares of another investment company) (collectively, the "Funds"); Wells Fargo Bank, N.A. ("Wells Fargo"), and any entity controlling, controlled by, or under common control (as defined in section 2(a)(9) of the Act) with Wells Fargo that serves as investment adviser to the Portfolios or to any investment company or portfolio thereof hereinafter referenced (the "Adviser"); and any future investment companies and series thereof that are advised by Wells Fargo or by any entity controlling, controlled by, or under common control (as defined in section 2(a)(9) of the Act), with Wells Fargo (collectively, with the Funds, the "Portfolios").

RELEVANT ACT SECTIONS: Exemptive relief requested pursuant to section 17(d) and rule 17d–1.

SUMMARY OF APPLICATION: Applicants seek a conditional order permitting the Portfolios to pool their uninvested cash balances in one or more joint accounts (the "Account"), and to use the daily balance of the Account to enter into one or more repurchase agreements having a maturity of not more than seven days.

FILING DATE: The application was filed on February 18, 1993 and amended on March 30, 1993 and April 21, 1993.

HEARING OR NOTIFICATION OF HEARING: An order granting the application will be issued unless the SEC orders a hearing. Interested persons may request a hearing by writing to the SEC's Secretary and serving applicants with a copy of the request, personally or by mail. Hearing requests should be received by the SEC by 5:30 p.m. on May 17, 1993, and should be accompanied by proof of service on applicants, in the form of an affidavit or, for lawyers, a certificate of service. Hearing requests should state the nature of the writer's interest, the reason for the request, and the issue contested. Persons who wish to be notified of a hearing may request such notification by writing to the SEC's Secretary.

ADDRESSES: Secretary, SEC, 450 Fifth Street, NW., Washington, DC 20549. Wells Fargo, 111 Sutter Street, 11th Floor, San Francisco, California 94163. Other applicants, 111 Center Street, Little Rock, Arkansas 72201.

FOR FURTHER INFORMATION CONTACT: Courtney S. Thornton, Staff Attorney, at (202) 272–5287, or C. David Messman, Branch Chief, at (202) 272–3018 (Division of Investment Management, Office of Investment Company Regulation).

SUPPLEMENTARY INFORMATION: The following is a summary of the application. The complete application may be obtained for a fee from the SEC's Public Reference Branch.

Applicants' Representations

1. Overland, Stagecoach and WellFunds are registered, open-end management investment companies, each of which consists of several series. CIT is a registered, open-end management investment company whose shares are not publicly offered or registered under the Securities Act of 1933.

2. Wells Fargo acts as investment adviser to all of the series of Overland, Stagecoach, CIT, and WellsFunds,[1] with the exception of Overland Sweep Fund, which invests all of its assets in CIT and, accordingly, has no direct adviser.[2] Stephens Inc. is the sponsor, distributor, and administrator for all series of Overland, Stagecoach and WellsFunds, and acts as the placement agent for CIT.

3. Each Fund has a custodial relationship with Wells Fargo or Wells Fargo Institutional Trust Company, N.A., but any of the Portfolios may use another custodian or a sub-custodian selected and qualified under section 17(f) of the Act (collectively, the "Custodians") if they deem it in their best interest to do so.

4. On any given day, each of the Portfolios has, or may be expected to have, cash balances held by its Custodian, which otherwise would not be invested in portfolio securities by the Adviser at the end of the trading day. Ordinarily, the Adviser would invest such cash in short-term investments authorized by the Portfolio's investment policy to earn additional income for the Portfolio. Applicants propose to establish with their respective Custodians one or more Accounts, which will be used exclusively to pool excess cash of the Portfolios participating in such Account to purchase one or more repurchase agreements.

5. Under the proposed arrangement, each repurchase transaction would be entered into by the Adviser calling one of the previously approved counterparties of repurchase agreements, indicating the size of the desired repurchase transaction, and negotiating the rate of interest. Master repurchase agreements with the approved counterparties establish minimum collateral levels, the securities eligible to be held as collateral, and the maximum term of a transaction. To facilitate repurchase

---

with each other and with the Equitable Affiliates, which as noted above does not include Equitable Capital. Applicants will continue to comply with this condition. In addition, because Alliance Incorporated is expected to replace Equitable Capital as investment adviser to and managing general partner of the Partnerships, Alliance Incorporated and its parent company, Alliance, will be excluded from the term "Equitable Affiliates"—thereby not permitting them to invest in the joint transactions.

[1] Wells Fargo Nikko Investment Advisors, an affiliate of Wells Fargo, serves as investment sub-adviser to several of the series of Stagecoach and WellsFunds. However, Wells Fargo will be responsible for all activities of these series with regard to the Account.

[2] Overland Sweep Fund will not participate directly in the Account.

transactions and to help obtain more attractive rates, the Custodian may enter into third-party arrangements for custody of assets and collateral securities with banks that report to the New York Federal Reserve Bank. The term of a repurchase transaction would typically be overnight (or over a holiday or weekend) and in no event more than seven days.

6. After the size of a repurchase transaction has been agreed to, the Custodian would be notified and, prior to releasing funds, would be required to verify that eligible collateral securities of sufficient value had been received. These securities would be either (a) wired to the account of the Custodian (or third-party custodian) at the appropriate Federal Reserve Bank, or (b) physically transferred to a segregated account of the Custodian (or third-party custodian).

7. All joint repurchase transactions would be effected in accordance with the established standards and procedures of the Funds and with the guidelines set forth in Investment Company Act Release No. 13005 (Feb. 2, 1983). If necessary, the Portfolios would modify their systems and standards to comply with any positions the SEC or its staff may take with respect to repurchase agreements by rule, interpretive release, no-action letter, any release adopting any new rule, or any release adopting any amendments to any existing rule.

8. Applicants believe that the proposed Account would have the following benefits for the Portfolios:

(a) The Portfolios would collectively save significant fees and expenses by reducing the number of transactions in which they would engage, compared with the number of transactions the Portfolios would engage in through separate accounts;

(b) Under normal market conditions, it is possible to negotiate a rate on return on large repurchase agreements that is greater than the rate of return that can be negotiated for small repurchase agreements. Thus, the Portfolios would benefit from a greater rate of return than would be available for repurchase agreements negotiated individually by each Portfolio;

(c) The reduction in the number of trade tickets written by each counterparty to a repurchase agreement will simplify the transaction for the parties involved and reduce the opportunities for errors.

Applicants' Legal Conclusions

1. Each Portfolio, by participating in the proposed Account, and the Adviser, by managing the proposed Account, could be deemed to be joint participants in a transaction within the meaning of section 17(d), and the proposed Account could be deemed to constitute a joint enterprise or other type of joint arrangement within the meaning of rule 17d–1. Furthermore, under the definition of "affiliated person" set forth in section 2(a)(3), each of the applicants could be deemed an affiliated person of each other applicant.

2. Applicants represent that the proposed method of operating the Account would not result in any conflicts of interest among any of the Portfolios, or between a Portfolio and an Adviser. Applicants also have determined that there does not appear to be any basis upon which to predicate greater benefits to one Portfolio than to another, because the daily uninvested cash balance of any one Portfolio on any given day is neither a function of the size of the Portfolio nor the particular securities in which it invests, but is rather a function of other factors, such as portfolio management decisions, shareholder purchases and redemptions or the timing of settlement of trades. Although the Adviser would gain some benefit through administrative convenience and some possible reduction in clerical costs, the primary beneficiaries would be the Portfolios and their shareholders, because the Account would provide a more efficient and productive way of administering daily investment transactions.

3. Applicants believe that it would be desirable to permit participation by future Portfolios without the necessity of applying for an amendment to the requested order. Future Portfolios would be required to participate in the Account on the same terms and conditions as the existing Funds.

4. Applicants believe that, because the Account will invest in repurchase agreements that (a) typically will have an overnight, over-the-weekend or holiday duration, and in no event will have a duration in excess of seven days, (b) by their nature are held to maturity, and (c) have no trading market, the value of the repurchase agreements held in the Account would be best reflected by the amortized cost method of valuation.

5. Rule 17d–1(b) under the Act provides that, in passing upon applications under rule 17d–1, the SEC will consider whether each party's participation in the proposed joint arrangement is consistent with the provisions, policies and purposes of the Act and the extent to which such participation is on a basis different from or less advantageous than that of other participants. Applicants believe that, for the reasons set forth above and in light of the conditions set forth below, the criteria for issuance of an order under section 17(d) of the Act and rule 17d–1 thereunder are met.

Applicants' Conditions

Applicants will operate the Account subject of the following conditions:

1. The Account will be established as one or more separate cash accounts on behalf of the Portfolios at the Custodian. The Portfolios may deposit daily all or a portion of their uninvested net cash balances into the Account.

2. Cash in the Account will be invested solely in repurchase agreements (which typically will have an overnight or over-the-weekend duration, and in no event will have a duration of more than seven days), collateralized by suitable U.S. Government obligations (i.e., obligations issued or guaranteed as to principal or interest by the Government of the United States or by any of its agencies or instrumentalities), and satisfying the uniform standards set by the Portfolios for such investments.

3. All repurchase agreements entered into by the Account will be valued on an amortized cost basis. Each Portfolio that relies upon rule 2a–7 will use the average dollar weighted maturity of such repurchase agreements for the purpose of computing the Portfolio's average portfolio maturity with respect to the portion of its assets held in such Account.

4. In order to ensure that there will be no opportunity for one Portfolio to use any part of a balance of the Account credited to another Portfolio, no Portfolio will be allowed to create a negative balance in the Account for any reason, although each Portfolio will be permitted to draw down its *pro rata* share of the entire balance at any time. Each Portfolio's decision to invest through the Account will be solely at the Portfolio's option, and no Portfolio will be obligated to invest through, or to maintain any minimum balance in, the Account. In addition, each Portfolio will retain the sole rights of ownership of any of its assets, including interest payable on such assets, invested in the Account. Each Portfolio's investment in the Account will be documented daily on the books of the Portfolio as well as on the respective Custodian's books.

5. Each Portfolio will participate in the income earned or accrued in the Account, including all investments held by such Account, on the basis of the percentage of the total amount in such Account on any day represented by its share of such Account.

6. The Adviser will administer, manage and invest the cash balance in the Account in accordance with the terms of its management contracts with the Portfolios, and will not collect any additional or separate fee for the administration of the Account.

7. The Portfolios and the Adviser will enter into an agreement to govern the arrangements in accordance with the foregoing principles.

8. The administration of the Account will be within the fidelity bond coverage required by section 17(g) of the Act and rule 17g–1 thereunder.

9. The board of each Portfolio participating in the Account will evaluate the Account arrangements annually and will authorize the continued participation of the Portfolio in the Account only if it determines that there is a reasonable likelihood that such continued participation will benefit the Portfolio and its shareholders.

10. Substantially all repurchase transactions will have an overnight, over-the-weekend or over a holiday maturity, and in no event will a transaction have a maturity of more than seven days.

11. The Account will not be distinguishable from any other accounts maintained by a Portfolio with its Custodian except that cash from the various Portfolios will be deposited in the Account on a commingled basis. The Account will not have any separate existence with indicia of a separate legal entity. The sole function of the Account will be to provide a convenient way of aggregating individual transactions that would otherwise require daily management and investment by each Portfolio of its cash balances.

For the SEC, by the Division of Investment Management, under delegated authority.

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 93–9922 Filed 4–27–93; 8:45 am]

BILLING CODE 8010–01–M

[Rel. No. IC–19428; File No. 812–8270]

The Variable Annuity Life Insurance Co. et al.

April 22, 1993.

AGENCY: Securities and Exchange Commission ("SEC" or "Commission").

ACTION: Notice of application for exemption under the Investment Company Act of 1940 (the "1940 Act").

APPLICANTS: The Variable Annuity Life Insurance Company ("VALIC"), The Variable Annuity Life Insurance Company Separate Account A ("Separate Account A"), and The Variable Annuity Marketing Company ("VAMCO") (collectively, the "Applicants").

RELEVANT 1940 ACT SECTIONS: Order requested under section 6(c) of the 1940 Act for exemptions from sections 22(e), 27(c)(1), and 27(d).

SUMMARY OF APPLICATION: Applicants seek an order with respect to certain variable annuity contracts ("Contracts") participating in Separate Account A to the extent necessary to comply with the Optional Retirement Program of the State University System of Florida ("Florida ORP") as administered by the Division of Retirement of the Florida Department of Management Services ("Division").

FILING DATE: The Application was filed on February 12, 1993.

HEARING OR NOTIFICATION OF HEARING: An order granting the application will be issued unless the Commission orders a hearing. Interested persons may request a hearing by writing to the SEC's Secretary and serving the Applicants with a copy of the request, personally or by mail. Hearing requests should be received by the SEC by 5:30 p.m., on May 17, 1993, and should be accompanied by proof of service on Applicants in the form of an affidavit or, for lawyers, a certificate of service. Hearing requests should state the nature of the writer's interest, the reason for the request, and the issues contested. Persons may request notification of a hearing by writing to the SEC's Secretary.

ADDRESSES: Secretary, SEC, 450 Fifth Street, NW., Washington, DC 20549. Applicants, c/o Cynthia A. Toles, Esq., The Variable Annuity Life Insurance Company, 2929 Allen Parkway, Houston, Texas 77019. Copies to Diane E. Ambler, Esq., Freedman, Levy, Kroll & Simonds, 1050 Connecticut Avenue, NW., Suite 825, Washington, DC 20036.

FOR FURTHER INFORMATION CONTACT: Thomas E. Bisset, Senior Attorney, at (202) 272–2058, or Micheal Wible, Special Counsel, on (202) 272–2060, Office of Insurance Products (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.

Applicants' Representations

1. VALIC is a Texas stock life insurance company, the predecessor of which was organized under the laws of the District of Columbia in 1955. VALIC transacts business in all fifty states and the District of Columbia and has total assets exceeding $17.4 billion. VALIC is the depositor of Separate Account A, which was established by VALIC's Board of Directors on April 18, 1979 in accordance with the Texas Insurance Code. Separate Account A funds variable annuity contracts, including the Contracts, issued by VALIC. VAMCO, a Texas corporation organized in 1970, is the principal underwriter for the variable annuity contracts issued by VALIC and Separate Account A, including the Contracts.

2. Separate Account A is registered as a unit investment trust under the 1940 Act and invests solely in portfolios of the American General Series Portfolio Company. Units of interest under the Contracts are registered under the Securities Act of 1933. The Contracts are also qualified under section 403(b) of the Internal Revenue Code of 1986, as amended ("Code").

3. The Florida ORP is a defined contribution plan designed to provide retirement and death benefits to participants through individual or group annuity contracts, which may be fixed or variable, or combination fixed and variable. The Florida ORP is available to certain faculty members within the State University System of Florida ("Florida University System"), as well as to persons holding certain administrative and professional staff positions within the Florida University System (collectively, "Eligible Employees" or "Participants"). The Florida ORP is an alternative to the Florida Retirement System, a defined benefit retirement plan, and Eligible Employees have the option of participating in the Florida Retirement System or the Florida ORP. A statutory presumption deems any employee who becomes eligible to participate on or after January 1, 1993 to have elected to participate in the Florida ORP, unless such employee specifically elects membership in the Florida Retirement System.

4. Under the Florida ORP, the universities in the Florida University System provide for employee retirement benefits by contributing a percentage of each Participant's gross compensation regardless of service to purchase an annuity when the employee retires. The Division has designated five companies from which annuity contracts may be purchased under the Florida ORP. In addition to VALIC, these companies include the Teachers Insurance and Annuity Association of America and the College Retirement Equities Fund, Capitol Life Insurance Company, Great American Reserve Insurance Company and The Independent Life and Accident Company.

5. Participants in the Florida ORP may themselves contribute, by way of salary reduction, a percentage of their respective gross compensation (not to exceed the percentage amount contributed by the employer). Payment of Participant contributions are made by the financial officer of the employer to the Division, which in turn forwards the contribution to a designated company or companies contracting for payment of benefits for the Participant under the Florida ORP.

6. In correspondence with VALIC, dated December 9, 1992, the Division informed VALIC that it will require VALIC to withdraw the Contracts from the Florida ORP unless it amends the Contracts to reflect certain restrictions based on the Division's administrative interpretations applicable to employer contributions made pursuant to the Florida ORP. The Division has administratively prohibited distributions of employer contributions under the Florida ORP to a Participant on a lump sum basis (other than upon the Participant's death) or exclusively on the basis of a period certain. These restrictions apply only to employer contributions and do not limit access to Participant contributions. (Participant contributions under the Contracts are, however, subject to the restrictions on distributions under section 403(b)(11) of the Code.) Participants are also free to transfer both employer and Participant contributions among the fixed or variable investment options available under the Contracts and to substitute entirely a qualified contract offered by any of the other companies designated under the Florida ORP.

7. The Division has required VALIC, in order to continue to participate as a designated company under the Florida ORP, to prepare an endorsement to the Contracts (the "Endorsement") applying to accumulations based on employer contributions which provides that: (1) Benefits based on employer contributions are payable only upon the Participant's death, retirement or termination of employment (as defined in section 121.021(39) of the Florida Statutes); (2) benefit payments will not be made based solely on a period certain; (3) accumulations based on employer contributions are not subject to withdrawal or surrender and may not be rolled over other than to a designated company or companies contracting for payment of benefits for the Participant under the Florida ORP; and (4) accumulations are not subject to loan, assignment, execution or attachment.

Applicants' Legal Analysis and Conditions

1. Section 22(e) of the 1940 Act provides that "no registered investment company shall suspend the right of redemption, or postpone the date of payment or satisfaction upon redemption of any redeemable security in accordance with its terms for more than seven days after the tender of such security to the company or its agent designated for that purpose for redemption," except in certain prescribed circumstances. Section 27(c)(1) of the 1940 Act makes it unlawful "for any registered investment company issuing periodic payment plan certificates, or for any depositor of or underwriter for such company, to sell any such certificate unless such certificate is a redeemable security." Section 27(d) of the 1940 Act makes it unlawful "for any registered investment company issuing periodic payment plan certificates, or for any depositor of or underwriter for such company, to sell any such certificate unless the certificate provides that the holder thereof may surrender the certificate at any time within the first eighteen months after the issuance of the certificate" and receive an amount equal to the account value plus excess sales load.

2. Applicants request exemptions from the provisions of sections 22(e), 27(c)(1) and 27(d) of the 1940 Act to the extent necessary to permit compliance with the Florida ORP, as administered by the Division with respect to the Contracts.

3. Applicants submit that the exemptive relief requested is consistent with Rule 6c–7 under the 1940 Act, which provides exemptions from sections 22(e), 27(c)(1) and 27(d) of the 1940 Act for registered separate accounts, and depositors of or underwriters for such separate accounts, to the extent necessary to permit compliance with certain restrictions on redemptions involving variable annuity contracts issued to certain employees participating in the Texas Optional Retirement Program ("Texas ORP"). The Texas ORP permits distributions to participants only upon death, retirement or termination of employment.

4. applicants further submit that the exemptive relief requested is also consistent with the position taken by the Commission staff in a 1988 letter to the American Council of Life Insurance, in which the staff advised that it would not recommend enforcement action to the Commission if registered separate accounts issuing variable annuity contracts as funding vehicles for retirement plans meeting the requirements of section 403(b) of the Code comply with the restrictions imposed by subsection (11) of that section.[1] In addition, the relief requested is consistent with exemptive relief more recently granted involving the Louisiana Optional Retirement Plan.[2]

5. The Division's administration of the Florida ORP, and its requirement that VALIC amend the Contracts to specifically restrict certain rights of redemption or cease participating in the Florida ORP program, present a direct conflict with the 1940 Act's redemption provisions. The terms of the Endorsement, as required by the Division in its administration of the Florida ORP, clearly permit payment of contract benefits only in the event of death, retirement, or termination of employment and are substantially identical to the Texas ORP limitations.

6. The legislative purpose of the Florida ORP is similar to that of the statutes discussed above. In each case, the constraints or redeemability are designed to ensure that the annuity contract is used for the principal purpose of long-term retirement accumulation.

Moreover, the Division has required VALIC to obtain the relief requested as a condition to continuing as a designated company under the Florida ORP. Thus, persons participating in the Florida ORP could be denied the opportunity to select the Contracts as a funding medium for their retirement benefits.

Furthermore, the limited restrictions on redemption would be voluntarily assumed by Participants (i.e., Eligible Employees may elect not to participate in the Florida ORP), were not formulated or suggested by Applicants, and are reasonable in light of the benefits of participating in the Florida ORP. In addition, consistent with the precedents cited above, Participants are able to transfer their account value among the investment alternatives available under the Contracts (including the fixed alternative funded through the General Account of VALIC) and to qualified contracts of other companies designated under the Florida ORP.

7. As noted above, the requested exemptive relief is substantially identical to that requested and obtained

[1] American Counsel of Life Insurance, [1989 Transfer Binder] Fed. Sec. L. Rep. (CCH) Section 78,904 (November 28, 1998).

[2] Nationwide Life Insurance Company, (File No. 812–7457), Investment Company Act Release No. 17615 (July 25, 1990), 55 Fed. Reg. 31,278 (Aug. 1, 1990) (Notice); Investment Company Act Release No. 17693 (Aug. 22, 1990) (Order).

in connection with similar constraints or redeemability imposed by other governing authorities. Applicants submit that the relief requested raises no novel issues of law or fact.

8. Applicants will ensure that appropriate disclosure is made to Eligible Employees, informing them of the restrictions stated in the Endorsement. Applicants represent that they will:

a. Include appropriate disclosure regarding the restrictions on redemption imposed by the Division in each registration statement, including the prospectus, relating to the Contracts issued in connection with the Florida ORP;

b. Include appropriate disclosure regarding the restrictions on redemption imposed by the Division in any sales literature used in connection with the offer of Contracts to Eligible Employees;

c. Instruct salespeople who solicit Eligible Employees to purchase the Contracts specifically to bring the restrictions on redemption imposed by the Division to the attention of the Eligible Employees;

d. Obtain from each Participant in the Florida ORP who purchases a Contract, prior to or at the time of such purchase, a signed statement acknowledging the Participant's understanding: (i) of the restrictions on redemption imposed by the Division, and (ii) that other investment alternatives are available under the Florida ORP, to which the Participant may elect to transfer his or her Contract values; and

e. Include in any registration statement filed in connection with the Contracts a representation that this exemptive application is being relied upon and that the provisions of sub-paragraphs (a) through (d) above have been complied with.

Conclusion

Applicants submit that the exemptive relief requested is necessary and appropriate in the public interest and consistent with the protection of investors and the purposes fairly intended by the policy and provisions of the 1940 Act.

For the Commission, by the Division of Investment Management, under delegated authority.

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 93–9921 Filed 4–27–93; 8:45 am]

BILLING CODE 8010–01–M

SMALL BUSINESS ADMINISTRATION

Small Business Innovation Research Program Policy Directive

AGENCY: Small Business Administration.

ACTION: Publication of policy directive.

SUMMARY: On October 28, 1992, Public Law 102–564, 106 Stat. 4249, authorized the Small Business Technology Transfer (STTR) Pilot Program. The Small Business Administration (SBA) is hereby publishing the policy directive for the STTR pilot program. This policy directive provides guidance to the participating Federal agencies for the general conduct of the STTR pilot program. Additional instructions may be issued by the SBA as a result of public comment or experience. Such instructions will be issued as additional or replacement pages for this directive.

DATES: Public comment on this policy directive must be received no later than May 28, 1993.

ADDRESSES: Written comments should be submitted to Richard J. Shane, Assistant Administrator, Office of Innovation, Research and Technology, U.S. Small Business Administration, 409 Third Street, SW., suite 8500, Washington, DC 20416.

FOR FURTHER INFORMATION CONTACT: Jack Sweeney, Deputy Assistant Administrator, Office of Innovation, Research and Technology, (202) 205–6450.

SUPPLEMENTARY INFORMATION: On October 28, 1992, the Small Business Technology Transfer Act of 1992 (the Act), title II of Public Law 102–564 (106 Stat. 4256), authorized the Small Business Technology Transfer (STTR) Pilot Program. Section 202(b)(3) of the Act defines the term "Small Business Technology Transfer Program" or "STTR" as "a pilot program under which a portion of a Federal agency's extramural research or research and development effort is reserved for award to small business concerns for cooperative research and development through a uniform process having * * * a first phase, * * * a second phase, * * * and where appropriate, a third phase * * *." The term "cooperative research and development" means research or research and development conducted jointly by a small business concern and a research institution.

Under the Act, the first phase of an STTR program is to determine, to the extent possible, the scientific, technical, and commercial merit and feasibility of ideas submitted pursuant to STTR program solicitations. The second phase of an STTR program is to further develop proposed ideas to meet particular program needs, in which awards shall be made based upon the scientific, technical, and commercial merit and feasibility of the idea, as evidenced by the first phase and by other relevant information. Finally, the third phase of an STTR program is to facilitate the funding of commercial applications of STTR-funded R/R&D, by non-Federal sources of capital, or, for products or services intended for use by the Federal Government, by follow-on, non-STTR Federal Funding awards. Additionally, awards from non-STTR Federal funding sources which are used for the continuation of R/R&D that has been competitively selected using peer review or scientific review criteria would be considered in the third phase of an STTR program.

The Act authorizes Federal agencies to establish STTR Pilot Programs if their Fiscal Years 1994, 1995, or 1996 extramural budgets for research or research and development (R/R&D) exceed $1 billion. If a Federal agency's extramural budget for R/R&D meets the threshold requirement, the agency is authorized to expend the following amounts with small business concerns: (a) Not less than 0.05% of such budget in FY 1994; (b) not less than 0.1% in FY 1995; and (c) not less than 0.15% in FY 1996. The Act prohibits the use of a Federal agency's STTR budget for administrative costs of the program, including costs associated with salaries and expenses.

Section 202(c) of the Act charges SBA with the responsibility of issuing a policy directive which provides for the general conduct of the STTR Pilot Program, including six specific areas: (1) Simplified, standardized, and timely STTR solicitations; (2) a simplified, standardized funding process; (3) minimizing regulatory burdens associated with participation in the STTR programs; (4) guidelines for a model agreement, to be used by all agencies for allocating between small business concerns and research institutions, intellectual property rights, and rights, if any, to carry out follow-on research, development, or commercialization; (5) procedures to ensure that recipients of STTR awards meet SBA's definition of a small business concern, as defined in section 3 of the Small Business Act (15 U.S.C. 631 *et seq.*) and the small business concern exercises management and control of the performance of the STTR funding agreement; and (6) procedures to ensure, to the extent practicable, that an agency which intends to pursue research, development, or production of a technology developed by a small

business concern under an STTR program enters into follow-on, non-STTR funding agreements with the small business concern for research, development, or production.

Pursuant to the Act, SBA has developed this policy directive with the above areas of concern in mind, and after consultation with the heads of the Federal agencies required to establish STTR programs, the Commissioner of Patents and Trademarks, and the Director of the Office of Federal Procurement Policy. Those Federal agencies who are required to establish STTR programs are: The Department of Defense, the Department of Energy, the Department of Health and Human Services, the National Aeronautics and Space Administration, and the National Science Foundation.

SBA is issuing this policy directive with a 30 day comment period. SBA will consider all comments carefully before issuing the policy directive in final form, as required by the Act, no later than July 31, 1993.

Richard J. Shane,

Assistant Administrator, SBA Office of Innovation, Research and Technology.

Small Business Technology Transfer Program Policy Directive

To the Heads of Executive Departments and Establishments

Subject: Small Business Research and Development Enhancement Act of 1992 Small Business Technology Transfer (STTR) Pilot Program

1. *Purpose.* To provide a policy directive for the general conduct of the Small Business Technology Transfer (STTR) Pilot Programs within the Federal government.

2. *Authority.* This policy directive is issued pursuant to the authority contained in 15 U.S.C. 638(j)—Small Business Research and Development Enhancement Act of 1992 (Pub. L. 102–564).

3. *Procurement Regulations.* It is recognized that the Federal Acquisition Regulation (FAR) may need to be modified to conform to the requirements of The Small Business Research and Development Enhancement Act of 1992 and this policy directive. Agencies responsible for these procurement regulations are encouraged to initiate such changes. Regulatory provisions pertaining to areas of SBA responsibility, as established by Public Law 102–564, will require approval of the SBA Administrator or designee. The SBA Office of Innovation, Research and Technology is the appropriate office for coordinating such regulatory provisions.

4. *Personnel Concerned.* All Federal government personnel who are involved in the administration, funding agreements and technical process of the Small Business Technology Transfer (STTR) Pilot Program.

5. *Distribution.* Federal government agencies and departments with Small Business Technology Transfer (STTR) Pilot Programs as authorized by Public Law 102–564.

6. *Originator.* U.S. Small Business Administration, Office of Innovation, Research and Technology.

Richard J. Shane,

Assistant Administrator, SBA Office of Innovation, Research and Technology.

Dayton J. Watkins,

Acting Administrator, U.S. Small Business Administration.

Contents

Paragraph

1. Purpose
2. Summary of Legislative Provisions
3. Minimizing Regulatory Burden
4. Definitions
5. Participating Federal Agency Expenditures for the STTR Program
6. Limitations of Participation
7. Small Business Technology Transfer Pilot Program
8. Unilateral Actions of Participating Agencies and Departments
9. SBA/STTR Source File
10. SBA Coordination of National Critical Technologies
11. SBA Coordination of STTR Solicitation Schedules
12. SBA (Phase I) STTR Program Pre-Solicitation Announcements
13. Simplified, Standardized and Timely STTR Program Solicitations
14. Simplified and Standardized STTR Funding Process
15. STTR Program Annual Report to SBA
16. SBA Program to Monitor and Survey STTR Activity
17. Socially and Economically Disadvantaged Small Business Concerns and Women-Owned Small Business Concerns
Appendix—Instructions for STTR Pilot Solicitation Preparation

1. Purpose

a. Section 9(p) of the Small Business Act (15 U.S.C. 638, as amended by P.L. 102–564) requires that the Small Business Administration issue a policy directive for the general conduct of the STTR Pilot Programs within the Federal government.

b. This policy directive fulfills the statutory obligation of the legislation and provides guidance to the participating Federal agencies for the general conduct of the STTR Pilot Program. Additional instructions may be issued by the Small Business Administration (SBA) as a result of public comment or experience. These instructions will be issued as additional or replacement pages for this directive.

2. Summary of Legislative Provisions

a. *The Small Business Research and Development Enhancement Act of 1992,* Public Law 102–564, that became law on October 28, 1992, amends Section 9 of the Small Business Act (15 U.S.C. 638).

Title II of this legislation is the "Small Business Technology Transfer Act of 1992" (the Act) for the establishment of the Small Business Technology Transfer Pilot Program.

(1) The Act authorizes Federal agencies to establish STTR Pilot Programs if their FY 1994, 1995, or 1996 extramural budgets for research or research and development (R/R&D) exceed stated threshold figures ($1 billion).

(2) The statutory requirements are aimed at assisting small business concerns by establishing a uniform, simplified process for the operation of the STTR Pilot Program while allowing the participating agencies flexibility in the content and operation of their individual STTR Pilot Programs.

(3) The Act authorizes each participating agency to establish an STTR Pilot Program by reserving a statutory percentage of its extramural budget to be awarded to small business concerns for R/R&D through a uniform, three-phase process.

(a) The first two phases will help agencies meet R/R&D and commercialization objectives.

(b) The third phase, where appropriate, is:

(1) To pursue commercial applications from the government-funded R/R&D in order to stimulate technological innovation and provide for the national return on investment from R/R&D and/or

(2) For further contracting or grant activities with Federal agencies through non-STTR funding agreements.

(4) The Act mandates that each agency authorized to have an STTR Pilot Program is to report annually to SBA. The Act also requires agencies with STTR Pilot Programs to report annually to the Office of Science and Technology Policy.

b. On October 28, 1992, the President signed P.L. 102–564 which authorizes the STTR Pilot Program for the fiscal years 1994, 1995, and 1996.

(1) Effective March 31, 1985, section 2732(a) of Title VII of the Competition in Contracting Act of 1984, Public Law 98–369, must be read in conjunction with the procurement notice publication requirements of section 8(e) of the Small Business Act (15 U.S.C. 637(e)).

Therefore, the notice publication requirements of the law apply to agencies participating in the STTR Pilot Program which use contracts as their STTR funding agreements.

(a) Any Federal Executive agency intending to solicit a proposal for contract for property or services valued above $25,000 is required to submit a notice of the impending solicitation for publication in the Commerce Business Daily. No agency shall issue its solicitation for at least 15 days from the date of the publication of the notice. The agency may not establish a deadline for submission of proposals in response to such solicitation that is earlier than 30 days after the date on which the solicitation was issued.

(b) The Competition in Contracting Act also requires that any executive agency awarding a contract for property or services valued at more than $25,000 submit a notice for publication to the Secretary of Commerce announcing such an award for publication if a subcontract is likely to result from such contract.

(2) The following are exemptions from the notice publication requirements:

(a) In the case of agencies intending to solicit Phase I proposals for contracts in excess of $25,000, the head of the agency may exempt a particular solicitation from the notice publication requirements if he/she makes a written determination, with the consultation of the Administrator of the Office of Federal Procurement Policy and the Administrator of the Small Business Administration, that it is inappropriate or unreasonable to publish a notice before issuing a solicitation.

(b) The STTR Phase II awards process is exempted.

3. Minimizing Regulatory Burden

a. Important objectives in implementing STTR Pilot Program procedures are to:

(1) Minimize the creation of new or complex regulations.

(2) Ensure that the program's requirements are met.

(3) Simplify and standardize application of existing regulations related to the program. The explicit nature of the STTR legislation concerning certain recognized acquisition procedures provides a strong base of authority for streamlining the process for obtaining R/R&D from small highly innovative business concerns.

(a) The above includes funding allocations, centralized STTR technology management, and routine operational implementation.

(b) Where not contrary to existing statutory requirements, each agency is authorized to establish financial procedures and financing mechanisms that it deems necessary to properly implement the STTR Pilot Program, including, but not limited to, obligating funds solely on the basis of proposal merit without regard to the purpose for which funds were originally appropriated, and transferring assessed funds to a single account to facilitate financial management, reporting, and oversight.

(c) The participating agencies are encouraged to initiate or continue their development of simplified procedures that may be used on STTR actions and to submit information concerning simplified procedures to the SBA for possible general program improvements.

b. No participating agency may promulgate a rule or regulation that is contrary to or inconsistent with the STTR legislation or this policy directive.

4. Definitions

a. *Small Business Technology Transfer Pilot Program (STTR).* A pilot program under which a portion of a Federal agency's extramural research or research and development effort is reserved for award to small business concerns for cooperative research and development through a uniform process having three phases. The program is described in this directive.

b. *Research or Research and Development (R/R&D).* Any activity that is:

(1) A systematic, intensive study directed toward greater knowledge or understanding of the subject studied.

(2) A systematic study directed specifically toward applying new knowledge to meet a recognized need.

(3) A systematic application of knowledge toward the production of useful materials, devices, and systems or methods, including design, development, and improvement of prototypes and new processes to meet specific requirements.

c. *Cooperative Research and Development.* For the purposes of the STTR Program this means research and development conducted jointly by a small business concern and a research institution in which not less than 40 percent of the work is performed by the small business concern, and not less than 30 percent of the work is performed by the research institution.

d. *Extramural Budget.* The sum of the total obligations for R/R&D minus amounts obligated for R/R&D activities by employees of the agency in or through government-owned, government-operated facilities.

e. *Federal Agency.* An executive agency as defined in 5 U.S.C. 105, or a military department as defined in 5 U.S.C. 102 except that it does not include any agency within the Intelligence Community as defined in Executive Order 12333, section 3.4(f), or its successor orders.

f. *Funding Agreement.* Any contract, grant, or cooperative agreement entered into between any Federal agency and any small business concern for the performance of experimental, developmental, or research work funded in whole or in part by the Federal government.

g. *Research Institution.* A research organization that is:

(1) A contractor-operated federally funded research and development center, as identified by the National Science Foundation in accordance with the government-wide Federal Acquisition Regulation issued in accordance with section 35(c)(1) of the Office of Federal Procurement Policy Act (or any successor legislation thereto), or

(2) A non-profit research institution as defined in section 4(5) of the Stevenson-Wydler Technology Innovation Act of 1980, or,

(3) A non-profit university.

h. *Subcontract.* Any agreement, other than one involving an employer-employee relationship, entered into by a Federal government funding agreement awardee calling for supplies or services required solely for the performance of the original funding agreement.

i. *Socially and Economically Disadvantaged Small Business Concern.* A socially and economically disadvantaged small business concern:

(1) Is one that is at least 51 percent owned by (i) an Indian tribe or a native Hawaiian organization, or (ii) one or more socially and economically disadvantaged individuals, and

(2) Whose management and daily business operations are controlled by one or more socially and economically disadvantaged individuals.

j. *Socially and Economically Disadvantaged Individual.* A member of any of the following groups:

(1) Black Americans

(2) Hispanic Americans

(3) Native Americans

(4) Asian-Pacific Americans

(5) Subcontinent Asian Americans

(6) Other groups designated from time to time by SBA to be socially disadvantaged; or

(7) Any other individual found to be socially and economically disadvantaged by SBA pursuant to section 8(a) of the Small Business Act, 15 U.S.C. 637(a).

k. *Small Business Concern.* A small business concern is one that, at the time

of award of Phase I and Phase II funding agreements, meets the following criteria:

(1) Is independently owned and operated, is not dominant in the field of operation in which it is proposing, has its principal place of business located in the United States and is organized for profit;

(2) Is at least 51 percent owned, or in the case of a publicly owned business, at least 51 percent of its voting stock is owned by United States citizens or lawfully admitted permanent resident aliens;

(3) Has, including its affiliates, a number of employees not exceeding 500, and meets the other regulatory requirements found in 13 CFR part 121. Business concerns, other than investment companies licensed, or state development companies qualifying under the Small Business Investment Act of 1958, 15 U.S.C. 661, *et seq.*, are affiliates of one another when either directly or indirectly:

(a) One concern controls or has the power to control the other; or

(b) A third party or parties controls or has the power to control both.

Control can be exercised through common ownership, common management, and contractual relationships. The term "affiliates" is defined in greater detail in 13 CFR part 121. The term "number of employees" is also defined in 13 CFR part 121. Business concerns include, but are not limited to, any individual, partnership, corporation, joint venture, association or cooperative.

l. *Women-Owned Small Business Concern.* A small business concern that is at least 51 percent owned by a women or women who also control and operate it. "Control" in this context means exercising the power to make policy decisions. "Operate" in this context means being actively involved in the day-to-day management.

m. *Program Solicitation.* A formal solicitation of proposals whereby a Federal agency notifies the small business community of its R/R&D needs and interests in selected areas and requests proposals in response to these needs from small business concerns. Announcements in the **Federal Register** or the Commerce Business Daily are not to be considered substitutes for an STTR Program solicitation.

n. *United States.* The 50 states, the territories and possessions of the U.S., the Commonwealth of Puerto Rico, the Trust Territory of the Pacific Islands, and the District of Columbia.

o. *Commercialization.* The process of developing markets and producing and delivering products for sale (whether by the origination party or by others); as used here, commercialization includes both government and commercial (private sector) markets.

5. Participating Federal Agency Expenditures for the STTR Program

a. Each Federal agency which has an extramural budget for R/R&D in excess of $1,000,000,000 for FY 1994, 1995, or 1996, is authorized to expend with small business concerns not less than .05% of such budget in fiscal year 1994; not less than .1% of each budget in fiscal year 1995; and not less than .15% of such budget in fiscal year 1996, specifically in connection with STTR Programs which meet the requirements of the Small Business Research and Development Enhancement Act of 1992, this policy directive, and regulations issued thereunder.

b. Funding agreements with small business concerns for research or research and development which result from competitive or sole source selections other than an STTR Program shall not be considered to meet any portion of the percentage required under the STTR Program.

6. Limitations of Participation

a. A Federal agency shall not use any of its STTR budget for the purpose of funding administrative costs of the program including costs associated with budgetary salaries and expenses, or in the case of a small business concern or a research institution, costs associated with salaries, expenses and administrative overhead other than those direct or indirect costs allowable under guidelines of the Office of Management and Budget and the governmentwide Federal Acquisition Regulation issued in accordance with section 25(c)(1) of the Office of Federal Procurement Policy Act.

b. Awards resulting from other than an STTR Program may not be counted toward meeting STTR Program funding levels or achievement.

c. Voluntary participation in the STTR Programs by Federal agencies not otherwise qualified for such participation may be permitted under this policy directive.

Federal agencies seeking to participate in STTR need to submit their requests to SBA. Voluntary participation requires the written approval of the SBA Assistant Administrator for Innovation, Research and Technology subsequent to review of the request.

7. Small Business Technology Transfer Pilot Program

a. The STTR Program is a phased process uniform throughout the Federal government of soliciting proposals and awarding funding agreements for R/R&D to meet stated agency needs or missions.

b. Each participating agency shall at least annually issue an STTR solicitation that sets forth a substantial number of R/R&D topic and subtopic areas consistent with stated agency needs or missions. Both the list of topics and the description of the topics and subtopics shall be sufficiently comprehensive to provide a wide range of opportunity for small business concerns to participate in the agency R/R&D program. Topics and subtopics shall emphasize the need for proposals with advanced concepts to meet specific agency R/R&D needs. Each topic and subtopic shall describe the needs in sufficient detail so as to assist small business concerns in providing on-target responses, but shall not involve detailed specifications to prescribed solutions of the problems.

Unsolicited proposals or proposals not responding to stated topics or subtopics are not eligible for STTR awards.

c. Research or research and development in the STTR Program is to be conducted jointly by a small business concern and a non-profit research institution. Not less than 40 percent of the work conducted under an STTR award is to be performed by the small business concern, and not less than 30 percent of the work is to be performed by the non-profit research institution.

Also, for both Phase I and Phase II, the R/R&D work must be performed by the small business concern in the United States, as defined in paragraph 4.n. of this policy directive.

d. To stimulate and foster scientific and technological innovation, including increasing commercialization of Federal R/R&D, the STTR Program must follow a uniform competitive process of three phases:

(1) *Phase I.* Phase I involves a solicitation of proposals to conduct feasibility related experimental or theoretical R/R&D related to described agency requirements. The object of this phase is to determine the scientific, technical and commercial merit and feasibility of the proposed cooperative effort and the quality of performance of the small business concern with a relatively small agency investment before consideration of further Federal support in Phase II.

(a) Several different proposed solutions to a given problem may be funded.

(b) Proposals will be evaluated on a competitive basis. Agency criteria used to evaluate STTR proposals shall give primary consideration to the scientific and technical merit of the proposal

along with its potential for commercialization. Secondary considerations may include program balance or critical agency requirements.

(c) Agencies may include a provision requiring submission of a Phase II proposal as a deliverable item under Phase I.

(d) Efforts shall be taken by agencies to reduce the procurement time frame for Phase II awards. Agencies are encouraged to develop gap-funding methods and to address the duration of Phase II award cycles.

(2) *Phase II.* The object of Phase II is to continue the R/R&D effort from Phase I. Only awardees in Phase I are eligible to participate in Phase II. Phase I awardees are eligible for consideration of Phase II STTR funding agreements only at the Federal participating agency which awarded Phase I of the project. Funding shall be based upon the results of Phase I and the scientific and technical merit and commercial potential of the Phase II proposal. Phase II awards may not necessarily complete the total research and development that may be required to satisfy commercial or Federal needs beyond the STTR Program. Completion of the research and development may be through Phase III. The government is not obligated to fund any specific Phase II proposal. The STTR Phase II award decision process requires, among other things, consideration of a proposal's commercial potential as evidenced by:

(a) The small business concern's record of commercializing STTR or other research,

(b) The existence of second phase funding commitments from private sector or non-STTR funding sources,

(c) The existence of third phase follow-on commitments for the subject of the research, and

(d) The presence of other indicators of commercial potential of the idea.

(3) *Phase III.* The term third phase agreement means a follow-on, non-STTR funded award as described in 1, 2 and 3 below. A Federal agency may enter into a third phase agreement with a small business concern for additional work to be performed during or after the second phase period. The second phase funding agreement with the small business concern may, at the discretion of the agency awarding the agreement, set out the procedures applicable to third phase agreements. The competition for Phase I and Phase II awards satisfies any competition requirement of the Competition in Contracting Act.

(a) Where appropriate, there will be a third phase which is funded by:

1. Non-Federal sources of capital for commercial applications of STTR funded research or research and development,

2. The Federal government by follow-on non-STTR awards for STTR derived products and processes for use by the Federal government,

3. Non-STTR Federal sources for the continuation of research or research and development that has been competitively selected using peer review or scientific review criteria.

(b) Agencies which intend to pursue research, research and development or production of a technology developed by a small business concern under the STTR Program will give special acquisition preference such as sole source awards to the STTR company which developed the technology. The Phase III funding agreement will be with non-STTR funds.

8. Unilateral Actions of Participating Agencies and Departments

a. The Act requires each participating agency to:

(1) Unilaterally determine the categories of projects to be included in its STTR Program.

(2) Release STTR solicitations in accordance with the SBA/STTR master schedule.

(3) Subject to paragraph 12, unilaterally determine research topics within its STTR solicitation(s) giving special consideration to broad research topics and to topics that further one or more critical technologies, as identified by:

(a) The National Critical Technologies Panel (or its successor) in the 1991 report required under section 603 of the National Science and Technology Policy Organization and Priorities Act of 1976, and in subsequent reports issued under that authority, or

(b) The Secretary of Defense in the 1992 report issued in accordance with section 2522 of title 10, United States Code, and in subsequent reports issued under that authority.

(4) Unilaterally receive and evaluate proposals resulting from STTR solicitations and make awards.

(5) Unilaterally select awardees for its STTR funding agreements.

(6) Administer its own STTR funding agreements or delegate such administration to another agency; and inform each awardee under such agreement, to the extent possible, of the costs of the awardee that will be allowable under the funding agreement.

(7) Each funding agreement under the STTR Program shall include provisions setting forth the respective rights of the United States and the small business concern with respect to intellectual property rights and with respect to any right to carry out follow-on research.

(8) Make payments to recipients of STTR funding agreements on the basis of progress toward or completion of the funding agreement requirements and in all cases make payment to recipients under such agreements in full, subject to audit, on or before the last day of the 12-month period beginning on the date of completion of such requirements.

(9) Make an annual report on the STTR Program to SBA and to the Office of Science and Technology Policy.

(10) Develop a model agreement, not later than July 31, 1993, to be approved by SBA, for allocating between small business concerns and research institutions intellectual property rights and rights if any, to carry out follow-on research, development or commercialization.

(11) Develop, in consultation with the Office of Federal Procurement Policy and the Office of Government Ethics, procedures to ensure that federally funded research and development centers that participate in STTR agreements:

(a) Are free from organizational conflicts of interests relative to the STTR Program;

(b) Do not use privileged information gained through work performed for an STTR agency or private access to STTR agency personnel in the development of an STTR proposal; and

(c) Use outside peer review as appropriate.

(12) Develop no later than July 31, 1993, procedures for assessing the commercial merit and feasibility of STTR proposals. These procedures should consider:

(a) The small business concern's record of successfully commercializing STTR or other research;

(b) The existence of second phase funding commitments from private sector or non-STTR funding sources;

(c) The existence of third phase follow-on commitments for the subject of the research; and

(d) The presence of other indicators of the commercial potential of the idea.

9. SBA/STTR Source File

a. *SBA Small Business Technology Transfer (STTR) Program Source File.* The SBA will develop and maintain an STTR mailing list of interested small business concerns. In maintaining this list, SBA will adhere to the provisions of The Freedom of Information Act, The Privacy Act of 1974, 13 CFR 102.20 and 13 CFR 102.3(j). Labels from this list will be available to the Federal participating agencies for STTR

solicitation purposes. Written requests containing justification for the need of labels from this mailing list should be submitted to the Office of Innovation, Research & Technology, U.S. Small Business Administration, 409 Third Street, SW., Washington, DC 20416. A two-week period is required to fill these requests.

b. *SBA Procurement Automated Source System (PASS).* SBA's Office of Procurement Assistance has a Procurement Automated Source System (PASS) that maintains capability profiles of small businesses interested in Federal government procurement opportunities. This system is used by Federal agencies and major prime contractors to identify small business concerns with capabilities needed by the agencies or prime contractors. Agencies interested in accessing PASS should contact their nearest SBA Procurement Assistance Office.

c. *Federal Procurement Data System (FPDS).* Participating agencies should review FPDS data that identify small business awardees of R/R&D contracts as a potential supplement to their existing source data base.

d. *Other Sources.* Agencies may maintain their own mailing lists or use other sources.

10. SBA Coordination of National Critical Technologies

a. SBA will annually obtain information on the current critical technologies from both the National Critical Technologies Panel (or its successor) and the Secretary of Defense and provide such information to the participating Federal agencies and potential STTR participants.

b. The SBA Office of Innovation, Research and Technology will contact the panel and the Department of Defense and request this data in *June* of each year. The data received will then be submitted by letter to each of the participating Federal agencies.

11. SBA Coordination of STTR Solicitation Schedules

a. The Act requires issuance of STTR (Phase I) Program solicitations in accordance with a master schedule coordinated between SPA and the Federal participating agency. The SBA organization responsible for coordination is: Office of Innovation, Research and Technology, U.S. Small Business Administration, 409 Third Street, SW., Washington, DC 20416.

b. For maximum participation by interested small business concerns, it is important that the planning, scheduling and coordination of agency STTR solicitation release dates be completed as early as practicable in order to accommodate the commencement of the fiscal year on October 1. Bunching of agency STTR solicitation release and closing dates may prohibit small business concerns from the preparation and timely submission of proposals for more than one STTR project. SBA's coordination of agency schedules will minimize the bunching of proposed release and closing dates. Participating agencies may elect to publish multiple solicitations within a given fiscal year to facilitate in-house agency proposal review and evaluation scheduling.

c. To accomplish the MASTER SCHEDULE coordination process, the following procedure will be followed:

(1) The SPA may publish STTR Pre-Solicitation Announcements annually. However, the STTR Pre-Solicitation Announcement will not be published for any period in which participating agencies are not soliciting proposals. The STTR solicitation release date shall not be prior to *10 days* after publication of the Pre-Solicitation Announcement (PSA) which contains notice of that specific STTR solicitation.

(2) Each agency representative will notify SBA in writing of its proposed STTR solicitation release and proposal due dates for the next fiscal year on or before *August 1.* The SBA and the agency representatives will coordinate the resolution of any conflicting agency solicitation dates by the second week of August. In all cases, final decisions will be made by SBA's Office of Innovation, Research and Technology.

12. SBA (Phase I) STTR Program Pre-Solicitation Announcements

a. *SBA Publication.* The SBA, as required by public law, shall prepare and publish STTR Phase I Pre-Solicitation Announcements (PSAs) covering all participating Federal agencies. Any agency solicitation announcement changes that occur prior to or after the release of the STTR PSA must immediately be reported in writing to the SBA by the agency STTR representative. If possible, announcement amendments will be released reflecting such changes. Each issue of the STTR PSA will be based upon data received from the participating agencies. However, the agencies are advised that:

(1) The publication of the STTR PSA is not intended to restrict or prohibit application of customary or other internal agency procedures designed to obtain publicity for its R/R&D programs.

(2) The STTR PSA publications by SBA shall not be interpreted as a substitute or relief vehicle for existing statutory and regulatory publication requirements related to individual or specific procurement/grant actions.

b. *STTR Pre-Solicitation Announcement (PSA) Content.* The STTR PSA will include sufficient data to effectively apprise interested small business concerns throughout the Nation of forthcoming STTR Program solicitions—thereby assisting the participating agencies in identifying prospective responsible sources. The agencies shall provide the required information to SBA no later than 30 days prior to the PSA release date in accordance with the master schedule. The following information is required:

(1) The list of topics upon which R/R&D proposals will be sought. Each R/R&D topic shall have up to 10 words in its title.

(2) Agency address and/or phone number from which STTR Program solicitations can be obtained.

(3) Names, addresses, and phone numbers of agency contact points where STTR-related inquires may be directed.

(4) Release date(s) of program solicitation(s).

(5) Closing date(s) for receipt of proposals.

(6) Estimated number and average dollar amounts or level of effort of Phase I awards to be made under the solicitation.

c. For those agencies which use both general topic and more specific subtopic designations in their STTR solicitations, the topic data to be submitted for purposes of the STTR PSA publication should accurately describe the research solicited. Rather than just announcing topic information characterized as "Chemistry" or "Aerodynamics," summarize the subtopic statements and, where appropriate, utilize National Critical Technologies.

d. The STTR PSA will also include notices of STTR conferences and seminars. Only STTR conferences/seminars sponsored by the STTR Federal participating agencies or STTR conferences/seminars sponsored or co-sponsored by the U.S. Small Business Administration will be considered for publication in the STTR Pre-Solicitation Announcement (PSA).

13. Simplified, Standardized and Timely STTR Program Solicitations

a. *Instructions for STTR Program Solicitation Preparation.* The Small Business Act requires "* * * simplified, standardized and timely STTR solicitations" (Section 9(p)(2)(A)). Further, the Act requires the STTR Programs of participating agencies to use a "simplified, standardized funding process" and that the regulatory burden

of participating in the STTR Programs be minimized.

b. Therefore, the instructions in the appendix to this policy directive purposely depart from normal government solicitation format and requirements. STTR Program solicitations shall be prepared according to the attached appendix.

c. Agencies shall provide the SBA Office of Innovation, Research and Technology, 5 copies of each solicitation and any modifications thereto no later than the date of release of the solicitation or modification to the public.

d. *Non-STTR R/R&D-Related Actions.* It is not intended that the STTR Program solicitation replace or be used as a substitute for unsolicited proposals or R/R&D awards to small business concerns authorized by existing regulations; or, are the STTR Program solicitation procedures intended to prohibit other agency R/R&D actions with small business concerns that are carried on in accordance with applicable statutory/regulatory authorizations.

14. Simplified and Standardized STTR Funding Process

In its requirement for the establishment of a "simplified, standardized funding process," the STTR legislation requires that specific attention be given to the following areas of STTR Program administration:

a. *Timely Receipt and Review of Proposals.*

(1) Participating agencies shall establish firm schedules and review formats for appropriate distribution of the proposals for reviewing recommendations and submission to the STTR Program manager for award determinations.

(a) All activities related to Phase I proposal reviews shall normally be completed and awards made within 6 months from the closing date of the STTR solicitation.

(b) The STTR Program solicitations for Phase I will establish proposal submission dates. Related to Phase II activity, an agency may establish set proposal submission dates. However, it is anticipated that each agency will negotiate mutually acceptable proposal submission dates with individual Phase I performers, accomplish proposal reviews expeditiously, and proceed with awards.

While it is recognized that Phase II arrangements between the agency and proposer may require more detailed negotiations to establish terms acceptable to both parties, the agencies must not sacrifice the R/R&D momentum created under Phase I by engaging in unnecessarily protracted Phase II proceedings.

(c) It can be anticipated that STTR participants will submit duplicate or similar proposals to more than one soliciting agency when the work projects appear to involve similar topics or requirements which are within the expertise and capability levels of the small business proposer. To the extent reasonably feasible, interagency funding duplications related to acquiring similar technology under the STTR or other Federal programs should not occur.

For this purpose, the standardized STTR Program solicitation will require the proposer to indicate the name and address of the agencies to which duplicate or similar proposals were made and to identify by subject the projects for which the proposal was submitted and the dates submitted. The same information will be required for any previous Federal government awards.

To assist in avoiding duplicate funding, each agency shall provide SBA and each participating STTR agency with a listing of Phase I and Phase II awardees including the complete address and title of the project. This information should be distributed no later than release of contract award information to the public.

b. *Review of STTR Proposals.* Agencies are encouraged to use their normal review process for STTR proposals whether internal or external evaluation is used. A more limited review process may be used for Phase I due to the larger number of proposals anticipated. Where appropriate, "peer" reviews, that are external to the agency, are authorized by the STTR legislation. Participating agencies are cautioned that all review procedures shall be formulated to minimize any possible conflict of interest as it pertains to proposer proprietary data. The standardized STTR solicitation will advise potential proposers that proposals may be subject to an established external review process, but that the proposer may include company designated proprietary information in its proposal.

c. *Proprietary Information Contained in Proposals.* In preparation of the standardized STTR Program solicitation as described in the Appendix of this policy directive, provisions will be included requiring confidential treatment of proprietary information to the extent permitted by law. Offerors will be discouraged from submitting information considered proprietary unless it is deemed essential for proper evaluation of the proposal. The solicitation will require that all proprietary information be clearly identified and marked with a prescribed legend. Agencies may elect to require proposers to limit proprietary information to that essential to the proposal and to have such information submitted on a separate page or pages keyed to the text.

d. *Selection of Awardees.* Participating agencies shall establish a proposal review cycle wherein successful and unsuccessful proposers shall be notified of final award decisions within 6 months of the agency's Phase I proposal closing date.

(1) The standardized STTR Program solicitation shall:

(a) Advise Phase I proposers that additional information may be requested by the awarding agency to evidence awardee responsibility for project completion.

(b) Contain information advising potential offerors of basic proposal evaluation criteria for Phase I and Phase II.

(2) Phase II proposal submissions, review, and selections shall be managed by arrangements between the agency and each Phase I awardee considered for Phase II award.

Within 30 days of the date of award of funding agreements—three copies of the Technical Abstract (containing all information described in the Appendix Paragraph III, C 1–6) for Phase I and Phase II awards shall be submitted to the SBA.

e. *Certification of Size of Firm.* The Act requires that participating agencies ensure that only small business concerns are recipients of STTR awards.

Awarding documents are to include a signed statement by the awardee that the definition of a small business concern as described in Section 4 of this policy directive is met.

f. *Management of the STTR Project.* The small business concern, and not the non-profit research institution, is to provide satisfactory evidence that it will exercise management direction and control of the performance of the STTR funding agreement. Regardless of the proportion of the work or funding of each of the performers under the contract, the small business concern is to be primary contractor or grantee with overall responsibility for its performance.

All agreements between the small business concern and the research institution cooperation in the STTR projects, or any business plans reflecting agreements and responsibilities between the parties during performance of Phase I or II of STTR, or for the commercialization of the resulting

technology, should reflect the controlling position of the small business concern.

g. *Rights in Data Developed Under STTR Funding Agreement.* The STTR legislation provides for "retention of rights in data generated in the performance of the contract by the small business concern".

(1) The intent of the statute is to provide authority for the participating agency to protect technical data generated under the funding agreement, and to refrain from disclosing such data to competitors of the small business concern or from using the information to produce future technical procurement specifications that could harm the small business concern that discovered and developed the innovation until the small business concern has a reasonable chance to seek patent protection, if appropriate.

(2) Therefore, except for program evaluation, participating agencies shall protect such technical data for a period of not less than 4 years from the completion of the project from which the data were generated unless the agencies obtain permission to disclose such data from the contractor or grantee. The government shall retain a royalty-free license for government use of any technical data delivered under an STTR funding agreement whether patented or not.

h. *Allocation of Rights:* A small business concern, before receiving an STTR award, must submit a written agreement between the small business concern and the research institution allocating intellectual property rights and rights, if any, to carry out follow-on research, development, or commercialization. The participating agency may accept an existing agreement between the two parties if it is fair to the small business concern and does not conflict with the interests of the Federal government.

In those instances where a small business concern requests assistance in developing a written agreement, the participating agency will provide a model agreement to be used as guidance by the small business in the development of an agreement.

The model agreement provided to the small business concern should direct the parties, as a minimum, to:

(1) State specially the degree of responsibility, and ownership of any product, process, or other invention or innovation resulting from the cooperative research. The degree of responsibility shall include responsibility for expenses and liability, and the degree of ownership shall also include the specific rights to revenues and profits.

(2) State which party may obtain U.S. or foreign patents or otherwise protect any inventions resulting from the cooperative research.

(3) State which party has the right to any continuation of research including non-STTR follow-on awards.

The Federal government will not normally be a party to any agreement between the small business concern and the research institution. Nothing in the agreement is to conflict with any provisions setting forth the respective rights of the United States and the small business concern with respect to intellectual property rights and with respect to any right to carry out follow-on research.

i. *Title Transfer of Agency Provided Property.* Under STTR legislation, title to equipment purchased in relation to project performance with funds provided under STTR funding agreements may be transferred to the awardee where such transfer would be more cost effective than recovery of the property by the government.

j. *Continued Use of Government Equipment.* STTR legislation directs that a small business concern participating in the third phase of the STTR Program be given continued use, as a directed bailment, of any property transferred by a Federal agency to the small business concern in the second phase of an STTR Program for a period of not less than 2 years, beginning on the initial date of the concern's participation in the third phase of such program.

k. *Cost Sharing.* (1) Cost participation could serve the mutual interest of the participating agencies and certain STTR awardee by helping to assure the efficient use of available resources. Cost-sharing, however, shall not normally be encouraged except where required by other statutes.

(2) Except where required by other statutes, participating agencies shall not, as a general policy, request or require cost sharing on Phase I projects. The standardized STTR Program solicitation (Appendix) will, however, provide information to prospective STTR performers concerning cost-sharing. Cost participation will not be a consideration factor in evaluation of Phase I proposals except where required by other statutes.

l. *Payment Schedules and Cost Principles.*

All STTR funding agreements shall use, as appropriate, current cost principles and procedures authorized for use by the participating agencies. At the time of award, agencies shall inform each STTR awardee, to the extent possible, of the applicable Federal regulations and procedures which refer to the costs that generally will be allowed under funding agreements.

m. *Funding Agreement Types and Fee or Profit.* The legislative requirements for uniformity and standardization require that there be consistency in application of STTR Program provisions among participating agencies. This consistency must consider, however, the need for flexibility by the various agencies in missions and needs as well as the wide variance in funds required to be devoted to STTR Programs in the agencies. The following guidelines are for the purpose of meeting these requirements:

(1) *Funding Agreement.* The choice of type of funding agreement (contract, grant, or cooperative agreement) rests with the awarding agency but must be consistent with the guidelines in Public Law 95–224 (41 U.S.C. 501), as amended by Public Law 97–258 (31 U.S.C. 6301–6308).

(2) *Fee or Profit.* Unless expressly excluded by statute, awarding agencies are to provide for a reasonable fee or profit on STTR funding agreements, including grants, consistent with normal profit margins provided to profit-making firms for R/R&D work.

n. *Periods of Performance and Extensions.*

(1) In keeping with the legislative intent to make a large number of relatively small awards, modification of funding agreements to extend periods of performance, increase the scope of work, or to increase the dollar amount should be minimized, except for options in the original Phase I or Phase II awards.

(2) *Phase I.* Period of performance should normally be approximately 1 year except where agency needs or research plans require otherwise. Exceptions should be minimized.

(3) *Phase II.* Period of performance under Phase II is the subject of negotiations between the selected Phase I recipient and the awarding agency. However, the duration of Phase II should normally be approximately 2 years. Exceptions should be minimized.

o. *Dollar Value of Awards.*

(1) The STTR legislation establishes 1-year awards for the first phase of an STTR program generally not to exceed $100,000, and 2-year awards for the second phase of an STTR program generally not to exceed $500,000.

(2) After award of any funding agreement exceeding $100,000 for Phase I or $500,000 for Phase II, the agency STTR representative shall provide SBA with written justification of such action.

The justification shall be submitted with the STTR Annual Report data. Similar justification is required for any dollar increase of a funding agreement which would bring the cumulative dollar amount to a total in excess of the aforestated amounts.

p. *Grant Authority.* The STTR legislation does not, in and of itself, convey grant authority. Each participating agency must secure grant authority in accordance with its normal procedures.

q. *Conflicts of Interest.* Participating agencies are cautioned that awards made to firms owned by or employing current or previous Federal government employees could create conflicts of interest for those employees in violation of the Ethics in Government Act of 1978 (Pub. L. 95–521, as amended). Each participating agency should refer to the standards of conduct review procedures currently in effect for its agency to ensure that such conflicts of interest do not arise.

15. STTR Program Annual Report to SBA

The STTR legislation requires an annual report from the participating agencies in the program. The following paragraphs cite the dates such reports are due, the kinds of information to be included, and the number of copies to be submitted to SBA.

a. *Reporting Dates to SBA.*

Reporting shall be on an annual basis and will be for the period ending September 30 of each fiscal year. The report is due to SBA by December 31 of each year. Example: The report for FY 1994 (October 1, 1993—September 30, 1994) should be submitted to SBA by December 31, 1994.

b. *Small Business Technology Transfer (STTR) Program*

(1) Agency total fiscal year, for FY 1994 and each year thereafter, extramural research and research and development total obligations as reported to the National Science Foundation pursuant to the annual Budget of the United States Government.

(2) STTR Program total fiscal year dollars derived by applying the statute per centum to the agencies' extramural research and research and development total obligations.

(3) STTR Program fiscal year dollars obligated through STTR Program funding agreements for Phase I and Phase II.

(4) Number of STTR individual solicitations released during the fiscal year and the number of topics and subtopics contained in each solicitation.

(5) Number of copies of each STTR solicitation distributed by the participating agency.

(6) Number of proposals received by the agency for each topic and subtopic in each STTR solicitation.

(7) For both Phase I and Phase II, the STTR awardee's name and address, research institution's name and address, dollar and percent of award performed by the small business concern and the research institution, solicitation topic and subtopic, solicitation number, project title, and total dollar amount of funding agreement. Identify minority small business, women-owned small business and Phase II awardees with a follow-on funding commitment.

(8) The names and addresses of small business concerns for whom the Phase I process exceeded the 6-month period from the closing date of the STTR solicitation to award of the funding agreement. (See 14.a.(1)(a) of this policy directive.)

(9) For an agency Phase III award using non-STTR Federal funds, to continue a Phase II project, the agency shall provide the name, address, project title and dollar amount obligated.

(10) Report the number of National Critical Technology topic or subtopic funding agreements, the percentage by number and dollar amount of total STTR awards to such National Critical Technologies.

16. SBA Program to Monitor and Survey STTR Activity

a. *Examples of STTR Areas To Be Monitored by SBA.*

(1) *STTR Funding Allocations.* Of major significance to the success of the STTR Program is the magnitude and nature of the agencies' funding allocations identified for fiscal year STTR applications. The STTR legislation explicitly relates to both the definition of the STTR effort, R/R&D (as defined in the Act and OMB Circular A–11), and the mathematical methodology for determining fiscal year participation levels for all work categorized within the statutory definitions. SBA will monitor these allocations.

(2) *STTR Program Solicitation and Award Status.* The accomplishment of scheduled STTR events, such as the release of STTR Program solicitation and the award of contract, grant, or cooperative agreement award, is critical to meeting statutory mandates and to operating an effective, useful program. SBA plans to monitor these and other operational features of STTR Program implementation including the status of awards taking longer than the 6-month period set forth in 14.a.(1)(a) of this policy directive.

Except in instances where SBA assistance is required related to a specific STTR project, contract, etc., SBA does not intend to monitor administration of the awards.

(3) *Follow-on Funding Commitments.* SBA may monitor whether follow-on non-Federal funding commitments obtained by Phase II awardees for Phase III were considered in the evaluation of Phase II proposals as required by the Act.

(4) *Agency Rules and Regulations.* It is essential that no implementing regulation be promulgated by the participating agencies that is inconsistent with or contradicts either the letter or intent of the legislation and this directive. SBA's monitoring activity will include review of rules and regulations and procedures generated to facilitate intra-agency STTR Program implementation.

17. Socially and Economically Disadvantaged Small Business Concerns and Women-Owned Small Business Concerns

To foster and encourage participation by socially and economically disadvantaged small business concerns in scientific and technological innovation, the legislation establishes as a purpose to improve the Federal government's dissemination of information concerning the Small Business Technology Transfer Program, particularly with regard to program participation by women-owned small business concerns and by socially and economically disadvantaged small business concerns.

a. To carry out this purpose of the statute, SBA and the Federal participating agencies will make outreach efforts to find and place innovative women-owned small business concerns and socially and economically disadvantaged small business concerns in the STTR Program information system.

b. The SBA will develop, participate in, and, when appropriate and feasible, sponsor seminars for innovative women-owned small business concerns and socially and economically disadvantaged small business concerns to inform them of the STTR Program.

c. The SBA will inform women-owned small business concerns and socially and economically disadvantaged small business concerns of Federal and commercial assistance and services available for STTR Program participants.

d. While these small business concerns will be required to compete for STTR awards on the same basis as all

other small business concerns, participating agencies are encouraged to work independently and cooperatively with SBA to develop methods to encourage qualified women-owned small business concerns and socially and economically disadvantaged small business concerns to participate in their STTR Programs.

Appendix—Instructions for STTR Pilot Program Solicitation Preparation

Section 9(p) of the Small Business Act (The Act) (15 U.S.C. 638(p), as amended by Public Law 102–564) requires "* * * simplified, standardized and timely STTR solicitations" (Section 9(p)(2)(A)). Further, the Act requires the STTR Programs of participating agencies to utilize a "uniform process" (15 U.S.C. 638(e)(6), as amended) and that the regulatory burden of participating in the STTR Programs be minimized. Therefore, the following instructions purposely depart from normal government solicitation formats and requirements. STTR solicitations will be prepared and issued a program solicitations in accordance with the following instructions.

Limitation in Size of Solicitation

In the interest of meeting the legislative requirement for simplified and standardized solicitations, the entire STTR solicitation with the exception of section VIII "Research Topics," described below, shall be limited to 23 pages. There is no page limit on Section VIII, "Research Topics."

Format

STTR Program solicitations will be prepared in a simplified, standardized, easily read and understand format including a cover sheet, a table of contents and the following sections in the order listed (content of each section is discussed below):

I. Program Description
II. Definitions
III. Proposal Preparation Instructions and Requirements
IV. Method of Section and Evaluation Criteria
V. Considerations
VI. Submission of Proposals
VII. Scientific and Technical Information Sources
VIII. Research Topics
IX. Submission Forms and Certifications

Cover Sheet

The cover sheet or title page of an STTR Program Solicitation shall clearly identify the solicitation as a Small Business Technology Transfer (STTR) Program Solicitation, identify the agency releasing the solicitation, specify date (or dates) on which proposals are due under the solicitation, and state the solicitatien number.

Instructions for Preparation of STTR Program Solicitation Sections I through IX

I. Program Description

A. Summarize in narrative form the invitation to submit proposals and the objectives of the STTR Program.

B. Describe in narrative form the agency's STTR Program including a description of the three phases. Note in your description that the solicitation is for Phase I proposals only.

C. Describe program eligibility, as follows:

Eligibility. Each concern submitting a proposal must qualify as a small business concern for R/R&D purposes at the time of award. The small business concern will submit a proposal for cooperative research and development with a non-profit research institution as defined in section 4(5) of the Stevenson-Wydler Technology Innovation Act of 1980 (15 U.S.C. 3701), and which includes Federally Funded Research and Development Centers as identified by the National Science Foundation in accordance with the governmentwide Federal Acquisition Regulations.

For both Phase I and Phase II, the R/R&D work must be performed in the United States.

D. List name, address and telephone number of agency contacts for general information on the STTR Program solicitation.

II. Definitions

Whenever terms are used that are unique to either the STTR Program, a specific STTR solicitation or a portion of a solicitation, they will be defined in a separate section entitled "Definitions." As a minimum, the definitions of "small business concern", "socially and economically disadvantaged small business concern", "cooperative research", "research institution", "women-owned small business concern", and "subcontract" as stated in Paragraph 4 of this policy directive shall be included.

III. Proposal Preparation Instructions and Requirements

The purpose of this section is to inform the proposer on what to include in his or her proposal and to set forth limits on what may be included. It should also provide guidance to assist proposers in improving the quality and acceptance of proposals particularly to firms that may not have previous government experience.

A. *Limitations on Length of Proposal.* Include at least the following information:

1. STTR Phase I proposals shall not exceed a total of 25 pages, including cover page, budget, and all enclosures or attachments. Pages should be of standard size (8½" x 11"; 21.6 cm x 27.9 cm) and should conform to the standard formatting instructions; in particular, 2.5 cm (1 inch) margins and type no smaller than 10 point font size.

2. A notice that no additional attachments, appendices or references beyond the 25-page limitation shall be considered in proposal evaluation and that proposals in excess of the 25-page limitation shall not be considered for review or award.

B. *Proposal Cover Sheet.* Every proposer will be required to include at least the following information on the first page of proposals. Items 9 and 11 are for statistical purposes only.

1. Agency and solicitation number.
2. Topic Number.
3. Subtopic Number.
4. Topic Area.
5. Project Title.
6. Name and Complete Address of Firm.
7. Name and address of research institution.
8. Small Business Certification as follows:

"The above concern certifies it is a small business concern and meets the definition as stated in this solicitation."

9. Socially and Economically Disadvantaged Small Business Concern Certification as follows:

"The above concern certifies that it ____ does ____ does not qualify as a socially and economically disadvantaged small business concern and meets the definition as stated in this solicitation."

10. The small business concern will certify that at least 40 percent of the work is to be performed by the small business concern and at least 30 percent of the work is to be performed by the research institution as follows:

"The above concern certifies that it will perform ____ percent of the work and the research institution will perform ____ percent of the work under this funding agreement."

11. Women-owned Small Business Concern Certification as follows:

The above concern certifies that it ____ does ____ does not qualify as a women-owned small business concern and meets the definition as stated in this solicitation.

12. A disclosure permission statement such as follows may be included at the discretion of the funding agency:

"Will you permit the government to disclose the title and technical abstract page of your proposed project, plus the name, address, and telephone number of the corporate official of your concern, if your proposal does not result in an award, to concerns that may be interested in contacting you for further information?"
Yes ____ No ____

13. Signature of a company official of the proposing small business concern and that individual's typed name, title, address, telephone number, and date of signature.

14. Signature of Principal Investigator or Project Manager and that individual's typed name, organization, title, address, telephone number, and date of signature.

15. Legend for proprietary information as described in the "Considerations" section of this program solicitation if appropriate.

C. *Abstract or Summary.* Proposers will be required to include a one-page project summary of the proposed R/R&D including at least the following:

1. Name and address of small business concern.
2. Name and address of cooperative research institution.
3. Name and title of principal investigator or project manager.
4. Agency name, solicitation number, solicitation topic and subtopic.
5. Title of project.
6. Technical abstract, limited to two hundred words.
7. Summary of the anticipated results and implications of the approach (both Phases I and II).
8. Summary of the potential commercial applications of the research.

D. *Technical Content.* STTR Program solicitations shall require as a minimum the following to be included in proposals submitted thereunder:

1. *Identification and Significance of the Problem or Opportunity.* A clear statement of the specific technical problem or opportunity addressed.

2. *Phase I Technical Objectives.* State the specific objectives of the Phase I research and development effort, including the technical questions it will try to answer to determine the feasibility of the proposed approach.

3. *Phase I Work Plan.* A detailed description of the Phase I R/R&D plan. The plan should indicate what will be done, where it will be done and how the R/R&D will be carried out. Phase I R/R&D should address the objectives and the questions cited in D.2. above. The methods planned to achieve each objective or task should be discussed in detail. The work plan will specifically address the amount and type of work to be performed by the small business concern and by the research institution.

4. *Related Research or Research and Development.* Describe significant R/R&D that is directly related to the proposal including any conducted by the project manager/principal investigator or by the proposing small business concern. Describe how it relates to the proposed effort, and any planned coordination with outside sources. The proposer must persuade reviewers of his or her awareness of key recent R/R&D conducted by others in the specific topic area.

5. *Key Personnel and Bibliography of Directly Related Work.* Identify key personnel involved in Phase I including their directly related education, experience, and bibliographic information. Where vitae are extensive, summaries that focus on the most relevant experience or publications are desired and may be necessary to meet the proposal size limitation.

6. *Relationship with Future Research or Research and Development.*

a. State the anticipated results of the proposed approach if the project is successful (Phase I and II).

b. Discuss the significance of the Phase I effort in providing a foundation for the Phase II R/R&D effort.

7. *Facilities.* A detailed description, availability and location of instrumentation and physical facilities proposed for Phase I should be provided.

8. *Consultants.* Involvement of consultants in the planning and research stages of the project is permitted.

a. If such involvement is intended, it should be described in detail.

9. *Potential Post Applications.* Briefly describe:

a. Whether and by what means the proposed project appears to have potential commercial application.

b. Whether and by what means the proposed project appears to have potential use by the Federal government.

10. *Similar Proposals or Awards.* A firm may elect to submit proposals for essentially equivalent work under other Federal program solicitations, or may have received other Federal awards for essentially equivalent work. In these cases, a statement must be included in each such proposal indicating:

a. The name and address of the agencies to which proposals were submitted or from which awards were received.

b. Date of proposal submission or date of award.

c. Title, number, and date of solicitations under which proposals were submitted or awards received.

d. The specific applicable research topics for each proposal submitted or award received.

e. Titles of research projects.

f. Name and title of project manager or principal investigator for each proposal submitted or award received.

E. *Cost Breakdown/Proposed Budget.* The solicitation will require the submission of simplified cost or budget data.

F. *Allocation of Rights.* The solicitation will require that a small business concern submit a written agreement between the small business concern and the research institution allocating intellectual property rights and rights, if any, to carry out follow-on research, development or commercialization.

G. *Written Cooperative Agreement.* The proposing small business concern is to provide an original of the agreement between the small business concern and the research institution. The agreement is to include the signature of an official of the small business concern and the signature of an official of the research institution.

IV. Method of Selection and Evaluation Criteria

A. *Standard Statement.* Essentially the following statement shall be included in all STTR Program solicitations:

All Phase I and II proposals will be evaluated and judged on a competitive basis. Proposals will be initially screened to determine responsiveness. Proposals passing this initial screening will be technically evaluated by engineers or scientists to determine the most promising technical and scientific approaches. Each proposal will be judged on its own merit. The agency is under no obligation to fund any proposal or any specific number of proposals in a given topic. It also may elect to fund several or none of the proposed approaches to the same topic or subtopic.

Phase II proposals may only be submitted by Phase I award winners within the same agency.

B. *Evaluation Criteria.*

1. The agency in its evaluation process shall develop a standardized method that will consider as a minimum the following factors:

a. The technical approach and the anticipated agency and commercial benefits that may be derived from the research.

b. The adequacy of the proposed effort and its relationship to the fulfillment of requirements of the research topic or subtopics.

c. The soundness and technical merit of the propose approach and its incremental progress toward topic or subtopic solution.

d. Qualifications of the proposed principal/key investigators supporting staff and consultants.

e. In Phase II, evaluations of proposals require, among other things, consideration of a proposal's commercial potential as evidenced by:

(1) The small business concern's record of commercializing STTR or other research,

(2) The existence of second phase funding commitments from private sector or non-STTR funding sources,

(3) The existence of third phase follow-on commitments for the subject of the research, and,

(4) The presence of other indicators of commercial potential of the ideal.

2. The factors in subparagraph B.1. and other approprate evaluation criteria, if any, shall be specified in the "Method of Selection" section of STTR Program solicitations.

C. *Peer Review.* If it is contemplated that as a part of STTR proposal evaluation external peer review will be used, the program solicitation must so indicate.

D. *Release of Proposal Review Information.* After final award decisions have been announced, the technical evaluations of the proposer's proposal may be provided to the proposer. The identify of the reviewer shall not be disclosed.

V. Considerations

This section shall include, as a minimum, the following information:

A. *Awards,* Indicate the estimated number and type of awards anticipated under the particular STTR Program solicitation in question including:

1. Approximate number of Phase I awards expected to be made.

2. Type of funding agreement, i.e., contract, grant or cooperative agreement.

3. Whether fee or profit will be allowed.

4. Cost basis of funding agreement, e.g., grant, firm-fixed-price, cost reimbursement, or cost-plus-fixed fee.

5. Information on the approximate average dollar value of awards for Phase I and Phase II.

B. *Reports.* Describe the frequency and nature of reports that will be required under Phase I funding agreements. Interim reports should be brief letter reports.

C. *Payment Schedule.* Specify the method and frequency of progress and final payment under Phase I and Phase II agreements.

D. *Innovations, Inventions and Patents.*

1. *Limited Rights Information and Data.*

a. *Proprietary Information.* Essentially the following statement shall be included in all STTR solicitations:

Information contained in unsuccessful proposals will remain the property of the proposer. The government may, however, retain copies of all proposals. Public release of information in any proposal submitted will be subject to existing statutory and regulatory requirements.

If proprietary information is provided by a proposer in a proposal which constitutes a trade secret, proprietary commercial or financial information, confidential personal information or data affecting the national security, it will be treated in confidence, to the extent permitted by law, provided this information is clearly marked by the proposer with the term "confidential proprietary information" and provided the following legend appears on the title page of the proposal:

"For any purpose other than to evaluate the proposal, this data shall not be disclosed outside the government and shall not be duplicated, used, or disclosed in whole or in part, provided that if a funding agreement is awarded to this proposer as a result of or in connection with the submission of this data, the government shall have the right to duplicate, use, or disclose the data to the extent provided in the funding agreement. This restriction does not limit the government's right to use information contained in the data if it is obtained from another source without restriction. The data subject to this restriction are contained on pages ____ of this proposal."

Any other legend may be unacceptable to the government and may constitute grounds for removing the proposal from further consideration and without assuming any liability for inadvertent disclosure. The government will limit dissemination of such information to within official channels.

b. *Alternative To Minimize Proprietary Information.* Agencies may elect to instruct proposers to:

(1) Limit proprietary information to only that absolutely essential to their proposal.

(2) Provide proprietary information on a separate page with a numbering system to key it to the appropriate place in the proposal.

c. *Rights in Data Developed Under STTR Funding Agreements.* To notify the small business concern of the policy stated in Para. 14.g. of this policy directive, essentially the following statement will be included in all STTR Program solicitations:

"These STTR data are furnished with STTR rights under Contract No. ____ (and subcontract ____ if appropriate). For a period of 4 years after acceptance of all items to be delivered under this contract, the government agrees to use these data for government purposes only, and they shall not be disclosed outside the government (including disclosure for procurement purposes) during such period without permission of the contractor, except that, subject to the foregoing use and disclosure prohibitions, such data may be disclosed for use by support contractors. After the aforesaid 4-year period the government has a royalty-free license to use, and to authorize others to use on its behalf, these data for government purposes, but is relieved of all disclosure prohibitions and assumes no liability for unauthorized use of these data by third parties. This Notice shall be affixed to any reproductions of these data, in whole or in part."

d. *Copyrights.* Include an appropriate statement concerning copyrights and publications; for example:

"With prior written permission of the contracting officer, the awardee normally may copyright and publish (consistent with appropriate national security considerations, if any) material developed with (agency name) support. (Agency name) receives a royalty-free license for the Federal government and requires that each publication contain an appropriate acknowledgement and disclaimer statement."

e. *Patents.* Include an appropriate statement concerning patents; for example:

"Small business concerns normally may retain the principal worldwide patent rights to any invention developed with government support. The government receives a royalty-free license for Federal government use, reserves the right to require the patentholder to license others in certain circumstances, and requires that anyone exclusively licensed to sell the invention in the United States must normally manufacture it domestically. To the extent authorized by 35 U.S.C. 205, the government will not make public any information disclosing a government-supported invention for a four-year period to allow the awardee a reasonable time to pursue a patent."

E. *Cost-Sharing.* Unless in conflict with another statute, include a statement essentially as follows:

"Cost-sharing is permitted for proposals under this program solicitation; however, cost-sharing is not required. Cost-sharing will not be an evaluation factor in consideration of your Phase I proposal."

Where cost-sharing is required by statute, include an appropriate statement.

F. *Profit or Fee.* Include a statement on the payment of profit or fee on awards made under the STTR Program solicitation.

G. *Joint Ventures or Limited Partnerships.* Include essentially the following language:

"Joint ventures and limited partnerships are eligible to participate provided the entity created qualifies as a small business as defined in this program solicitation."

H. *Research and Analytical Work.* Include essentially the following statement:

"The STTR Pilot program is a cooperative research or research and development effort conducted jointly by a small business concern and a research institution in which not less than 40 percent of the work is performed by the small business concern and not less than 30 percent of the work is performed by the research institution."

I. *Contractor Commitments.* To meet the legislative requirement that STTR solicitations be simplified, standardized and uniform, clauses expected to be in or required to be included in STTR funding agreements shall not be included in full or by reference in STTR Program solicitations. Rather, proposers shall be advised that they will be required to make certain legal commitments at the time of execution of funding agreements resulting from STTR Program solicitations. Essentially, the following statement shall be included in the "Consideration" section of STTR Program solicitations:

"Upon award of a funding agreement, the awardee will be required to make certain legal commitments through acceptance of numerous clauses in Phase I funding agreements. The outline that follows is illustrative of the types of clauses to which the contractor will be committed. This list should not be understood to represent a complete list of clauses to be included in Phase I funding agreements, or to be specific wording of such clauses. Copies of complete terms and conditions are available upon request."

J. *Summary Statements.* The following are illustrative of the type of summary statements to be included immediately following the statement in the subparagraph I. These statements are examples only and may vary depending upon the type of funding agreement.

1. *Standards of Work.* Work performed under the funding agreement must conform to high professional standards.

2. *Inspection.* Work performed under the funding agreement is subject to government inspection and evaluation at all times.

3. *Examination of Records.* The Comptroller General or other Federal auditor organization shall have the right to examine any directly pertinent records of the awardee involving transactions related to this funding agreement.

4. *Default.* The government may terminate the funding agreement if the contractor fails to perform the work contracted.

5. *Termination for Convenience.* The STTR funding agreement may be terminated at any time by the government if it deems termination to be in its best interest, in which case the awardee will be compensated for work performed and for reasonable termination costs.

6. *Disputes.* Any dispute concerning the funding agreement which cannot be resolved by agreement shall be decided by the contracting officer with right of appeal.

7. *Contract Work Hours.* The awardee may not require an employee to work more than eight hours a day or forty hours a week unless the employee is compensated accordingly (e.g., overtime pay).

8. *Equal Opportunity.* The awardee will not discriminate against any employee or applicant for employment because of race, color, religion, sex, or national origin.

9. *Affirmative Action for Veterans.* The awardee will not discriminate against any employee or application for employment because he or she is a disabled veteran or veteran of the Vietnam era.

10. *Affirmative Action for Handicapped.* The awardee will not discriminate against any employee or applicant for employment because he or she is physically or mentally handicapped.

11. *Officials Not To Benefit.* No government official shall benefit personally from the STTR funding agreement.

12. *Covenant Against Contingent Fees.* No person or agency has been employed to solicit or secure the funding agreement upon an understanding for compensation except bonafide employees or commercial agencies maintained by the awardee for the purpose of securing business.

13. *Gratuities.* The funding agreement may be terminated by the government if any gratuities have been offered to any representative of the government to secure the contract.

14. *Patent Infringement.* The awardee shall report each notice or claim of patent infringement based on the performance of the funding agreement.

K. *Additional Information.* Information pertinent to an understanding of the administration requirements of STTR proposals and funding agreements not included elsewhere shall be included in this section. As a minimum, statements essentially as follows shall be included under "Additional Information" in STTR Program solicitations:

1. This program solicitation is intended for informational purposes and reflects current planning. If there is any inconsistency between the information contained herein and the terms of any resulting STTR funding agreement, the terms of the funding agreement are controlling.

2. Before award of an STTR funding agreement, the government may request the proposer to submit certain organizational, management, personnel, and financial information to assure responsibility of the proposer.

3. The government is not responsible for any monies expended by the proposer before award of any funding agreement.

4. This program solicitation is not an offer by the government and does not obligate the government to make any specific number of awards. Also, awards under the STTR Program are contingent upon the availability of funds.

5. The STTR Program is not a substitute for existing unsolicited proposal mechanisms. Unsolicited proposals shall not be accepted under the STTR Program in either Phase I or Phase II.

6. If an award is made pursuant to a proposal submitted under this STTR Program solicitation, the contractor or grantee or party to a cooperative agreement will be required to certify that he or she has not previously been, nor is currently being, paid for essentially equivalent work by any agency of the Federal government.

VI. Submission of Proposals

A. This section shall clearly specify the closing date on which all proposals are due to be received.

B. This section shall specify the number of copies of the proposal that are to be submitted.

C. This section shall clearly set forth the complete mailing and/or delivery address(es) where proposals are to be submitted.

D. This section may include other instructions such as the following:

1. *Bindings.* Please do not use special bindings or covers. Staple the pages in the upper left corner of the cover sheet of each proposal.

2. *Packaging.* All copies of a proposal should be sent in the same package.

VII. Scientific and Technical Information Sources

Wherever descriptions of research topics or subtopics include reference to publications, information on where such publications will normally be available shall be included in a separate

section of the solicitation entitled "Scientific and Technical Information Sources."

VIII. Research Topics

Describe the R/R&D topics and subtopics for which proposals are being solicited sufficiently to inform the proposer of technical details of what is desired while leaving sufficient flexibility in order to obtain the greatest degree of creativity and innovation consistent with the overall objectives of the STTR Programs.

IX. Submission Forms and Certifications

Up to three copies each of proposal preparation forms necessary to the contracting and granting process may be required. This section may include Proposal Summary, Proposal Cover, Budget, Checklist, and other forms the sole purpose of which is to meet the mandate of law or regulation and simplify the submission of proposals.

This section may also include certifying forms required by legislation, regulation or standard operating procedures, to be submitted by the proposer to the contracting or granting agency. This would include certifying forms such as those for the protection of human and animal subjects.

[FR Doc. 93–9905 Filed 4–27–93; 8:45 am]
BILLING CODE 8025–01–M

DEPARTMENT OF STATE

[Public Notice 1799]

Advisory Committee on Historical Diplomatic Documentation; Meeting

The Advisory Committee on Historical Diplomatic Documentation will meet May 20–21, 1993, at 9:30 a.m. in the Department of State.

The Committee will meet in open session from 9:30 a.m. on the morning of Thursday, May 20, 1993, until noon of that day, in room 1408, Main State. The remainder of the Committee's sessions, until the end of this meeting on Friday, May 21, at 4 p.m., will be closed to the public in accordance with section 10(d) of the Federal Advisory Committee Act (Pub. L. 92–463), and will be held in room 1205, Main State. It has been determined that discussion during these portions of the meeting will involve consideration of matters not subject to public disclosure under 5 U.S.C. 552b (c)(1), and that the public interest requires that such activities will be withheld from disclosure.

Questions concerning the meeting should be directed to William Z. Slany, Executive Secretary, Advisory Committee on Historical Diplomatic Documentation, Department of State, Office of the Historian, Washington, DC, 20520, telephone (202) 663–1123.

Dated: April 22, 1993.

William Z. Slany,

Executive Secretary.

DEPARTMENT OF THE TREASURY

Public Information Collection Requirements Submitted to OMB for Review

Dated: April 21, 1993.

The Department of Treasury has submitted the following public information collection requirement(s) to OMB for review and clearance under the Paperwork Reduction Act of 1980, Public Law 96–511. Copies of the submission(s) may be obtained by calling the Treasury Bureau Clearance Officer listed. Comments regarding this information collection should be addressed to the OMB reviewer listed and to the Treasury Department Clearance Officer, Department of the Treasury, room 3171 Treasury Annex, 1500 Pennsylvania Avenue, NW., Washington, DC 20220.

Bureau of Alcohol, Tobacco and Firearms

OMB Number: 1512–0057
Form Numbers: ATF F 487–B (5107.7)
Type of Review: Extension
Title: Application and Permit to Ship Liquors and Articles of Puerto Rican Manufacture Taxpaid.
Description: ATF F 487–B (5107.7) is used to document the shipment of tax paid Puerto Rican liquors and articles into the United States. The form is verified by Puerto Rican and U.S. Treasury officials to certify that products are either taxpaid or deferred under an appropriate bond. Serves as method of protection of the revenue.
Respondents: Businesses or other for-profit
Estimated Number of Respondents: 20
Estimated Burden Hours Per Respondent: 30 minutes
Frequency of Response: On occasion
Estimated Total Reporting Burden: 100 hours

OMB Number: 1512–0167
Form Number: ATF F 3072 (5210.14)
Type of Review: Extension
Title: Transportation in Bond, and Notice of Release of Puerto Rican Cigars, Cigarette Papers, or Cigarette Tubes.
Description: ATF 3072 (5210.14) is used to document the shipment of taxable tobacco products brought into the United States in bond from Puerto Rico. The form documents certification by ATF to account for the tax liability as well as any adjustments assessed to the bonded licensee. The form also describes the shipment and identification of licensee who receives the products.
Respondents: Businesses or other for-profit
Estimated Number of Respondents: 50
Estimated Burden Hours Per Respondent: 15 minutes
Frequency of Response: On occasion
Estimated Total Reporting Burden: 200 hours

OMB Number: 1512–0171
Form Number: ATF F 3373 (5220.3)
Type of Review: Extension
Title: Inventory—Export Warehouse Proprietor.
Description: This form is necessary to establish the contingent tax liability on tobacco products on the bonded premises of an export tobacco warehouse. The inventory occurs at the beginning and closing of the business and upon the request of ATF.
Respondents: Businesses or other for-profit, Small businesses or organizations
Estimated Number of Respondents: 10
Estimated Burden Hours Per Respondent: 5 hours
Frequency of Response: On occasion
Estimated Total Reporting Burden: 50 hours

OMB Number: 1512–0493
Form Number: ATF F 5300.3
Type of Review: Extension
Title: Letterhead Request for Information in Regard to Federal Firearms Dealer's Records (Dealer's Records of Acquisition, Disposition and Supporting Data).
Description: This letter gives the user a simplified format to list the required information ATF needs to perform its functions in regard to the law. The respondent saves time because the questions are simple and a return address is supplied. The form is used to maintain a current status of firearms licensees.
Respondents: Individuals or households, Businesses or other for-profit, Small businesses or organizations
Estimated Number of Respondents: 28,000
Estimated Burden Hours Per Respondent: 5 minutes
Frequency of Response: On occasion
Estimated Total Reporting Burden: 2,380 hours
Clearance Officer: Robert N. Hogarth, (202) 927–8930, Bureau of Alcohol,

Tobacco and Firearms, Room 3200, 650 Massachusetts Avenue, NW., Washington, DC 20226.

OMB Reviewer: Milo Sunderhauf, (202) 395–6880, Office of Management and Budget, Room 3001, New Executive Office Building, Washington, DC 20503.

Lois K. Holland,

Departmental Reports, Management Officer.

[FR Doc. 93–9891 Filed 4–27–93; 8:45 am]

BILLING CODE 4830–31–M

Public Information Collection Requirements Submitted to OMB for Review

Dated: April 22, 1993.

The Department of Treasury has submitted the following public information collection requirement(s) to OMB for review and clearance under the Paperwork Reduction Act of 1980, Public Law 96–511. Copies of the submission(s) may be obtained by calling the Treasury Bureau Clearance Officer listed. Comments regarding this information collection should be addressed to the OMB reviewer listed and to the Treasury Department Clearance Officer, Department of the Treasury, Room 3171 Treasury Annex, 1500 Pennsylvania Avenue, NW., Washington, DC 20220.

Internal Revenue Service

OMB Number: 1545–0004

Form Number: IRS Form SS–8

Type of Review: Revision

Title: Determination of Employee Work Status for Purposes of Federal Employment Taxes and Income Tax Withholding

Description: This form is used by employers and workers to furnish information to IRS in order to obtain a determination as to whether a worker is an employee for purposes of Federal employment taxes and income tax withholding. IRS uses the information on Form SS–8 to make the determination.

Respondents: Individuals or households, State or local governments, Farms, Businesses or other for-profit, Federal agencies or employees, Non-profit institutions, Small businesses or organizations.

Estimated Number of Respondents/ Recordkeepers: 9,730

Estimated Burden Hours Per Respondent/Recordkeeper:

Recordkeeping—34 hours, 41 minutes

Learning about the law or the form—6 minutes

Preparing and sending the form to the IRS—40 minutes

Frequency of Response: On occasion

Estimated Total Reporting Burden: 344,831 hours

Clearance Officer: Garrick Shear, (202) 622–3869, Internal Revenue Service, Room 5571, 1111 Constitution Avenue, NW., Washington, DC 20224.

OMB Reviewer: Milo Sunderhauf, (202) 395–6880, Office of Management and Budget, Room 3001, New Executive Office Building, Washington, DC 20503.

Lois K. Holland,

Departmental Reports, Management Officer.

[FR Doc. 93–9890 Filed 4–27–93; 8:45 am]

BILLING CODE 4830–01–M

Public Information Collection Requirements Submitted to OMB for Review

Dated: April 21, 1993.

The Department of Treasury has submitted the following public information collection requirement(s) to OMB for review and clearance under the Paperwork Reduction Act of 1980, Public Law 96–511. Copies of the submission(s) may be obtained by calling the Treasury Bureau Clearance Officer listed. Comments regarding this information collection should be addressed to the OMB reviewer listed and to the Treasury Department Clearance Officer, Department of the Treasury, Room 3171 Treasury Annex, 1500 Pennsylvania Avenue, NW., Washington, DC 20220.

U.S. Customs Service

OMB Number: 1515–0129

Form Number: None

Type of Review: Extension

Title: Change in Status of Transaction

Description: The person submitting a request for a ruling in connection with a Customs transaction should advise Customs in writing when a transaction described as prospective becomes current. This is essential so that the field office concerned is advised of the fact that the ruling is pending.

Respondents: Businesses or other for-profit, Small businesses or organizations

Estimated Number of Respondents: 40

Estimated Burden Hours Per Respondent: 1 hour

Frequency of Response: On occasion

Estimated Total Reporting Burden: 1 hour

Clearance Officer: Ralph Meyer (202) 927–1552, U.S. Customs Service, Paperwork Management Branch, room 6316, 1301 Constitution Avenue, NW., Washington, DC 20229.

OMB Reviewer: Milo Sunderhauf (202) 395–6880, Office of Management and Budget, room 3001, New Executive Office Building, Washington, DC 20503.

Lois K. Holland,

Departmental Reports Management Officer.

[FR Doc. 93–9892 Filed 4–27–93; 8:45 am]

BILLING CODE 4820–02–M

Sunshine Act Meetings

Federal Register
Vol. 58, No. 80
Wednesday, April 28, 1993

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 MINE SAFETY AND HEALTH REVIEW COMMISSION

DATE: Week of April 26, 1993.

PLACE: Room 600, 1730 K Street, NW., Washington, DC.

STATUS: Open and Closed.

MATTERS TO BE CONSIDERED:

Tuesday, April 27, 1993

10:00 a.m., the Commission will hear oral argument on the following in open session:

Air Products & Chemicals, Inc., Docket No. PENN 91–1488–R (Issues include whether Air Product's coal handling facilities at the Cambria Co-Generation Facility are subject to the jurisdiction of the Federal Mine Safety and Health Act of 1977.)

Immediately following oral argument, the Commission will consider and act upon this matter. This meeting will be closed pursuant to 5 U.S.C. § 552b(c)(10).

Wednesday, April 28, 1993

10:00 a.m., the Commission will hear oral argument on the following in open session:

Twentymile Coal Co., Docket No. WEST 91–449 (Issues include whether the judge erred in finding that Twentymile's violation of 30 CFR 70.100(a) was of a significant and substantial nature.)

Immediately following oral argument, the Commission will consider and act upon this matter. This meeting will be closed pursuant to 5 U.S.C. § 552b(c)(10).

Thursday, April 29, 1993

10:00 a.m., the Commission will hear oral argument on the following in open session:

Asarco, Inc., Docket No. WEST 92–624–RM (Issues include whether the judge erred in finding that Asarco violated 30 CFR 57.3360 by failing to provide adequate ground support.)

Immediately following oral argument, the Commission will consider and act upon this matter. This meeting will be closed pursuant to 5 U.S.C. § 552b(c)(10).

Any person wishing to attend any of these oral arguments 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(e).

CONTACT PERSON FOR MORE INFO: Jean Ellen (202) 653–5629/(202) 708–9300 for TDD Relay/1–800–877–8339 for toll free.

Dated: April 19, 1993.

Jean H. Ellen,

Agenda Clerk.

[FR Doc. 93–10034 Filed 4–26–93; 11:01 am]

BILLING CODE 6735–01–M

BOARD OF GOVERNORS OF THE FEDERAL RESERVE SYSTEM

FEDERAL REGISTER CITATION OF PREVIOUS ANNOUNCEMENT: 58 FR 19874, April 16, 1993.

PREVIOUSLY ANNOUNCED TIME AND DATE OF THE MEETING: Approximately 11:00 a.m., Wednesday, April 21, 1993, following a recess at the conclusion of the open meeting.

CHANGES IN THE MEETING: Addition of the following closed item(s) to the meeting:

Briefing on bank examination policy.

CONTACT PERSON FOR MORE INFORMATION: Mr. Joseph R. Coyne, Assistant to the Board; (202) 452–3204.

Dated: April 26, 1993.

Jennifer J. Johnson,

Associate Secretary of the Board.

[FR Doc. 93–10099 Filed 4–26–93; 2:08 pm]

BILLING CODE 6210–01–M

BOARD OF GOVERNORS OF THE FEDERAL RESERVE SYSTEM

TIME AND DATE: 11:30 a.m., Monday, May 3, 1993.

PLACE: Marriner S. Eccles Federal Reserve Board Building, C Street entrance between 20th and 21st Streets, N.W., Washington, D.C. 20551.

STATUS: Closed.

MATTERS TO BE CONSIDERED:

1. Personnel actions (appointments, promotions, assignments, reassignments, and salary actions) involving individual Federal Reserve System employees.

3. Any items carried forward from a previously announced meeting.

CONTACT PERSON FOR MORE INFORMATION: Mr. Joseph R. Coyne, Assistant to the Board; (202) 452–3204. You may call (202) 452–3207, beginning at approximately 5 p.m. two business days before this meeting, for a recorded announcement of bank and bank holding company applications scheduled for the meeting.

Dated: April 23, 1993.

Jennifer J. Johnson,

Associate Secretary of the Board.

[FR Doc. 93–10054 Filed 4–26–93; 11:19 am]

BILLING CODE 6210–01–M

DEPARTMENT OF JUSTICE

UNITED STATES PAROLE COMMISSION

Record of Vote of Meeting Closure

(Public Law 94–409)

(5 U.S.C. Sec. 552b)

I, Edward F. Reilly, Jr., Chairman of the United States Parole Commission, presided at a meeting of said Commission which started at approximately nine-thirty a.m. on Monday, April 19, 1993 at the Commission's Central Office, 5550 Friendship Boulevard, Chevy Chase, Maryland 20815. The purpose of the meeting was to decide fourteen appeals from National Commissioners' decisions pursuant to 28 C.F.R. Section 2.27. Further, also discussed was the approval of parole hearing examiner appointments. Five Commissioners were present, constituting a quorum when the vote to close the meeting was submitted.

Public announcement further describing the subject matter of the meeting and certifications of General Counsel that this meeting may be closed by vote of the Commissioners present were submitted to the Commissioners prior to the conduct of any other business. Upon motion duly made, seconded, and carried, the following Commissioners voted that the meeting be closed: Edward F. Reilly, Jr., Carol Pavilack Getty, Jasper Clay, Jr., Vincent Fechtel, Jr., and John R. Simpson.

IN WITNESS WHEREOF, I make this official record of the vote taken to close this meeting and authorize this record to be made available to the public.

Dated: April 19, 1993.

Edward F. Reilly, Jr.,

Chairman, U.S. Parole Commission.

[FR Doc. 93–10100 Filed 4–26–93; 2:08 pm]

BILLING CODE 4410–01–M

NATIONAL COMMISSION ON LIBRARIES AND INFORMATION SCIENCE

Open Forum on Children and Youth Services: Redefining the Federal Role for Libraries

DATE AND TIME: May 4, 1993–1:00–4:30 p.m.; May 5, 9 a.m.–4:30 p.m.

PLACE: Boston Public Library, Rabb Lecture Hall, 666 Boylston Street, Boston, MA 02117.

STATUS: Open.

Purpose: Open forum on the changing role of the Federal government in support of library and information services, and literacy programs for children and youth. The forum provides an opportunity for representatives from school library media centers, public libraries, academic libraries, educational, literacy, and information services organizations, companies, associations, and institutions to offer comments, observations, and suggestions related to Federal roles and responsibilities for library and information services, and literacy programs offered to children and youth.

Parties interested in presenting oral or written statements should notify Kim Miller or Peter Young at NCLIS, 1110 Vermont Avenue, NW., Suite 820, Washington, DC 20005 (202–606–9200) by 30 April 1993. Written statements must be received at the NCLIS office by 15 June 1993.

To request further information or to make special arrangements for physically challenged persons, contact Barbara Whiteleather, NCLIS, no later than one week in advance of the forum.

Dated: April 15, 1993.

Peter R. Young,

Executive Director.

[FR Doc. 93–10122 Filed 4–26–93; 4:00 pm]

BILLING CODE 7527–01–M

SECURITIES AND EXCHANGE COMMISSION

Agency Meeting

"FEDERAL REGISTER" CITATION OF PREVIOUS ANNOUNCEMENT: [58 FR 21775 April 26, 1993].

STATUS: Open meeting.

PLACE: 450 Fifth Street, N.W., Washington, D.C.

DATE PREVIOUSLY ANNOUNCED: Friday, April 16, 1993.

CHANGE IN THE MEETING: Time/Room change.

An open meeting scheduled for Tuesday, April 27, 1993, at 3:30 p.m. has been changed to 2:30 p.m., in Room 6059.

Commissioner Schapiro, as duty officer, determined that Commission business required the above change and that no earlier notice thereof was possible.

At times, changes in Commission priorities require alterations in the scheduling of meeting items. For further information and to ascertain what, if any, matters have been added, deleted or postponed, please contact: George Kramer at (202) 272–2000.

Dated: April 26, 1993.

Margaret McFarland,

Deputy Secretary.

[FR Doc. 93–10119 Filed 4–26–93; 4:00 pm]

BILLING CODE 8010–01–M

Corrections

Federal Register
Vol. 58, No 80
Wednesday, April 28, 1993

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

Agricultural Marketing Service

7 CFR Part 1160

[DA–92–29]

RIN 0581–AA44

Fluid Milk Promotion Program; Invitation To Submit Comments and Notice of Public Meeting

Correction

In proposed rule document 93–9282 beginning on page 21512 in the issue of Wednesday, April 21, 1993, make the following correction:

§ 1160.501 [Corrected]

1. On page 21518, in the third column, in § 1160.501(a), in the fifth line, "1990O(c)" should read "1999O(c)".

BILLING CODE 1505–01–D

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

18 CFR Part 365

[Docket No. RM93–1–001; Order No. 550–A]

Filing Requirements and Ministerial Procedures for Persons Seeking Exempt Wholesale Generator Status; Order Addressing Motions for Rehearing, Reconsideration and Clarification; Amending Regulations; and Interpreting PUHCA Section 32(a)(1)

Correction

In rule document 93–9178 beginning on page 21250 in the issue of Tuesday, April 20, 1993, the Docket No. should read as set forth above.

BILLING CODE 1505–01–D

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket Nos. ER93–538–000, et al.]

PacifiCorp, et al.; Electric Rate, Small Power Production, and Interlocking Directorate Filings

Correction

In notice document 93–9021 beginning on page 21149 in the issue of Monday, April 19, 1993, make the following corrections:

1. On page 21149, in the third column, under **5. City of Albany**, "[Docket No. EG93–30–000]" should read "[Docket No. EL93–30–000]".

2. On page 21150, in the second column, under **12. Gulf States Utilities Co.**, "[Docket No. ER93–31–000]" should read "[Docket No. ES93–31–000]".

BILLING CODE 1505–01–D

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. TQ93–8–17–000]

Texas Eastern Transmission Corp.; Proposed Changes in FERC Gas Tariff

Correction

In notice document 93–9144 appearing on page 21301 in the issue of Tuesday, April 20, 1993, in the first column, following the heading, "**April 15, 1993.**" should read "**April 14, 1993.**".

BILLING CODE 1505–01–D

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

49 CFR Part 571

[Docket No. 74–09; Notice 28]

RIN 2127–AE28

Federal Motor Vehicle Safety Standards; Child Restraint Systems

Correction

In rule document 93–8793 beginning on page 19776 in the issue of Friday, April 16, 1993, make the following corrections:

§ 571.213 [Corrected]

1. On page 19779, in the third column, in paragraph number 5., in the firt line, insert "S5.1.3.1" in front of "(introductory text)".

2. On page 19780, in the first column, in paragraph number 7., in the first line, "S5.2.2.2(a)" should read "S5.2.2.2(a)(2)".

3. On the same page, in the second column, in the third line, "restrain" should read "restraint".

BILLING CODE 1505–01–D

federal register

Wednesday
April 28, 1993

Part II

Department of Health and Human Services

Food and Drug Administration

21 CFR Part 876

Gastroenterology-Urology Devices; Effective Date of the Requirement for Premarket Approval of the Penile Inflatable Implant; Proposed Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 876

[Docket No. 92N–0445]

Gastroenterology-Urology Devices; Effective Date of the Requirement for Premarket Approval of the Penile Inflatable Implant

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule; opportunity to request a change in classification.

SUMMARY: The Food and Drug Administration (FDA) is proposing to require the filing of a premarket approval application (PMA) or a notice of completion of a product development protocol (PDP) for the penile inflatable implant, a medical device. The agency is also summarizing its proposed findings regarding the degree of risk of illness or injury designed to be eliminated or reduced by requiring the device to meet the statute's approval requirements, and the benefits to the public from the use of the device. In addition, FDA is announcing an opportunity for interested persons to request that the agency change the classification of the device based on new information.

DATES: Written comments by June 28, 1993; requests for a change in classification by May 13, 1993. FDA intends that if a final rule is issued, based on this proposed rule, PMA's will be required to be submitted within 90 days of the effective date of the final rule.

ADDRESSES: Written comments or requests for a change in classification to the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Mark D. Kramer, Center for Devices and Radiological Health (HFZ–470), Food and Drug Administration, 1390 Piccard Dr., Rockville, MD 20850, 301–427–1194.

SUPPLEMENTARY INFORMATION:

I. Background

Section 513 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360c) requires the classification of medical devices into one of three regulatory classes: Class I (general controls), class II (special controls), and class III (premarket approval). Generally, devices that were on the market before May 28, 1976, the date of enactment of the Medical Device Amendments of 1976 (the amendments) (Pub. L. 94–295), and devices marketed on or after that date that are substantially equivalent to such devices, have been classified by FDA. For the sake of convenience, this preamble refers to both the devices that were on the market before May 28, 1976, and the substantially equivalent devices that were marketed on or after that date as "preamendments devices."

Section 515(b)(1) of the act (21 U.S.C. 360e(b)(1)) establishes the requirement that a preamendments device that FDA has classified into class III is subject to premarket approval. A preamendments class III device may be commercially distributed without an approved PMA or declared completed PDP until 90 days after FDA's promulgation of a final rule requiring premarket approval for the device, or 30 months after final classification of the device under section 513 of the act, whichever is later. Also, a preamendments device is not required to have an approved investigational device exemption (IDE) (21 CFR part 812) contemporaneous with its interstate distribution until the date identified by FDA in the final rule requiring the submission of a PMA for the device.

Section 515(b)(2)(A) of the act provides that a proceeding to promulgate a final rule to require premarket approval shall be initiated by publication, in the **Federal Register**, of a notice of proposed rulemaking containing:

(1) The proposed rule;

(2) Proposed findings with respect to the degree of risk of illness or injury designed to be eliminated or reduced by requiring the device to have an approved PMA or declared completed PDP and the benefit to the public from the use of the device;

(3) An opportunity for the submission of comments on the proposed rule and the proposed findings; and

(4) An opportunity to request a change in the classification of the device based on new information relevant to the classification of the device.

Section 515(b)(2)(B) of the act provides that if FDA receives a request for a change in the classification of the device within 15 days of the publication of the notice, FDA shall, within 60 days of the publication of the notice, consult with the appropriate FDA advisory committee and publish a notice denying the request for change of classification or announcing its intent to initiate a proceeding to reclassify the device under section 513(e) of the act. If FDA does not initiate such a proceeding, section 515(b)(3) of the act provides that FDA shall, after the close of the comment period on the proposed rule and consideration of any comments received, promulgate a final rule to require premarket approval, or publish a notice terminating the proceeding. If FDA terminates the proceeding, FDA is required to initiate reclassification of the device under section 513(e) of the act, unless the reason for termination is that the device is a banned device under section 516 of the act (21 U.S.C. 360f).

If a proposed rule to require premarket approval for a preamendments device is made final, section 501(f)(2)(A) of the act (21 U.S.C. 351(f)(2)(A)) requires that a PMA or notice of completion of a PDP for any such device be filed within 90 days of the date of promulgation of the final rule or 30 months after final classification of the device under section 513 of the act, whichever is later. If a PMA or notice of completion of a PDP is not filed by the later of the two dates, commercial distribution of the device is required to cease. The device may, however, be distributed for investigational use if the manufacturer, importer, or other sponsor of the device complies with the IDE regulations. If a PMA or notice of completion of a PDP is not filed by the later of the two dates, and no IDE is in effect, the device is deemed to be adulterated within the meaning of section 501(f)(1)(A) of the act, and subject to seizure and condemnation under section 304 of the act (21 U.S.C. 334) if its distribution continues. Shipment of the device in interstate commerce will be subject to injunction under section 302 of the act (21 U.S.C. 332), and the individuals responsible for such shipment will be subject to prosecution under section 303 of the act (21 U.S.C. 333). FDA has in the past requested that manufacturers take action to prevent the further use of devices for which no PMA or notice of completion of a PDP has been filed and may determine that such a request is appropriate for penile inflatable implants.

The act does not permit an extension of the 90-day period after promulgation of a final rule within which an application or a notice is required to be filed. The House Report on the amendments states that "the thirty month 'grace period' afforded after classification of a device into class III * * * is sufficient time for manufacturers and importers to develop the data and conduct the investigations necessary to support an application for premarket approval." (H. Rept. 94–853, 94th Cong., 2d sess. 42 (1976).)

A. Classification of the Penile Inflatable Implant

In the **Federal Register** of November 23, 1983 (48 FR 53023), FDA issued a final rule classifying the penile inflatable implant into class III (21 CFR 876.3350). The preamble to the proposal to classify the device (46 FR 7577, January 23, 1981) included the recommendation of the Gastroenterology-Urology Devices Advisory Panel (the Panel), an FDA advisory committee, which met on September 26 and 27, 1976, regarding the classification of the device. The Panel recommended that the device be in class III, and identified certain risks to health presented by the device. FDA agreed with the Panel's recommendation and proposed that the penile inflatable implant be classified into class III. The proposal stated that the agency believed that insufficient information existed to determine that general controls would provide reasonable assurance of the safety and effectiveness of the device, or to establish a performance standard to provide this assurance. The proposal stated that premarket approval is necessary for this device because it presents a potential unreasonable risk of injury due to: (1) Additional surgery that might be required as a result of a malfunction of the device; (2) infection resulting from defects in the design, construction, packaging, or processing of the device; and (3) adverse tissue reaction and erosion. In support of its proposal to strengthen regulatory surveillance of the device, FDA cited references supporting the proposed classification.

The preamble to the November 23, 1983 final rule (48 FR 53012) classifying the device into class III advised that the earliest date by which PMA's for the device could be required was June 30, 1986, or 90 days after promulgation of a rule requiring premarket approval for the device, whichever occurs later.

In the **Federal Register** of January 6, 1989 (54 FR 550), FDA published a notice of intent to initiate proceedings to require premarket approval of 31 preamendments class III devices assigned a high priority by FDA for the application of premarket approval requirements. Among other things, the notice described the factors FDA takes into account in establishing priorities for proceedings under section 515(b) of the act for promulgating final rules requiring that preamendments class III devices have approved PMA's. Although the penile inflatable implant was not included in this list of 31 devices, the agency has received more than 6,500 Medical Device Reports (MDR's) for this device since 1984. Additionally, the types of problems identified in these reports are similar to those identified during the classification proceedings of the device. Therefore, FDA has determined that the penile inflatable implant identified in 21 CFR 876.3350 has a high priority for initiating a proceeding to require premarket approval. Accordingly, FDA is commencing a proceeding under section 515(b) of the act to require that the penile inflatable implant has an approved PMA or a declared completed PDP.

B. Dates New Requirements Apply

In accordance with section 515(b) of the act, FDA is proposing to require that a PMA or notice of completion of a PDP be filed with the agency for the penile inflatable implant within 90 days after promulgation of any final rule based on this proposal. An applicant whose device was in commercial distribution before May 28, 1976, or has been found by FDA to be substantially equivalent to such a device, will be permitted to continue marketing the penile inflatable implant during FDA's review of the PMA or notice of completion of the PDP. FDA intends to complete the review of any PMA for the device within 180 days and a notice of completion of a PDP within 90 days. FDA cautions that, under section 515(d)(1)(B)(i) of the act, FDA may not enter into an agreement to extend the review period for a PMA beyond 180 days unless the agency finds that "* * * the continued availability of the device is necessary for the public health."

FDA intends that, under § 812.2(d) (21 CFR 812.2(d)), the preamble to any final rule based on this proposal will state that, as of the date on which a PMA or notice of completion of a PDP is required to be filed, the exemptions in § 812.2 (c)(1) and (c)(2) from the requirements of the IDE regulations for preamendments class III devices will cease to apply to any penile inflatable implant which is: (1) Not legally on the market on or before that date, or (2) legally on the market on or before that date but for which a PMA is not filed by that date, or for which PMA approval has been denied or withdrawn.

If a PMA or notice of completion of a PDP for the penile inflatable implant is not filed with FDA within 90 days after the date of promulgation of any final rule requiring premarket approval for the device, commercial distribution of the device must cease. The device may be distributed for investigational use only if the requirements of the IDE regulations regarding significant risk devices are met. The requirements for significant risk devices include submitting an application to FDA for its review and approval. An approved IDE is required to be in effect before an investigation of the device may be initiated or continued. FDA, therefore, cautions that IDE applications should be submitted to FDA at least 30 days before the end of the 90-day period to avoid interrupting investigations.

C. Description of the Device

A penile inflatable implant is a device that consists of two inflatable cylinders implanted in the penis, connected to a reservoir filled with radiopaque fluid implanted in the abdomen, and a subcutaneous manual pump implanted in the scrotum. These devices may be constructed from silicone or polyurethane elastomers and some models also contain silicone gel. Also included within this device classification are those models of the penile inflatable implant that have the reservoir and the pump combined into one component that is implanted within the scrotum, or that have a reservoir and pump combined within each of the two cylinders. When the cylinders are inflated, they provide rigidity to the penis. These devices are used in the treatment of erectile impotence.

The proposed rule to require premarket approval of penile inflatable implants applies to legally marketed penile inflatable implants identified above that were commercially distributed before May 28, 1976, and to devices introduced into commercial distribution since that date that have been found to be substantially equivalent to such penile inflatable implants.

D. Proposed Findings With Respect to Risks and Benefits

As required by section 515(b) of the act, FDA is publishing its proposed findings regarding: (1) The degree of risk of illness or injury designed to be eliminated or reduced by requiring the penile inflatable implant to have an approved PMA, and (2) the benefits to the public from the use of the device.

E. Degree of Risk

After considering the information discussed by the Panel during the classification proceedings, as well as the published literature and MDR's, FDA has evaluated the risks associated with the penile inflatable implant. FDA now believes that the following are significant risks associated with the use of the penile inflatable implant:

1. Infection

Infection, a risk of any surgical implant procedure, is associated with the use of penile inflatable implants (Refs. 1 through 7). It is one of the most serious potential complications of implantation and can cause significant patient morbidity (Refs. 3 through 6). Infections usually result in removal of the device and may result in an inability to replace the device due to corporeal fibrosis and cavernositis (Refs. 1 and 6 through 8). Occasionally, infections lead to genital gangrene and extensive tissue loss (Refs. 1 and 9). As in any implantation procedure, compromised device sterility and surgical techniques may be major contributing factors to this risk (Refs. 1 and 2). Additionally, a life-long risk for hematogenously seeded infection probably exists for these patients and antibacterial prophylaxis for subsequent dental and surgical procedures may be needed (Refs. 1, 3, and 7).

2. Migration and Extrusion of the Penile Inflatable Implant

Migration, in general, is the movement of the penile inflatable implant within the body. Extrusion is the specific type of migration where the penile inflatable implant occupies an abnormal external position (Ref. 10). Implant extrusion is usually associated with concurrent wound dehiscence at the incision site (Refs. 2, 4, 7, and 11 through 15), but proximal migration has also been reported (Refs. 2, 7, and 16). Migration of the reservoir intra-abdominally, either shifting to an open space or over an organ; movement of the pump to midscrotum; and movement of the cylinder to the site of perforation (e.g., extrusion in the urethra), posteriorly into the buttocks, and from one corpus cavernosum to the opposite side have all been reported. Component migration increases the risk of pressure necrosis and, in some cases, of erosion (Refs. 2, 14, and 17 through 20). Migration and extrusion of the penile inflatable implant sometimes requires surgical intervention (Refs. 2, 14, 17, 19, and 21).

3. Erosion of the Penile Inflatable Implant

Erosion is the destruction of tissue (Ref. 10) which, with penile inflatable implants, usually occurs distally through the urethra on the glans penis by the cylinders (Refs. 2, 17, 20, 22, and 23). Erosion has also been reported through adjacent visceral structures (bowel, bladder, ileal conduit, etc.) by the reservoir and through the scrotal wall by the pump (Refs. 12, 16, and 22). Erosion through the urethra has been associated primarily with intermittent and/or indwelling catheterization (Ref. 23). In addition, erosion into the tunica albuginea by the cylinders has been noted (Refs. 2, 24, and 25). Skin erosion has been reported following implantation of the penile inflatable implant due to the insertion of an oversized device (Ref. 26), vigorous dilatation of the cavernosa or supporting structures at the time of implantation (Refs. 2 and 7), aggressive dissection of the subdartos pocket (Refs. 2 and 27), or other iatrogenic injury to the urethra. Skin erosion may result in subsequent infection or device extrusion.

4. Fibrous Capsule Formation

Fibrous capsules form around the various components of penile inflatable implants (Refs. 1, 2, and 28 through 30). The formation of fibrous encapsulations around the reservoir and/or pump may prevent complete deflation of the cylinders (Refs. 5, 19, 29, and 31) or cause spontaneous inflation of the cylinders (Ref. 32). If leakage occurs from the reservoir, the fibrous capsule becomes much thicker and, if adhesions form to adjacent structures, rupture of the fibrous capsule during reinflation of the reservoir can cause damage to adjacent structures (Ref. 30). Problems due to encapsulation may sometimes be corrected by device manipulation (Refs. 31 and 32), but corrective surgery may also be required (Refs. 19, 32, and 33). Additionally, the fibrous capsule that forms may cause genital changes which are not reversed by explantation of the device (Ref. 31).

The formation of fibrous capsules has been reported to be related to a foreign body reaction (Refs. 1 and 28) and a reaction to silicone (Ref. 31).

5. Mechanical Malfunctions

Mechanical problems with the cylinders of penile inflatable implants are the most frequently cited cause of device failure (Ref. 34). Cylinder leaks can occur as a result of trauma to the cylinders during implantation (Ref. 35), either at the point of connection with the inflation tubing or as a result of friction when the tubing is positioned against the cylinder (Refs. 35 through 39). Cylinder ruptures (Ref. 41), buckling (Refs. 42 through 44) and aneurysms have various etiologies and result when the cylinders spontaneously inflate (Ref. 42), over-inflate, under-inflate, or when inflation is not uniform (Refs. 7, 35, and 45 through 48). Asymmetrical distention of the cylinders can result in penile angulation and a gradual loss of penile rigidity (Ref. 2).

Tubing leaks and kinks can occur when nonreinforced silicone tubing is used or when the tubes separate from the cylinder (Ref. 4). Positioning of the tubing in the mobile scrotum may increase tubing stress, resulting in premature tubing wear (Ref. 4). Folds and kinks can occur in the tubing from the reservoir to the pump when the pump migrates from the scrotum, causing excess tubing length (Refs. 32, 39, and 49). Connector leaks and separations have also been reported (Refs. 4, 50, and 51).

Hypersensitive valves or valve failures that result in inadequate inflation or premature deflation during sexual activity have been reported in the literature (Refs. 39 and 52). Mechanical problems associated with the pump include pump noise, abnormal pump position (e.g., intussusception (Ref. 5), migration (Refs. 32, 39, and 49), and difficulty with inflation/deflation (Refs. 53 and 54). Fibrous encapsulation of the reservoir, which prevents complete cylinder deflation (Ref. 5), has also been documented (Refs. 41, 55, and 56). Fluid leaks from the reservoir result in fluid loss from the device and may result in the need for reoperation (Refs. 40, 42, and 57). Finally, material fatigue will eventually cause most hydraulic penile inflatable implants to malfunction (Ref. 37).

Device malfunctions may require replacement or revision (Ref. 34). When replacement of a malfunctioning device is required, the complication rate is increased (Ref. 4). Multiple revision procedures significantly increase the risk of irreversible fibrotic complications, such as corporeal fibrosis, which decreases penile length and penile function, and partial or complete denervation, which decreases penile sensation (Refs. 2 and 4).

6. Iatrogenic Disorders

Improper device handling (including cutting or nicking of the device), inadequate or vigorous dilatation (Refs. 2, 4, and 7), aggressive dissection (Refs. 2 and 27), malpositioning of the device (Refs. 2, 58, and 59), cylinder suturing (Ref. 58), cylinder cross-over (Refs. 7 and 20), and cylinder missizing (Refs. 26, 52, and 60) are among the preventable complications caused as a result of surgical technique. Iatrogenic causes may be responsible for various adverse conditions (e.g., product damage or failure, "SST deformity," where the glans forms a ventral chordee-like angulation relative to the shaft of the penis (Ref. 2), aneurysm, perforation, erosion, migration, rupture of the corporeal body, infection, sensory loss, and gangrene (Refs. 1, 2, 4, 7, 9, 24,

26, 45, 55, 59 through 64)), necessitating device removal and/or replacement.

7. Patient Dissatisfaction

Patient dissatisfaction with penile inflatable implants results in a high reoperation rate (Ref. 34). Dissatisfaction occurs due to surgical complications such as infection, unresolved pain or fibrotic changes that can result in sensory loss (Refs. 2 and 4), as well as disappointment in cosmetic appearance (Refs. 5 and 70), concealability, (Refs. 39, 52, and 53), rigidity/firmness (Refs. 53, 54, and 66) and decreased sensation (Refs. 54 and 67). Dissatisfaction can result when the patient and/or his partner have unrealistic expectations about the size of the penis after surgery (Ref. 67) (e.g., inadequate penile length and girth (Refs. 5, 54, and 66)), or are unaware of available alternative treatments (Refs. 53, 54, and 66). Dissatisfaction with the device also occurs when the patient has not had proper training in the use of the device or is unwilling and/or unable to follow proper inflation/deflation procedures (Ref. 18).

8. Human Carcinogenicity

Carcinogenesis has been widely discussed as a reputed risk secondary to implantation of any material. Evidence from the literature indicates that, in animal studies, different forms of silicone have been associated with various types of cancer (Refs. 68 through 72). Cases of several types of cancer in humans have been reported in association with various forms of implanted silicone (Refs. 73 through 76).

9. Human Reproductive and Teratogenic Effects

The effect of certain silicone compounds on the reproductive potential of the male is largely unknown. Le Vier and Jankowiak report that at least one form of organosiloxane, which is known to be present in some silicone gels, mimics estrogens in the male rat, leading to rapid testicular atrophy (Ref. 77).

Teratogenesis includes the origin or mode of production of a malformed fetus and the disturbed growth processes involved in the production of a malformed fetus. Studies using silicone fluid in animals have been minimal, and yield contradictory and inconclusive results (Refs. 78 through 80). Prolonged contact with either silicone elastomer, or silicone gel-filled membrane in devices containing silicone gel, presents a potential risk of teratogenicity in humans. Additionally, the theoretical risk of abnormalities appearing later in life in normally appearing offspring also warrants investigation.

10. Immune Related Connective Tissue Disorders—Immunological Sensitization

Immunological sensitization may be a serious risk associated with the implantation of a penile inflatable implant. Immune related connective tissue disorders have been reported in women who have silicone gel-filled devices or who have had silicone injections in augmentation mammoplasty. There are clinical reports of several patients who have undergone augmentation mammoplasty with silicone gel-filled breast prostheses and later presented with connective tissue disease-like syndromes (Ref. 81). Because penile inflatable implants may consist of similar silicone elastomers and gels, further study of the potential risk of immune related connective tissue disorders in humans with these implants is warranted.

11. Biological Effects of Silica

Amorphous (fumed) silica is bound to the silicone in the elastomer of the penile inflatable implant, and may be fibrogenic and immunogenic. Fumed silica and the silicone elastomer each elicit cellular responses in rats (Ref. 82). The biological effects of silica, particularly the immunologic component of these reactions, present a potential risk and need to be examined.

12. Silicone Particle Shedding, Silicone Gel Leakage and Associated Migration

Silicone particle shedding and subsequent migration have been reported with genitourinary prosthetic devices, including penile inflatable implants (Ref. 28). Silicone gel leakage and migration from the silicone elastomer envelope, either from rupture of the envelope or by leaking of the gel through the envelope (gel "bleed"), are also significant risks of penile inflatable implants containing silicone gel. Rupture of the envelope with gel leakage and subsequent migration may be secondary to surgical technique, or may result from mechanical stresses such as device usage, trauma, and wear on the envelope, and necessitates removal of the implant. In addition, silicone gel-filled breast implants are reported to "bleed" micro amounts of silicone through the intact silicone elastomer shell into the surrounding tissues (Refs. 83 through 92). Although diffusion of silicone gel through the elastomer envelope and silicone particle shedding have not specifically been measured in the penile inflatable implant, particle shedding and gel bleed continue to be potential risks with this device and need to be evaluated. Migration of the particles and gel into the human body presents the potential for development of adverse effects such as granulomas or lymphadenopathy (Refs. 28, 73, and 74). The ultimate fate of migrating silicone particles or silicone gel within the body is currently not well understood.

The following potential risk is associated only with those penile inflatable implants that contain polyurethane elastomer.

13. Degradation of Polyurethane Elastomer

The polyurethane elastomer materials, which have been used to cover some penile inflatable implants, may degrade over time and release degradation products such as methylene diamine or toluene diamine, which are potential carcinogens in animals (Refs. 93 and 94).

14. Other Reported Complications

The following are among the additional risks which have also been reported with penile inflatable implants: Hematomas/seromas (Refs. 2, 8, 15, 25, and 42), discomfort/pain (Refs. 2, 15, 21, 29, 31, 32, 42, 54, and 95), penile and scrotal pain (Refs. 5, 13, and 37), scrotal swelling (Ref. 5), scrotal erythema (Ref. 42), scrotal abscess (Ref. 50), scrotal heaviness (Ref. 13), edema (Refs. 2, 5, and 42), adhesions requiring lysis (Ref. 23), inflammatory hydrocele (Ref. 23), ulceration (Ref. 58), necrosis (Refs. 5 and 42), vascular compromise (Refs. 58 and 96), ventral chordee and penile curvature (Refs. 1, 29, 31, and 97), ventral band formation (Ref. 1), ischemia (with resultant loss of tissue) (Ref. 31), genital change (Ref. 31), scarring (Ref. 29), urinary retention (Refs. 95 and 98), inguinal hernia (Ref. 35), difficulty with ejaculation (Ref. 54), phimosis (Ref. 58), allergic reaction to contrast medium (Ref. 40), and deformity (Ref. 54).

F. Benefits of the Device

The penile inflatable implant is intended to provide rigidity to the penis upon demand to simulate an erection, and is indicated in subjects who have lost the ability to produce or maintain an erection sufficient for intromission. Device implantation is a discretionary surgical procedure performed for reasons related to quality of life, rather than medical reasons.

Implants have been used to treat impotence resulting from diabetes mellitus, spinal cord injury, Peyronie's disease, pelvic surgery, priapism, hypertension, coronary artery disease,

and other medical conditions. These devices also have been implanted in men with psychological impotence (Ref. 53).

The loss of sexual function can result in social and psychological problems for the impotent male. Feelings of frustration and despair, the loss of self-esteem, and a sense of being unmasculine often accompany the loss of normal sexual function (Refs. 46, 65, and 99). Such psychological problems can also lead to associated physical manifestations such as hypertension, and some men contemplate suicide (Ref. 65). For single men, impotence may cause the subject to cease normal social interactions (Ref. 11). The partner of the impotent male also suffers, and impotence can be damaging to marriages and relationships (Refs. 46, 65, and 100). Some women feel that their partner's condition is due to their lack of femininity or some sexual failing on their part (Ref. 100).

Implantation of a penile inflatable implant can help to alleviate feelings of inadequacy in impotent males, thereby improving their quality of life (Refs. 46, 54, and 65). Published studies indicate that the recipients of penile inflatable implants exhibit a moderately high degree of satisfaction with respect to sexual function and overall quality of life (Refs. 44, 46, 53, 54, 62, 65, 101, and 102). The literature also notes a positive impact on the partners of males who have received penile implants and on the relationship as a whole (Refs. 46, 65, 101, and 102).

In addition, because device implantation allows for improved intromission, natural methods of conception (as opposed to alternate methods such as artificial insemination) can be utilized to father children by the male who has normal ejaculatory function and semen quality prior to and after implantation.

G. Need for Information for Risk/BenefitAssessment of the Device

As the above sections indicate, there is reasonable knowledge of the risks and benefits associated with the penile inflatable implant. There is, however, insufficient valid scientific evidence to permit FDA to perform a risk/benefit analysis. Therefore, FDA is now seeking further information on the following safety and effectiveness issues associated with the penile inflatable implant:

(1) Long-term safety and effectiveness data for the device is needed. The incidence of implant failure and attendant causes, as well as the incidence of reoperations required, have not been clearly identified. Such device failures include, but are not limited to: Cylinder rupture, leakage, and aneurysm; tubing leakage, wear, and kinking; pump and valve failure; reservoir leakage; and implant migration, extrusion, and erosion. Also, the incidence rates of infection, pain/discomfort, hematoma, edema, ulceration, necrosis, scarring, iatrogenic injury, penile curvature, sensory loss, and patient dissatisfaction secondary to implantation of the penile inflatable implant are poorly understood and need to be studied.

(2) It is unknown for which subgroups of the population with erectile dysfunction the benefits of implantation of penile inflatable implants outweigh the attendant risks. Factors which may increase the rate of complications include the etiology and duration of impotence, concomitant medical conditions, various anatomical abnormalities, patient and/or partner manual dexterity, and prior treatments for the disorder, including prior surgery. An appropriate benefit/risk analysis is needed for each subgroup for whom the device will be indicated.

(3) The required presurgical workup of patients prior to device implantation must be clarified. Because the adverse events that may occur following implantation of the device may not be reversible, investigation is needed to determine which prior conservative therapies a patient should have failed before being considered an appropriate candidate for a penile inflatable implant.

(4) The anatomical and physiological effects of implantation of penile inflatable implants need to be examined. Patient dissatisfaction with penile length and/or girth and rigidity/firmness leading to reoperation need to be factored into the benefit/risk analysis. In addition, the ability of the device to provide adequate rigidity to permit coitus must be substantiated.

(5) The immediate postsurgical and long-term psychological benefits of the device, as compared to presurgical levels, need to be examined and quantified. In order to document the benefits of restoration of erectile function with penile inflatable implants, such factors as patient and partner satisfaction, improved self-image, and improved psychological outlook, need to be studied using well-established standardized tests.

(6) The effect of penile inflatable implant use on future male fertility is poorly understood. The benefits of the ability to conceive naturally as a result of improved intromission following device implantation need to be examined and quantified.

(7) The effect of device implantation on future medical diagnoses and treatments needs to be examined. It is not well understood whether the device's presence may interfere with the ability to diagnose and treat disorders affecting organs or structures in proximity to the implant components.

(8) The incidence and types of problems associated with fibrous capsular formation must be clarified. It is not clear what methods are used in the prevention and treatment of problems arising from capsular formation in patients with penile inflatable implants, nor is it clear how these approaches may reduce the risks associated with use of this device.

(9) The potential risks associated with silicone particle shedding and silicone gel leakage and the subsequent migration of the particles and gel need further clarification. This would include consideration of gel cohesiveness, envelope thickness/strength, diffusion of the gel through the envelope (gel "bleed"), and the role that physical, mechanical, and chemical characteristics of silicone elastomers and gels play in the immediate or long-term rupture of penile inflatable implants.

(10) The potential long-term adverse effects of penile inflatable implants, such as cancer, immune related connective tissue disorders, reproductive and teratogenic effects, and later effects in offspring, are unknown. Likewise, in the polyurethane elastomer covered penile inflatable implant, the long-term effects of the degradation of polyurethane elastomer (such as mechanical integrity and carcinogenicity) are also not understood. The agency notes that neither the silicone particles, which may be shed from the device (Refs. 28, 103, and 104), nor the chemical forms of silicone monomers or other additives, which may leach from the device, have been characterized, and their metabolic fates are not known (Ref. 79). Furthermore, no satisfactory independent study has thoroughly evaluated the chronic long-term toxicology of cross-linked silicone polymers of different molecular sizes. Because young adult males are among the potential recipients of these implants, information regarding the chronic toxic effects including possible reproductive and teratogenic effects of silicone could be of substantial importance in determining the risk to these patients and their offspring.

(11) The malfunction rate and longevity reported for penile inflatable implants have generally not reflected the predictions of preclinical testing.

Further investigation is warranted to determine how the laboratory and animal studies can be designed to predict more accurately device reliability under actual conditions of use.

FDA believes, therefore, that the penile inflatable implant should undergo premarket approval to obtain valid scientific evidence in order for FDA to determine whether the risks of using the device are adequately balanced by its benefits.

II. PMA Requirements

Any PMA for the device must include the information required by section 515(c)(1) of the act and the implementing provisions under 21 CFR 814.20. Such a PMA shall include a detailed discussion, accompanied by the results of applicable preclinical and clinical studies, of the above identified risks and the effectiveness of the device. In particular, the PMA shall include all known or otherwise available data and other information regarding: (1) Any risks known to the applicant that have not been identified in this document, and (2) the effectiveness of the specific penile inflatable implant that is the subject of the application. Valid scientific evidence, as defined in 21 CFR 860.7, addressing the safety and effectiveness of the device should be presented, evaluated and summarized in a section or sections of the PMA separate from known or otherwise available safety and effectiveness information that does not constitute valid scientific evidence (e.g., isolated case reports, random experiences, etc.).

A. Manufacturing Information

All manufacturing information for the device should be completely described. The information should include, but is not necessarily limited to, the chemical formulation and manufacturing procedures and processes, presented in a step-by-step manner from the starting materials to finished product, including, but not limited to, all nonreactants and reactants (including intermediate precursors) for the cylinders, pumps, reservoirs, tubing, and all internal components, adhesives, colorants, and filling agents (e.g., gel, saline, contrast medium, etc.). A complete master list of the common chemical names and alternate names (manufacturer's trade name or code) for all nonreactants, reactants (including intermediate precursors) and products should be provided. Chemical characterization of the elastomer intermediates, outer shell of the cylinders, pump, and reservoir, and internal gel (if applicable) sufficient to demonstrate control of the chemical processing of the device materials should be provided. This should be based on lot-to-lot comparisons (10 consecutive lot minimum) of the following information: (1) The molecular weight distribution, expressed as weight average molecular weight (Mw), number average molecular weight (Mn), peak molecular weight (Mp), polydispersity (MWD), and viscosity average molecular weight (Mv) of these precursors; (2) the results of analyses for residual levels of volatile and nonvolatile cyclic compounds (where applicable); (3) a comparison of viscosity, number average molecular weight, and percent volatiles on a single graph (where applicable); and (4) isocyanate content, acidity, isomer ratios, hydroxyl number, water content, acid number, and peroxide content (where applicable). Documentation establishing the extent of cross-linking (where applicable) in the materials of the cylinders, pumps, reservoirs, tubing, and all internal components and filling agents, or the silicone-hydride and vinyl content of cross-linked materials of the cylinders, pumps, reservoirs, tubing, and all internal components and filling agents, as well as the particle size and surface area of the silica if present in the cylinders, pumps, reservoirs, tubing, and all internal components and filling agents, or gel should be provided. A complete description of the medium used to inflate the device (saline, contrast medium, etc.) and whether and how the implant will be prefilled must also be provided.

The standard operating procedures for sterility and materials qualifications must be provided. Sterilization information should include the method of sterilization; the detailed sterilization validation protocol and results; the sterility assurance level; the type of packaging; the packaging validation protocol and results; residual levels of ethylene oxide, ethylene glycol, and ethylene chlorohydrin remaining on the device after the sterilization quarantine period, if applicable; and the radiation dose, if applicable. Because the penile inflatable implant comes into contact with the bloodstream, procedures for routine pyrogen testing also must be provided.

A complete description of the functional testing of subassemblies and finished products performed during the manufacturing process and during quality assurance/quality control (QA/QC) testing must be provided. Functional testing performed during manufacturing and QA/QC procedures should detect any device flaws that could lead to short-term failure and should demonstrate functional integrity of the device. A QA/QC plan that demonstrates how raw materials, components, subassemblies, and any filling agents will be received, stored, and handled in a manner designed to prevent damage, mixup, contamination, and other adverse effects must be provided. This plan shall specifically include, but not necessarily be limited to, a record of raw material, component, subassembly, and filling agent acceptance and rejection, visual examination for damage, and inspection, sampling and testing for conformance to specifications.

Written procedures for finished device inspection to assure that device specifications are met must be provided. These procedures shall include, but are not limited to, the requirement that each production run, lot or batch be evaluated and, where necessary, tested for conformance with device specifications prior to release for distribution. A representative number of samples shall be selected from a production run, lot or batch and tested under simulated use conditions and to any extremes to which the device may be exposed. Appropriate functional testing should also be performed at the component, subassembly, and final assembly levels (e.g., valve checks; valve release limits; joint checks; minimum, nominal and maximum pressure ratings; pressure decay rate; device firmness; leak tests; and any other appropriate tests) to detect any deficiencies that could compromise functional integrity.

Furthermore, the QA/QC procedures must include appropriate visual testing of the packaging, packaging seal, and product. Sampling plans for checking, testing, and release of the device shall be based on an acceptable statistical rationale (21 CFR 820.80 and 820.160).

B. Preclinical Data

Complete identification and quantification of all chemicals, including residual amine containing components, volatile and nonvolatile silicone cyclics and oligomers below a molecular weight of 1,500 exhaustively extracted from each of the individual structural components (cylinders, pump, reservoir, tubing, and any other materials or filling agents) as they are found in the final sterilized device should be reported. The solvents used for extraction should have varying polarities and should include, but not be limited to, ethanol, ethanol/saline (1:9), and dichloromethane. Other, more contemporary extraction techniques, such as analytical-scale supercritical fluid extraction, may also be useful, at least for exhaustive extraction of the

silicone materials. Experimental evidence must be provided establishing that exhaustive extraction is achieved with one of the selected solvents, and the percent recovery, especially for the more volatile components, must be reported. The molecular weight distribution of the extract should also be provided along with the number and weight average molecular weight, and polydispersity. All experimental methodology must be described, and raw data (including instrument reports) must be provided along with all chromatographs, spectrograms, etc. The limit of detection (2X noise level) must be provided when the analyte of interest is not detected. Laboratory test methods and animal experiments used in the characterization of the physical, chemical (other than exhaustive extraction) and mechanical properties of the device should be applicable to the intended use of the device in humans. Data on the distribution and metabolic fate of amine containing components, silicone, and any other materials used in the manufacturing of the device should be supplied.

Biocompatibility testing data must be provided for all materials (cylinder, pump, reservoir, tubing, filling agents, gel, and any other materials) in the penile inflatable implant, including all color additives (ink, dyes, markings, etc.) used to fabricate the penile inflatable implant. FDA guidance on biocompatibility testing is available in the document entitled "Tripartite Biocompatibility Guidance for Medical Devices." A copy may be obtained upon request from the Division of Small Manufacturers Assistance (HFZ–220), Center for Devices and Radiological Health, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Biocompatibility evaluation should follow the methodology of tests for blood contacting, long-term internal devices.

Toxicological effects (e.g., cytotoxicity, mutagenicity, suppression of the immune system, allergenicity, and reproductive and developmental toxicity) and hemocompatibility should be identified. Complete mutagenicity testing of each chemical extracted from the finished, sterilized components of the device should include the following tests: Bacterial mutagenicity, mammalian mutagenicity, DNA damage, and cell transformation assay.

Acute, subchronic, and chronic toxicity studies using the chemicals recovered by the above exhaustive extraction processes should be provided in the evaluation of the long-term biocompatibility of the device, including dose response and time to response as well as gross and histopathological findings in tissues both surrounding implants and distal to implant sites (lymph nodes, prostate, bladder, testes, liver, kidneys, lungs, etc.). Animal studies of carcinogenicity, reproductive toxicity, teratogenicity and later effects on offspring must be performed using scientifically justified test methods. These studies must include animal testing of the individual compounds extracted from the final sterilized device. In particular, a subset of these studies must test the compounds extracted from the materials of the sterilized device for estrogen-like antigonadotropic activity in an appropriate animal model using scientifically valid methods. Teratology/reproductive testing of the final sterilized device and extractables should be performed in an appropriate species using validated methods.

Pharmacokinetic/biodegradation studies of all materials contained in the finished device should be reported. Of special concern are questions regarding the ultimate fate, quantities, sites/organs of deposition, routes of excretion, and potential clinical significance of silicone shedding, retention, and migration.

Animal testing should also be conducted to study the effect of implantation upon device function and material integrity. Complete device chemical characterization and mechanical testing should be performed after devices have been implanted in an appropriate animal model for an appropriate length of time. Of special concern is the material integrity of the cylinders, reservoir, pump, tubing, joints, etc., which should be functionally tested and investigated using electron microscopy. The results of this testing should be compared to the failure rates noted in vitro testing and clinical studies in order to demonstrate that the animal model and study duration chosen are appropriate.

For the penile inflatable implant designs that contain silicone gel, the gel bleed performance of the device, as determined from the results of measurements using a standard diffusion cell maintained at a temperature simulating physiologic conditions, using stirred, physiologic saline as a receptacle medium for the bleed, must be reported. Each variation in device thickness or design must be measured to accurately determine diffusion coefficients (with appropriate time dependencies). The chemical identification of the bleed product, including, but not limited to, amine containing components, volatile and nonvolatile silicone cyclics and oligomers below a molecular weight of 1500, and molecular weight distribution, must be reported.

For designs using polyurethane elastomers, in vivo implant studies must be performed to identify and determine the bioabsorption, distribution, and elimination of the polyurethane elastomers (as well as their degradation products) in experimental animals. It is also important to identify and determine the mechanism and rate of degradation, as well as the quantity of degradation products generated by the breakdown of polyurethane elastomers after prolonged exposure under physical conditions in animals. Additionally, the agency recommends that retrospective epidemiological and prospective clinical studies be designed to assess the potential of cancer and other long-term complications related to polyurethane penile inflatable implants in humans. The agency suggests that these preclinical and epidemiological studies be conducted as a separate subset of penile inflatable implant safety studies.

In vitro testing should be conducted at the component, subassembly, and final device levels and must examine all aspects of device design, construction, and operation. This testing should also demonstrate how the device design and manufacturing processes address the failure mode and effects analysis. The failure mode and effects analysis should be provided. Copies of the original data sheets from all tests must be included in the PMA. All device failures must be completely described, and the corrective actions taken to eliminate or minimize further recurrence should also be identified.

A statistically valid number of samples of each model should be tested. If marketing approval is sought for multiple device versions, each version requires its own set of preclinical tests and results. If sample devices of each available size are not tested, it must be clearly indicated which device sizes were used for each test. The absence of testing on each size must be justified by analysis demonstrating that the results from the tested devices will accurately predict results for the untested device sizes.

The test conditions and acceptance criteria for all tests should be completely explained and justified. All tests should be performed in an environment simulating the possible range of anticipated in vivo conditions (temperatures, pressures, forces, stress, etc.), including capsular formation, where possible. All methods used to determine the condition of the device after testing, e.g., visual examination, electrical continuity, electron microscope examination, functional

testing, etc., must be discussed and justified.

All data collected from in vitro and animal testing, regarding the useful lifetime or long-term reliability of the device, must be compared to data from clinical studies (prospective and/or retrospective) where the useful lifetime of the device has been determined. This comparison must validate the ability of the in vitro and animal tests to accurately predict the useful lifetime of an implanted device.

Testing should be performed on final sterilized devices exposed to accelerated aging to simulate implanted device conditions. The accelerated aging process should be completely described, and the calculations showing expected aging should be provided. In addition, all tests should be performed on devices and components sterilized under the final validated sterilization procedure.

All physical, chemical and functional properties of the device should be completely characterized and the design specifications must be adequately justified. Chemical characterization should include, where applicable, molecular weight and molecular weight distribution, cross-linked density, infrared analysis (free isocyanate content, side reaction products), and thermal analysis. The physical tests should include, but are not necessarily limited to, tensile, fatigue and shear strengths, elastic modulus of the sterilized finished device, and the tests discussed below.

Testing should include the following specific methods or their equivalents: ASTM Test Method D412 to measure ultimate elongation and total energy to rupture of the cylinders, pump, reservoir, tubing, and bulk of the finished product; ASTM Test Method D624 to determine tear and abrasion resistance of all components; applied pressure at the rate of 1 Hertz in air versus number of cycles (S/N) curve, constructed on the basis of cyclical compression testing of intact sterilized devices; and ASTM Test Method F703 (section 7.2) to test integrity of adhered or fused joints. A complete report of the cohesivity testing of the gel must also be reported for the devices containing silicone gel. The results of these tests must be compared to the energy, forces, etc., that the device will encounter in vivo.

Life testing should demonstrate that the device is sufficiently durable to withstand the demands of use while maintaining operational characteristics sufficient for intercourse throughout the expected operational lifetime of the penile inflatable implant, as stated in the physician and patient labeling. Life testing should include measurements of all component and material wear and bond strength after the device is cycled between inflated and deflated conditions. Horizontal and vertical motions of inflated and deflated devices over the expected operational lifetime of the device must also be evaluated. A discussion comparing the rate of cycling performed in each test to the approximate maximum rate of cycling of the device in vivo and to the expected longevity of the implant should be included.

Appropriate "downtimes" at predetermined cyclical intervals should be included in the life tests to evaluate relevant performance characteristics and conformance to design specifications. Material characteristics indicative of material degradation that could induce device malfunction should be completely evaluated. Cyclical testing beyond the expected longevity of the implant and recording of failure mode must also be included as part of the life tests.

Filling agent permeability from the reservoir and body of the device must be evaluated to demonstrate that fluid loss due to osmosis will be acceptable over the expected life of the penile inflatable implant.

Component-specific tests are also necessary. Reliability over the expected life of the device, proper operation, and conformance to predetermined operational specifications must be demonstrated for each component. Resistance of each component to abrasion, tears, crazing, fracture, material fatigue (including wear between each component), change of position (e.g., valve seats), and permanent deformation also must be demonstrated.

Cylinder characterization and testing should include, but not be limited to:

(1) Maximum expansion capability;

(2) Measurement of stiffness and rigidity, including resistance to buckling;

(3) Resistance to aneurysms;

(4) Confirmation of concentricity;

(5) Inflation and deflation characteristics; and

(6) Wear characteristics if a fold in the cylinder develops.

Pump characterization and testing should include, but not be limited to: Volume displaced per stroke, pressure generated per stroke, force required per pump stroke, squeeze force versus fluid displacement, fluid displacement versus pressure generated, pressure generated versus squeeze force, etc. (provided in graphic representation of data); pump efficiency; buckling characteristics; filling time and number of pump strokes required for full inflation; and objective confirmation of uniform pump discharge to both penile cylinders.

Valve characterization and testing should include, but not be limited to: Activation and deactivation pressure; pressure required for valve failure; fluid and pressure loss between each component at maximum operating pressure; and prevention of spontaneous inflation and deflation under movements and loads simulating those expected to be sustained by the implanted device in both inflated and deflated states. Long-term pressure drop of an erect device in an animal model may also be useful in demonstrating adequacy of the valve and permeability of the device.

Reservoir characteristics should be evaluated and should include, but not be limited to: Volume capacity; pressures generated over the inflation/deflation cycle; rate of maximum fluid outflow and inflow; and wear characteristics if a fold in the reservoir envelope occurs.

Tubing testing should include, but not be limited to: Tensile characteristics (with and without tubing connectors, if any); tear rupture and kink resistance; wear characteristics if a fold in the tubing develops; and ability of the tubing to remain intact under loads simulating and exceeding those expected in vivo.

Testing to demonstrate the inflation/deflation characteristics of the device should include, but not be limited to: Amount of pressure generated during inflation in the penile cylinder; amount of pressure drop (deflation) and rise (inflation) per unit time; ability to maintain the cylinder diameter; and time to deflate from a specified starting pressure equal to the fully inflated penile cylinder.

All bonds within the device and between components should undergo appropriate testing including, but not limited to, measurement of bond shear and tensile strength. Bond strength should exceed the loads expected during device handling and after implantation.

Other components of the inflatable penile implant or accessories such as tubing connectors, extension adapters, and specialized tools used during the insertion procedure should be evaluated appropriately. Testing of these components or accessories should reflect the anticipated conditions of use. For example, extension adapters and tubing connectors should be demonstrated to be able to maintain connection to the device for the expected life of the device.

C. Clinical Data

Valid scientific evidence, as defined in 21 CFR 860.7, should include information from well-controlled clinical studies, with statistically justified sample size and detailed long-term followup, in order to provide reasonable assurance of the safety and effectiveness of the penile inflatable implant. Detailed protocols for the clinical trials, with explicit patient inclusion/exclusion criteria and a well-defined followup schedule, should be specified. FDA believes that 5-year followup data are necessary in order to characterize the safety and effectiveness of the device over its expected lifetime; however, appropriately justified alternate followup schedules will be considered. Any deviations from the protocol should be stated and justified. Time course presentations of patient/partner satisfaction with and psychological benefit from the implantation of this device, as well as information on the anatomical and physiological effects of the penile inflatable implant (including all adverse events), should be provided. Full patient accounting should be reported, including: (1) Theoretical followup (the number of patients that would have been examined if all patients were examined according to their followup schedules); (2) patients lost to followup, including the measures taken to minimize such events (with all information obtained on patients lost to followup); (3) time course of revisions, including all explant and repair data; and (4) time course of deaths (stating the cause of death, including the reports from any postmortem examinations). As part of this patient accounting, each clinical report should clearly state the date that the data base was closed to the addition of new information. Detailed patient demographic analyses and characterizations should be presented, and should show that the patients enrolled in the study are representative of the population for whom the device is intended.

A statistical demonstration, based on the number of patients who complete the required study period, should show that the sample size of the clinical study is adequate to provide accurate measures of the safety and effectiveness of this device. The statistical demonstration should identify the effect criteria, reasonable levels for Type I (alpha) and Type II (beta) errors, and anticipated variances of the response variables. The statistical demonstration should also provide any assumptions or statistical formulas with copies of any references used and all calculations made. A complete description of all patient randomization techniques used, and how these techniques were employed to exclude potential sources of bias, should be provided. Statistical justifications for pooling across several variables such as the etiology and duration of impotence, anatomical abnormalities of the genitalia, the number and type of treatments (if any) attempted to restore potency prior to device implantation, device usage (initial implantation versus revision), the frequency of device use postimplantation, degree of manual dexterity, investigational site, surgeon experience and technique, and incision site should be provided. The data collected and reported should include all possible relevant variables in order to permit stratification and analysis of the study data. This is necessary in order to evaluate the risk/benefit ratio for each unique subpopulation of patients.

Appropriate control/comparison groups should be included and justified and, if not, their absence must be justified. All hypotheses to be tested must be clearly stated. Appropriate statistical techniques must be employed to test these hypotheses and support claims of safety and effectiveness. For each relevant subgroup, a sufficient number of patients need to be followed for a sufficient length of time to adequately support all claims (explicit and implied) in any PMA submission.

To evaluate the risks to the patient from the penile inflatable implant, such studies should include time course presentations of clinical data demonstrating the presence or absence of device leakage, tube bending/kinking or disconnection, cylinder aneurysm or rupture, valve failure, spontaneous inflation/deflation, component migration, extrusion, skin erosion, infection, iatrogenic injury, hematoma, excessive fibrous capsular growth, pain, sensory loss, patient dissatisfaction leading to surgical removal, or any other device malfunction or adverse health event, including any effects on the immune system (both local to the device and systemic) and the reproductive system, without regard to the device relatedness of the event. The diagnostic criteria for each type of immunological and allergic phenomenon should be defined at the beginning of the study, and all cases should be well documented utilizing these criteria. Patients must be regularly monitored for the occurrence of such adverse events for a minimum of 5 years postimplantation.

FDA recognizes that the primary benefit of the penile inflatable implant is the restoration of penile erectile function. The effectiveness of the device can probably be measured by assessing: (1) The ability of the device in vivo to provide adequate rigidity (as well as length/girth enhancement, if such claims are made) to the penis to permit coitus; (2) the degree of maintenance or enhancement of a male's psychological well-being postimplantation; (3) partner satisfaction with the device; and (4) the enhancement of the male's ability to conceive naturally, as a result of the improved intromission provided by the implant (provided that the patient's semen quality was sufficient for conception prior to implantation); all of which can be balanced against any risk of illness or injury from the use of the device. FDA understands that evaluation of the degree of benefit involves, in part, an assessment of patient satisfaction and psychological well-being, particularly in light of the function of the device. Such evaluation includes subjective factors, relates to patient expectations, and may be transient in nature. Device effectiveness is also dependent upon the degree of partner satisfaction with the implant's performance, since partner satisfaction can directly relate to the patient's own self image. Assessments of enhanced fertility and penile rigidity, length, and girth postimplantation, on the other hand, should provide some objective measure of device effectiveness.

The evaluation parameters for this portion of the clinical study should be structured for an objective and standardized recording/measurement of: (1) The psychological benefit of the device to the implant recipient (as well as to his sexual partner), including any improvement in quality of life; (2) the quality of the erection provided by the implant; and (3) any increase in the rate of conception (in those patients interested in future fertility). The primary requirements for an acceptable scientific documentation of psychological benefits of the device (to both the implant recipient and his partner) are the use of (1) prospective research designs, including pre and postsurgical repeated measures; (2) appropriate control/comparison groups; and (3) standardized test questions rather than informal, yet-validated questionnaires. Any questionnaire utilized in the documentation of the psychological consequences of penile inflatable implants must be shown to provide a scientifically valid measure of the psychological effects of impotency upon males and their partners. Documentation of these psychological consequences shall include (1)

presurgical baseline assessment of psychological status, including measures of the perceived loss that these subjects experience and their expectations for improvement with the device; (2) postsurgical followup of any changes in psychological status for at least 5 years; (3) statistical comparison of postsurgical psychological test scores with presurgical test scores within the group of treated patients; (4) statistical comparison of psychological test scores of treated patients with untreated control patients at all pre and postsurgical assessment intervals; and (5) correlation of the psychological data with the physical outcomes of the implant procedure.

Documentation of the anatomical and physiologic outcomes of implantation of a penile inflatable implant shall include:

(1) Regular postsurgical evaluations of the inflation, dimensional, rigidity/stiffness, and deflation characteristics of the device for at least 5 years postimplantation; and

(2) Patient/partner assessments of the mechanical function of the implant (such as ease of inflation, quality of the erection, ability of the device to operate and function reliably, etc.) during this followup period (which may be influenced by the manual dexterity of the patient and/or partner).

Documentation of the effect of the penile inflatable implant upon the fertility of the male shall include:

(1) An assessment of the conception rate among those implant recipients who are interested in future fertility; and

(2) Comparison of this rate to either the conception rate of this patient cohort prior to receiving the implant, or to the rate of conception in an appropriate control population.

Any PMA for the penile inflatable implant should separately analyze the degree of device safety and efficacy by the following variables: (1) Etiology of erectile dysfunction; (2) frequency of device usage postimplantation; and (3) degree of sexual therapy provided to the subject postoperatively. Furthermore, for each explantation procedure performed on the study subjects, the following information must be provided: (1) The mode of failure of the removed device; (2) whether or not the explanted device was replaced with a new device; and (3) either the manufacturer, type, and model of the new device (if another penile implant was implanted), or the type of treatment (if any) that the patient received for his impotence (if revision surgery was not performed). Additionally, the effect of the presence of these implants upon future medical diagnoses/treatments involving the lower pelvic region in recipients of penile inflatable implants must be analyzed. Furthermore, any accessories that are sold with the penile inflatable implant (such as corporal dilators, suturing tools, etc.) must be shown to have been effectively used in implant procedures without adverse effects. Finally, each clinical investigation should validate the physician and patient instructions for use (labeling) that were utilized.

For polyurethane elastomer implants, the following additional information needs to be presented:

(1) The kinetics of the end products formation generated from the degradation of the polyurethane material (in vivo); and

(2) The neoplasticity of the material, as well as its general toxicity, including neurological, physiological, biochemical, and hematological effects, as well as pathology following prolonged and repeated exposure to polyurethane penile inflatable implants.

Any epidemiological studies submitted should contain enough subjects to permit detection of a small but significant increase in one or more connective tissue diseases (especially scleroderma) that may be associated with the use of the device.

The agency believes that insufficient time has elapsed to permit a direct evaluation of the risks of cancer and immune related connective tissue disorders posed by the presence of silicone in the human body and that insufficient epidemiological and experimental animal data are available to make a reasonable and fair judgment of these risks. Therefore, the agency will require long-term postapproval followup for any penile inflatable implant permitted to continue in commercial distribution. Well-designed clinical prospective studies with long-term followup together with experimental animal studies will be considered essential to the determination of the safety and effectiveness of the device. Further, these clinical studies must collect long-term data on the reproductive/teratogenic effects of the device as well as on the later effects on offspring.

The risk/benefit assessment (as with the entire PMA) must rely on valid scientific evidence as defined in 21 CFR 860.7(c)(2) from well-controlled studies as described in 21 CFR 860.7(f) in order to provide reasonable assurance of the safety and effectiveness of the penile inflatable implant in the treatment of erectile dysfunction in the male.

D. Labeling

Copies of all proposed labeling for the device, including any information, literature, or advertising that constitutes labeling under section 201(m) of the act (21 U.S.C. 321(m)], should be provided. The general labeling requirements for medical devices are contained in 21 CFR part 801. These regulations specify the minimum requirements for all devices. Additional guidance regarding device labeling can be obtained from FDA's publication "Labeling: Regulatory Requirements for Medical Devices," and from the Office of Device Evaluation's "Device Labeling Guidance"; both documents are available upon request from the Division of Small Manufacturers Assistance (HFZ–220), Center for Devices and Radiological Health, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Highlighted below is additional guidance for some of the specific labeling requirements for penile inflatable implants.

The intended use statement should include the specific indications for use and identification of the target populations. Specific indications and target populations must be completely supported by the clinical data described above. For example, it may be necessary to restrict the intended use to patients who have failed prior less invasive therapies and/or to patients with specific etiologies of impotence in whom safety and effectiveness have been demonstrated.

The directions for use should contain comprehensive instructions regarding the preoperative, perioperative and postoperative procedures to be followed. This information includes, but is not necessarily limited to: (1) A description of any preimplant training necessary for the surgical team; (2) a description of how to prepare the patient (e.g., prophylactic antibiotics), operating room (e.g., what supplies must be on hand), and penile inflatable implant (e.g., handling instructions, resterilization instructions) for device implantation; (3) instructions for implantation, including surgical approach, sizing, fluid adjustment (including what filling solutions may be used and how they must be prepared), device handling, and intraoperative test procedures to ensure implant functionality and proper placement; and (4) instructions for followup, including whether antibiotic prophylaxis is recommended during the postimplant period and/or during any subsequent dental or other surgical procedures, how to determine when patients are ready to attempt intercourse and begin periodic

activation, and how to evaluate, and how often to evaluate, proper functionality and placement. The directions should instruct caregivers to specifically question patients prior to surgery for any history of allergic reaction to any of the device materials or filling agents. Troubleshooting procedures should be completely described. The directions for use should incorporate the clinical experience with the implant, and should be consistent with those provided in other company-provided labeling.

The labeling should include both implant and explant forms to allow the sponsor to adequately monitor device experience. The explant form should allow collection of all relevant data, including the reason for the explant, any complications experienced and their resolution, and any action planned (e.g., replacement with another implant).

Patient labeling must be provided which includes the information needed to give prospective patients realistic expectations of the benefits and risks of device implantation. Such information should be written and formatted so as to be easily read and understood by most patients and should be provided to patients prior to scheduling implantation, so that each patient has sufficient time to review the information and discuss it with his physician(s) and sexual partner. Technical terms should be kept to a minimum and should be defined if they must be used. Patient information labeling should not exceed the seventh grade reading comprehension level.

The patient labeling should provide the patient with the following information: (1) The indications for use and relevant contraindications, warnings, precautions and adverse effects/complications should be described using terminology well known and understood by the average layman; (2) the anticipated benefits and risks associated with the device must be provided to give patients realistic expectations of device performance and potential complications. The known, suspected and potential risks of device implantation should be identified and the consequences, including possible methods of resolution, should be described. The patient should be advised that penile length and/or width reductions may occur, and that any latent erectile capability will be impaired by implantation of a penile inflatable implant; (3) alternatives available to the use of the device, including less invasive treatments, should be identified, along with a description of the associated benefits and risks of each. The patient should be advised to contact his physician for more information on which of these alternatives might be appropriate given his specific condition; (4) instructions for how to use the device must be provided to the patient. This information should include the expected length of recovery from surgery and when to resume intercourse following implantation, whether and how often the device should be periodically inflated (if applicable), warnings against certain actions (e.g., repeated flexing) that could damage the device, how to identify conditions that require physician intervention, who to contact if questions arise, and other relevant information; (5) the fact that the implant should not be considered a "lifetime" implant must be emphasized. Where possible, the patient labeling should provide information on the approximate number of revisions necessary for the average patient, and indicate the average longevity of each implant so that patients are fully aware that additional surgery for device modification, replacement, or removal may be necessary. This information must be supported by the clinical experience (i.e., not merely bench studies) with the implant or by published reports of experience with similar devices.

The physician's labeling should instruct the urologist or implanting surgeon to provide the implant candidate with the patient labeling prior to surgery to allow each patient sufficient time to review and discuss this information with his physician(s) and sexual partner.

The adequacy and appropriateness of the instructions for use provided to physicians and patients should be verified as part of the clinical investigations.

Applicants should submit any PMA in accordance with FDA's "Premarket Approval (PMA) Manual." The manual is available upon request from the Division of Small Manufacturers Assistance (HFZ–220), Center for Devices and Radiological Health, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857.

III. Request for Comments With Data

FDA is providing a 60-day period for interested persons to submit to the Dockets Management Branch (address above) written comments regarding this proposal and its findings. Two copies of any comments are to be submitted, except that individuals may submit one copy.

Comments are encouraged to discuss all aspects of the proposed findings regarding the:

(1) Degree of risk, illness, or injury associated with the use of the penile inflatable implant;

(2) Laboratory, animal, and human studies required in a PMA for the device in order to assess its safety and effectiveness;

(3) Feasibility of these studies within the time permitted by the act, etc.; and

(4) Benefits to the public from the use of the device.

The comments must discuss in detail, for example, the reasons why important new information on the safety and effectiveness of the device could not feasibly be submitted within the time permitted, or why animal studies may not be available to assess long-term effects such as connective tissue disorders, or that carefully designed epidemiological studies may not be available to evaluate the long-term silicone related illnesses, etc.

The Center for Devices and Radiological Health staff are available to provide guidance to manufacturers on any proposed laboratory, animal, or epidemiological studies needed in a PMA.

IV. Opportunity To Request a Change in Classification

Before requiring the filing of a PMA or notice of completion of a PDP for a device, FDA is required by section 515(b)(2)(A)(i) through (b)(2)(A)(iv) of the act and 21 CFR 860.132 to provide an opportunity for interested persons to request a change in the classification of the device based on new information relevant to its classification. Any proceeding to reclassify the device will be under the authority of section 513(e) of the act.

A request for a change in the classification of the penile inflatable implant is to be in the form of a reclassification petition containing the information required by § 860.123 (21 CFR 860.123), including new information relevant to the classification of the device, and shall, under section 515(b)(2)(B) of the act, be submitted by May 13, 1993.

The agency advises that to assure timely filing of any such petition, any request should be submitted to the Dockets Management Branch (address above) and not to the address provided in § 860.123(b)(1). If a timely request for a change in the classification of the penile inflatable implant is submitted, the agency will, by June 28, 1993, after consultation with the appropriate FDA advisory committee and by an order published in the **Federal Register**, either deny the request or give notice of its intent to initiate a change in the classification of the device in

accordance with section 513(e) of the act and 21 CFR 860.130.

V. References

The following references have been placed on display in the Dockets Management Branch (address above) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Carson, C. C., "Infections in Genitourinary Prostheses," *Urologic Clinics of North America*, 16(1):139–147, 1989.

2. Fishman, I. J., "Complicated Implantations of Inflatable Penile Prostheses," *Urologic Clinics of North America*, 14(1):217–239, 1987.

3. Kabalin, J. N., and R. Kessler, "Infectious Complications of Penile Prosthesis Surgery," *The Journal of Urology*, 139(5):953–955, 1988.

4. Merrill, D. C., "Clinical Experience With the Mentor Inflatable Penile Prosthesis in 301 Patients," *The Journal of Urology*, 140(6):1424–1427, 1988.

5. Merrill, D. C., "Mentor Inflatable Penile Prostheses," *Urologic Clinics of North America*, 16(1):51–66, 1989.

6. Walters, F. P., D. E. Neal, Jr., A. B. Rege, W. J. George, M. J. Ricci, and W. J. G. Hellstrom, "Cavernous Tissue Antibiotic Levels in Penile Prosthesis Surgery," *The Journal of Urology*, 147(5):1282–1284, 1992.

7. Wilson, S. K., G. E. Wahman, and J. L. Lange, "Eleven Years of Experience With the Inflatable Penile Prosthesis," *The Journal of Urology*, 139(5):951–952, 1988.

8. Parulkar, B. G., and D. M. Barrett, "Combined Implantation of Artificial Sphincter and Penile Prosthesis," *The Journal of Urology*, 142(3):732–735, 1989.

9. McClellan, D. S., and B. K. Masih, "Gangrene of the Penis as a Complication of Penile Prosthesis," *The Journal of Urology*, 133(5):862–863, 1985.

10. Thomas, C. L. (ed.), "Taber's® Cyclopedic Medical Dictionary," 15th ed., F. A. Davis Co., Philadelphia, pp. 569, 591, and 1052, 1985.

11. Carson, C. C., "Genitourinary Prostheses," in S. D. Graham, Jr. (ed.), *Urologic Oncology*, New York, Raven Press, pp. 459–470, 1986.

12. Dupont, M. C., and H. I. Hochman, "Erosion of an Inflatable Penile Prosthesis Reservoir into the Bladder, Presenting as Bladder Calculi," *The Journal of Urology*, 139(2):367–368, 1988.

13. Fein, R. L., "Clinical Evaluation of Inflatable Penile Prosthesis With Combined Pump-Reservoir," *Urology*, 32(4):311–314, 1988.

14. Gasser, T. C., E. H. Larsen, and R. G. Bruskewitz, "Penile Prosthesis Reimplantation," *The Journal of Urology*, 137(1):46–47, 1987.

15. Godiwalla, S. Y., J. Beres, and S. C. Jacobs, "Erosion of an Inflatable Penile Prosthesis Reservoir into an Ileal Conduit," *The Journal of Urology*, 137(2):297–298, 1987.

16. Mulcahy, J. J., "A Technique of Maintaining Penile Prosthesis Position to Prevent Proximal Migration," *The Journal of Urology*, 137(2):294–296, 1987.

17. Brooks, M. B., "42 Months of Experience With the Mentor Inflatable Penile Prosthesis," *The Journal of Urology*, 139(1):48–49, 1988.

18. Fein, R. L., "Cylinder Problems With AMS 700 Inflatable Penile Prosthesis," *Urology*, 31(4):305–308, 1988.

19. Fein, R. L., "The G. F. S. Mark II Inflatable Penile Prosthesis," *The Journal of Urology*, 147(1):66–68, 1992.

20. Kabalin, J. N., and R. Kessler, "Penile Prosthesis Surgery: Review of Ten-Year Experience and Examination of Reoperations," *Urology*, 33(1):17–19, 1989.

21. Moul, J. W., and D. G. McLeod, "Negative Pressure Devices in the Explanted Penile Prosthesis Population," *The Journal of Urology*, 142(3):729–731, 1989.

22. Furlow, W. L., and B. Goldwasser, "Salvage of the Eroded Inflatable Penile Prosthesis: A New Concept," *The Journal of Urology*, 138(2):312–314, 1987.

23. Steidle, C. P., and J. J. Mulcahy, "Erosion of Penile Prostheses: A Complication of Urethral Catheterization," *The Journal of Urology*, 142(3):736–739, 1989.

24. Furlow, W. L., and R. C. Motley, "The Inflatable Penile Prosthesis: Clinical Experience With a New Controlled Expansion Cylinder," *The Journal of Urology*, 139(5):945–946, 1988.

25. Knoll, L. D., W. L. Furlow, and R. C. Motley, "Clinical Experience Implanting an Inflatable Penile Prosthesis With Controlled-Expansion Cylinder," *Urology*, 36(6):502–504, 1990.

26. Weese, D. L., and P. E. Zimmern, "Corporeal Perforation or Undersized Prosthesis? The Role of Corpus Cavernosum Endoscopy," *The Journal of Urology*, 144(3):714–716, 1990.

27. Sender, M. B., M. A. Koyle, and J. Rajfer, "Complications of Scrotal Surgery," in R. B. Smith and R. M. Ehrlich (eds.), *Complications of Urologic Surgery: Prevention and Management*, Philadelphia, Harcourt, Brace, & Jovanovich, Inc., pp. 528–529, 1990.

28. Barrett, D. M., D. C. O'Sullivan, A. A. Malizia, H. M. Reiman, and P. C. Abell-Aleff, "Particle Shedding and Migration From Silicone Genitourinary Prosthetic Devices," *The Journal of Urology*, 146(2):319–322, 1991.

29. Bertram, R. A., C. C. Carson, III, and L. F. Altaffer, "Severe Penile Curvature After Implantation of an Inflatable Penile Prosthesis," *The Journal of Urology*, 139(4):743–745, 1988.

30. Fitch, III, W. P., and T. Roddy, "Erosion of Inflatable Penile Prosthesis Reservoir into Bladder," *The Journal of Urology*, 136(5):1080, 1986.

31. Montague, D. K., "Penile Prostheses: An Overview," *Urologic Clinics of North America*, 16(1):7–12, 1989.

32. Kaufman, J. J., A. Linder, and S. Raz, "Complications of Penile Prosthesis Surgery for Impotence," *The Journal of Urology*, 128(6):1192–1194, 1982.

33. Fallen, M. J., and R. W. Lewis, "Experience With a Two-Piece Inflatable Penile Prosthesis," Abstract, *The Journal of Urology*, 143(4):409A, 1990.

34. McLaren, R. H., and R. W. Lewis, "Analysis of Reoperation in the Patient With Inflatable Penile Prosthesis," Abstract, *The Journal of Urology*, 143(4):408A, 1990.

35. Montague, D. K., "Experience With Semirigid Rod and Inflatable Penile Prostheses," *The Journal of Urology*, 129(5):967–968, 1983.

36. Joseph, D. B., R. C. Bruskewitz, and R. C. Benson, "Long-Term Evaluation of the Inflatable Penile Prosthesis," *The Journal of Urology*, 131(4):670–673, 1984.

37. Malloy, T. R., A. J. Wein, and V. L. Carpiniello, "Reliability of AMS M700 Inflatable Penile Prosthesis," *Urology*, 28(5):385–387, 1986.

38. Merrill, D. C., "Clinical Experience With Mentor Inflatable Penile Prosthesis in 206 Patients," *Urology*, 28(3):185–189, 1986.

39. Stanisic, T. H., and J. C. Dean, "The Flexi-Flate and Flexi-Flate II Penile Prostheses," *Urologic Clinics of North America*, 16(1):39–49, 1989.

40. Fallon, B., and W. L. Gerber, "New Complication of Inflatable Penile Prosthesis," *Urology*, 18(4):405, 1981.

41. Goulding, F. J., "Fracture of Hydroflex Penile Implant," *Urology*, 30(5):490–491, 1987.

42. Furlow, W. L., B. Goldwasser, and J. C. Gundian, "Implantation of Model AMS 700 Penile Prosthesis: Long-Term Results," *The Journal of Urology*, 139(4):741–742, 1988.

43. Mulcahy, J. J., "The Hydroflex Penile Prosthesis," *Urologic Clinics of North America*, 16(1):33–38, 1989.

44. Mulcahy, J. J., "The Hydroflex Self-Contained Inflatable Penile Prosthesis: Experience With 100 Patients," *The Journal of Urology*, 140(6):1422–1423, 1988.

45. Gregory, J. G., and M. H. Purcell, "Scott's Inflatable Penile Prosthesis: Evaluation of Mechanical Survival in the Series 700 Model," *The Journal of Urology*, 137(4):676–677, 1987.

46. Beaser, R. S., C. Van der Hoek, A. M. Jacobson, T. M. Flood, and R. E. Desautels, "Experience With Penile Prostheses in the Treatment of Impotence in Diabetic Men," *Journal of the American Medical Association*, 248(8):943–948, 1982.

47. Diokno, A. C., "Asymmetric Inflation of the Penile Cylinders: Etiology and Management," *The Journal of Urology*, 129(6):1127–1130, 1983.

48. Earle, C. M., G. R. Watters, A. G. S. Tulloch, Z. S. Wisniewski, D. J. Lord, and E. J. Keogh, "Complications Associated With Penile Implants Used to Treat Impotence," *Australia and New Zealand Journal of Surgery*, 59:959–962, 1989.

49. Casey, W. C., "Tubing Kinks in Inflatable Penile Prosthesis: A Cause and Prevention," *Urology*, 20(5):542, 1982.

50. Engel, R. M. E., and R. L. Fein, "Mentor GFS Inflatable Prostheses," *Urology*, 35(5):405–406, 1990.

51. Malloy, T. R., V. L. Carpiniello, and A. J. Wein, "Mechanical Stability AMS M700 CX Inflatable Penile Prosthesis Cylinders," Abstract, *The Journal of Urology*, 139(4):329A., 1988.

52. Stanisic, T. H., J. C. Dean, J. M. Donovan, and L. E. Beutler, "Clinical Experience With a Self-Contained Inflatable Penile Implant: The Flexi-Flate," *The Journal of Urology*, 139(5):947–950, 1988.

53. McLaren, R. H., and D. M. Barrett, "Patient and Partner Satisfaction With the

AMS 700 Penile Prosthesis," *The Journal of Urology*, 147(1):62–65, 1992.

54. Whalen, R. K., and D. C. Merrill, "Patient Satisfaction With Mentor Inflatable Penile Prosthesis," *Urology*, 37(6):531–539, 1991.

55. Boyd, S. D., and W. M. Schiff, "Inflatable Penile Prostheses in Patients Undergoing Cystoprostatectomy With Urethrectomy," *The Journal of Urology*, 141(1):60–62, 1989.

56. Merrill, D. C., "Clinical Experience With Scott Inflatable Penile Prosthesis in 150 Patients," *Urology*, 22(4):371–375, 1983.

57. Fallon, B., S. Rosenberg, and D. A. Culp, "Long-Term Follow-up in Patients With an Inflatable Penile Prosthesis," *The Journal of Urology*, 132(2):270–271, 1984.

58. Medical Device Reporting (MDR) and Product Problem Reporting (PPR), Device Experience Network (DEN), FDA.

59. Witherington, R., "Mechanical Devices for the Treatment of Erectile Dysfunction," *American Family Physician*, 43(5):1611–1620, 1991.

60. Klabalin, J. N., and R. Kessler, "Experience With the Hydroflex Penile Prosthesis," *The Journal of Urology*, 141(1):58–59, 1989.

61. Ball, Jr., T. P., "Surgical Repair of Penile 'SST' Deformity," *Urology*, 15:603–604, 1980.

62. Engel, R. M. E., J. K. Smolev, and R. Hackler, "Mentor Inflatable Penile Prosthesis," *Urology*, 29(5):498–500, 1987.

63. Knoll, L. D., W. L. Furlow, and R. C. Benson, Jr., "Management of Peyronie Disease by Implantation of Inflatable Penile Prosthesis," *Urology*, 36(5):406–409, 1990.

64. Walther, P. J., R. T. Andriani, M. I. Maggio, and C. C. Carson, III, "Fournier's Gangrene: A Complication of Penile Prosthetic Implantation in a Renal Transplant Patient," *The Journal of Urology*, 137(2):299–300, 1987.

65. Tiefer, L., S. Moss, and A. Melman, "Follow-up of Patients and Partners Experiencing Penile Prosthesis Malfunction and Corrective Surgery," *Journal of Sex and Marital Therapy*, 17(2):113–128, 1991.

66. Schover, L. R., "Sex Therapy for the Penile Prosthesis Recipient," *Urologic Clinics of North America*, 16(1):91–98, 1989.

67. Nelson, R. P., "Male Sexual Dysfunction: Evaluation and Treatment," *Southern Medical Journal*, 80(1):69–74, 1987.

68. Bischoff, F., and G. Bryson, "Carcinogenesis Through Solid State Surfaces," *Progress in Experimental Tumor Research*, 5:85–133, 1964.

69. Hueper, W. C., "Cancer Induction by Polyurethane and Polysilicone Plastics," *Journal of the National Cancer Institute*, 33:1005–1027, 1964.

70. Hueper, W. C., "Carcinogenic Studies on Water-Soluble and Insoluble Macromolecules," *Archives of Pathology and Laboratory Medicine*, 67:589–617, 1959.

71. Maekawa, A., T. Ogiu, H. Onodera, K. Furuta, C. Matsuoka, Y. Ohno, H. Tanigawa, G. S. Salmo, M. Matsuyama, and Y. Hayashi, "Malignant Fibrous Histiocytomas Induced in Rats by Polymers," *Cancer Research and Clinical Oncology*, 108:364–365, 1984.

72. Pedley, R. B., G. Meachim, and D. F. Williams, "Tumor Induction by Implant Materials," in "Fundamental Aspects of Biocompatibility," vol. 2, D. F. Williams (ed.), CRC Critical Reviews in Biocompatibility, CRC Press, Boca Raton, FL, pp. 165–202, 1981.

73. Benjamin, E., A. Ahmed, A. T. F. Rashid, and D. H. Wright, "Silicone Lymphadenopathy: A Report of Two Cases, One With Concomitant Malignant Lymphoma," *Diagnostic Histopathology*, 5:133–141, 1982.

74. Digby, J. M., and A. L. Wells, "Malignant Lymphoma With Intranodal Refractile Particles After Insertion of a Silicone Prostheses," *Lancet*, 2:580, 1981.

75. Morgenstern, L., S. H. Gleischman, S. L. Michel, J. E. Rosenberg, I. Knight, and D. Goodman, "Relation of Free Silicone to Human Breast Carcinoma," *Archives of Surgery*, 120:573–577, 1985.

76. Zafiracopoulos, P., and A. Rouskas, "Breast Cancer at Site of Implantation of Pacemaker Generator," letter to the editor, *Lancet*, p. 1114, June 1, 1974.

77. Le Vier, R. R., and M. E. Jankowiak, "Effects of Oral 2,6-cis-Diphenylhexamethylcyclotetrasiloxane on the Reproductive System of the Male Rat," *Toxicology and Applied Pharmacology*, 21:80–88, 1972.

78. Bates, H., R. Filler, and C. Kimmel, "Developmental Toxicity Study of Polydimethylsiloxane Injection in the Rat," *Teratology*, 31:50A, 1985.

79. Haley, T. J., "Biocompatibility of Monomers," in Systemic Aspects of Biocompatibility, vol. 2, pp. 59–90, Williams, D. F. (ed.), CRC Series in Biocompatibility, Boca Raton, FL, 1981.

80. Kennedy, G. L., M. L. Keplinger, and J. C. Calandra, "Reproductive, Teratologic and Mutagenic Studies With Some Polydimethylsiloxanes," *Journal of Toxicology and Environmental Health*, 1:909–920, 1976.

81. Varga, J., H. R. Schumacher, and S. A. Jimenez, "Systemic Sclerosis After Augmentation Mammoplasty With Silicone Implants," *Annals of Internal Medicine*, 111:377–383, 1989.

82. Picha, G. J., and J. A. Goldstein, "Analysis of the Soft-Tissue Response to Components Used in the Manufacture of Breast Implants: Rat Animal Model," *Plastic and Reconstructive Surgery*, 87:490–500, 1991.

83. Baker, J. L. et al., "Positive Identification of Silicone in Human Mammary Capsular Tissue," *Plastic and Reconstructive Surgery*, 69:56–60, 1982.

84. Barker, D. E., M. I. Retsky, and S. Schultz, "Bleeding of Silicone From Bag-gel Breast Implants, and Its Clinical Relation to Fibrous Capsule Reaction," *Plastic and Reconstructive Surgery*, 61:836–841, 1978.

85. Brody, G. S., "Fact and Fiction About Breast Implant 'Bleed'," *Plastic and Reconstructive Surgery*, 60:615–616, 1977.

86. Gayou, R., and R. Rudolph, "Capsular Contraction Around Silicone Mammary Prostheses," *Annals of Plastic Surgery*, 2(1):62–71, 1979.

87. Gibbons, D. F., et al., "Wear and Degradation of Retrieved Ultrahigh Molecular Weight Polyethylene and Other Polymeric Implants," in B. C. Syrett and A. Acharya (eds.), "Corrosion and Degradation of Implant Materials," American Society for Testing and Materials (ASTM), Kansas City, MO, Philadelphia ASTM, pp. 20–40, 1979.

88. Hausner, R. J., et al., "Migration of Silicone Gel to Auxiliary Lymph Nodes After Prosthetic Mammoplasty," *Archives of Pathology Laboratory Medicine*, 105:371–372, 1981.

89. Jenny, H., and J. Smahel, "Clinicopathologic Correlations in Pseudocapsule Formation After Breast Augmentation," *Aesthetic Plastic Surgery*, 5:63–68, 1981.

90. Mandel, M. A., and D. F. Gibbons, "The Presence of Silicone in Breast Capsules," *Aesthetic Plastic Surgery*, 3:219–225, 1979.

91. Smahel, J., "Foreign Material in the Capsules Around Breast Prostheses and the Cellular Reaction To It," *British Journal of Plastic Surgery*, 32:35–42, 1979.

92. Wickham, M. G., et al., "Silicon Identification in Prosthesis-Associated Fibrous Capsules," *Science*, 199:437–439, 1978.

93. "Bioassay of 2,4-Diaminotoluene for Possible Carcinogenicity," Bethesda, Maryland: National Institutes of Health, U.S. Department of Health, Education and Welfare, Publication 79–1718, 1979.

94. "Carcinogenesis Studies of 4,4-Methylenedianiline Dihydrochloride (CAS No. 13552–44–8) in F344/N Rats and B6C3F$_1$ Mice (Drinking Water Studies)," National Toxicology Program, Technical Report Series No. 248, 1983.

95. Kessler, R., "Complications of Inflatable Penile Prostheses," *Urology*, 18(5):470–472, 1981.

96. Flanagan, M. J., E. B. Krisch, and W. L. Gerber, "Complication of a Penile Prosthesis Reservoir: Venous Compression Masquerading as a Deep Venous Thrombosis," *The Journal of Urology*, 146(3):847–848, 1991.

97. Nelson, R. P., and J. C. Gregory, "Gonococcal Infections of Penile Prostheses," *Urology*, 31(5):391–394, 1988.

98. Scott, F. B., "Outpatient Implantation of Penile Prostheses Under Local Anesthesia," *Urologic Clinics of North America*, 14(1):177–185, 1987.

99. Lief, H. I., "Sex and the Physician," *Sexual Problems in Medical Practice*, American Medical Association, pp. 3–8, 1981.

100. Masters, W. H., and V. E. Johnson, "Secondary Impotence," *Human Sexual Inadequacy*, Boston, Little, Brown and Co., pp. 157–192, 1970.

101. Pedersen, B., L. Tiefer, M. Ruiz, and A. Melman, "Evaluation of Patients and Partners 1 to 4 Years After Penile Prosthesis Surgery," *The Journal of Urology*, 139(5):956–958, 1988.

102. Tiefer, L., B. Pedersen, and A. Melman, "Psychosocial Follow-up of Penile Prosthesis Implant Patients and Partners," *Journal of Sex and Marital Therapy*, 14(3):184–201, 1988.

103. Domanskis, E., and J.Q. Owsley, "Histological Investigation of the Etiology of Capsule Contracture Following Augmentation Mammaplasty," *Plastic and Reconstructive Surgery*, 58:689–693, 1976.

104. Vargas, A., "Shedding of Silicone Particles From Inflated Breast Implants,"

letter to the editor, *Plastic and Reconstructive Surgery*, 64:252–253, 1979.

VI. Environmental Impact

The agency has determined under 21 CFR 25.24(a)(8) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

VII. Economic Impact

FDA has examined the economic consequences of this proposed rule in accordance with the criteria in section 1(b) of Executive Order 12291 and finds that this proposal would not be a major rule as specified in the Order. The agency believes that only a small number of firms will be affected by this proposed rule, and the agency certifies under the Regulatory Flexibility Act (Pub. L. 96–354) that the proposed rule will not have a significant economic impact on a substantial number of small entities. An assessment of the economic impact of any final rule based on this proposal has been placed on file in the Dockets Management Branch (address above) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

VIII. Comments

Interested persons may, on or before June 28, 1993, submit to the Dockets Management Branch (address above) written comments regarding this proposal. Two copies of any comments are to be submitted, except that individuals may submit one copy. Interested persons may, on or before May 13, 1993, submit to the Dockets Management Branch a written request to change the classification of the penile inflatable implant. Two copies of any requests are to be submitted, except that individuals may submit one copy. Comments or requests are to be identified with the docket number found in brackets in the heading of this document. Received comments and requests may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday. Comments are encouraged to discuss all aspects of the proposed findings and the recommended PMA Contents.

List of Subjects in 21 CFR Part 876

Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR part 876 be amended as follows:

PART 876—GASTROENTEROLOGY-UROLOGY DEVICES

1. The authority citation for 21 CFR part 876 is revised to read as follows:

Authority: Secs. 501, 510, 513, 515, 520, 522, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351, 360, 360c, 360e, 360j, 3601, 371).

2. Section 876.3350 is amended by revising paragraph (c) to read as follows:

§ 876.3350 Penile inflatable implant.

* * * * *

(c) *Date PMA or notice of completion of a PDP is required.* A PMA or notice of completion of a PDP is required to be filed with FDA on or before (insert date 90 days after the effective date of a final rule based on this proposed rule), for any penile inflatable implant that was in commercial distribution before May 28, 1976, or that has on or before (insert date 90 days after the effective date of a final rule based on this proposed rule), been found to be substantially equivalent to the penile inflatable implant that was in commercial distribution before May 28, 1976. Any other penile inflatable implant shall have an approved PMA or declared completed PDP in effect before being placed in commercial distribution.

Dated: April 21, 1993.

Michael R. Taylor,

Deputy Commissioner for Policy.

[FR Doc. 93–9845 Filed 4–27–93; 8:45 am]

BILLING CODE 4160–01–P

federal register

Wednesday
April 28, 1993

Part III

Department of Health and Human Services

Food and Drug Administration

21 CFR 312 et al.
Retention of Bioavailability and Bioequivalence Testing Samples; Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 312, 314, and 320

[Docket No. 89N–0367]

RIN 0905–AC94

Retention of Bioavailability and Bioequivalence Testing Samples

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing final regulations to amend its current bioavailability/bioequivalence regulations to require the retention for a specified period of reserve samples of the drug products used to conduct certain bioavailability or bioequivalence studies submitted in support of the approval of new drug applications (NDA's) and abbreviated new drug applications (ANDA's), and when specifically requested, to release the reserve samples to FDA. The requirement applies to manufacturers who conduct in-house bioavailability and bioequivalence testing and to testing facilities who conduct such testing under contract for a drug manufacturer. The requirement also applies to foreign manufacturers who conduct their own studies for new drug product approval and to foreign testing facilities under contract for a U.S. manufacturer or foreign manufacturer. This action is intended to help ensure bioequivalence between generic drugs and their brand-name counterparts and to help the agency investigate more fully instances of possible fraud in bioavailability and bioequivalence testing. This final rule adopts the interim rule published in the **Federal Register** of November 8, 1990, with minor changes based on comments the agency received on the interim rule.

DATES: Effective May 28, 1993. Submit information on the Economic Impact section of this document (section III.) by May 28, 1993.

ADDRESSES: Submit information on the Economic Impact section of this document to the Dockets Management Branch (HFA–305) Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Marilyn L. Watson, Center for Drug Evaluation and Research (HFD–360), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–295–8038.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of November 8, 1990 (55 FR 47034), FDA published interim regulations to require the retention for a specified period of reserve samples of the drug products used to conduct bioavailability or bioequivalence studies of drug products, and when specifically requested, to release the reserve samples to FDA. The interim regulations were effective on the date of publication. FDA provided 60 days for public comment. The final rule incorporates all of the main provisions of the interim rule; the agency has made a number of minor clarifying changes in response to the comments received on the interim rule.

Highlights of the final rule are summarized below, followed by a summary and discussion of the comments.

I. Highlights of the Final Rule

In the November 8, 1990, interim rule, the agency codified requirements regarding the retention of bioavailability and bioequivalence testing samples as part of the bioavailability/bioequivalence regulations existing at that time by adding §§ 320.32 and 320.63 (21 CFR 320.32 and 320.63), and by adding conforming amendments to § 320.31 (21 CFR 320.31) and to FDA's investigational new drug application (IND) and NDA regulations, new §§ 312.57(c), 314.125(b)(17), and 314.150(b)(9) (21 CFR 312.57(c), 314.125(b)(17), and 314.150(b)(9)). The purpose of these new requirements is to make available to FDA reserve samples of tested products for analysis to ensure that the bioequivalence and bioavailability results upon which FDA bases approval of NDA's and ANDA's are reliable. The rule also permits the agency the discretion to refuse to approve and to withdraw approval of an application if an applicant or testing laboratory refuses to permit an inspection of the facilities or records relevant to a bioavailability or bioequivalence study or to release to FDA reserve samples when requested.

In the **Federal Register** of July 10, 1989 (54 FR 28872 at 28911), FDA proposed changes in the regulations in existing 21 CFR part 320. Those proposed changes would, among other things, remove subpart C and those regulations that apply to establishing a bioequivalence requirement, move to subpart B the remaining regulations under existing subpart C, and where appropriate, combine the remaining regulations with the existing subpart B regulations. In the **Federal Register** of April 28, 1992 (57 FR 17950 at 17997), the proposed new subpart B structure was issued as a final rule. The agency is now conforming this rule to the new subpart B structure.

A. Scope

The final rule applies to domestic and foreign sponsors and applicants (hereinafter called a study sponsor) who perform in-house bioavailability or bioequivalence testing for new drug product approval under an NDA, ANDA, or supplemental application and to any domestic and foreign testing facility that performs such bioavailability or bioequivalence testing under contract (contract research organization) for a study sponsor.

B. Sample Retention Requirement

A study sponsor or contract research organization, whoever performs bioavailability or bioequivalence testing for new drug product approval, must retain a reserve sample of each test article and reference standard used to perform in vivo bioavailability or in vivo or in vitro bioequivalence studies that is representative of each batch of the test article and of the reference standard provided by the study sponsor for the testing. The final rule clarifies the types of in vivo bioavailability and bioequivalence studies for which reserve samples are to be retained. The study sponsor or contract research organization will retain a sufficient quantity of each reserve sample of the test article and of the reference standard to permit FDA to perform five times all of the release tests required in the NDA, ANDA, or supplemental application. In addition, each reserve sample is required to be: (1) Adequately identified so that it can be positively identified as having come from the same sample as used in the specific bioavailability or bioequivalence study, (2) stored under specified conditions, and (3) retained for a specified period. An ambiguity in the interim rule regarding storage conditions has been clarified to accurately reflect the agency's intent. In addition, the final rule also includes a provision for the transfer of reserve samples when a contract research organization goes out of business.

C. Collection of Samples

Ordinarily, the reserve samples, or a portion of the reserve samples, will be collected by an FDA investigator at the place of storage during a preapproval inspection of the facilities involved in manufacturing the test article and of any contract testing facility that conducts bioavailability or bioequivalence testing for the study sponsor. Where FDA has reason to believe fraud was involved in performing a bioavailability or bioequivalence study that was

conducted by a foreign testing facility, the facility may be asked to consent to FDA inspection or to submit to FDA reserve samples of the products used in the study.

Because access to test samples and related records may be essential to assess the validity and reliability of the results of a required bioavailability or bioequivalence study, the final rule, like the interim rule, adds as a reason for refusing to approve an application and as a circumstance under which FDA has discretion to withdraw approval of an application, refusal to permit an inspection of the facilities or records relevant to a bioavailability or bioequivalence study contained in an application or to submit or release reserve samples when requested by the agency.

II. Comments

FDA received 27 comments on the interim rule. The comments came from pharmaceutical manufacturers, trade associations, a professional group, and contract testing facilities. Most of the comments raised questions or concerns about the reserve sample retention period, quantity of the samples to be retained, and storage requirements for the samples. Several comments requested clarification of the types of in vivo bioavailability studies for which test samples would have to be retained under the new rule. Comments also were received in response to the agency's questions about whether additional requirements were necessary to ensure that the integrity of the reserve samples is not compromised during the retention period.

A. Definition of an "NDA Biobatch" and an "ANDA Biobatch"

1. A number of comments requested clarification of the types of bioavailability studies from which test samples would have to be retained. The comments asked whether the many types of clinical pharmacology, pharmacokinetic, and pharmacodynamic studies in which blood samples are routinely collected for analysis would be considered bioavailability studies for purposes of this rule. Some of the comments suggested that reserve samples be retained only from studies which define the absolute or relative bioavailability of a new drug and studies necessary to demonstrate the bioequivalence of a new formulation to that which was previously studied in clinical trials.

One comment asserted that sample retention should be limited to the lot of test and reference formulations used in the pivotal bioequivalence study. The comment stated that, in the case of an NDA, this would be the lot of the product used in the study or studies conducted to demonstrate equivalence between the investigational formulation(s) and the formulation proposed for marketing. For an ANDA or supplemental application, this would be the study conducted to demonstrate equivalence between the currently marketed form and that proposed for marketing.

Two comments asked whether reserve samples should be kept for all in vivo "biostudies," whether or not the studies were submitted in support of the approval of an application or only for those studies required for approval of an application. The comments' question was based on a perceived conflict between the language of the interim rule at § 320.32(a) (requires retention of samples used in an in vivo bioavailability study "required for approval of the application or supplemental application"), §§ 312.57(c) and 320.31(d)(1) (requires sponsors of all IND's for "biostudies" and persons conducting such studies under an exemption from the IND requirements to retain samples of the products tested, "in accordance with * * * § 320.32"), and § 320.63 (retention of samples is required for products used in an in vivo or in vitro bioequivalence study "required for approval of, or submitted in support of the approval of, the full or abbreviated application or supplemental application * * * in accordance with * * * § 320.32." The comments further asked whether the requirements apply to in vitro studies, noting that § 320.63 refers to sample retention for certain in vitro studies in accordance with § 320.32, but § 320.32 does not apply to in vitro studies.

The agency's Compliance Program 7346.832[1] defines "NDA biobatches" as those NDA batches comparing the product planned for marketing with that studied during clinical trials to establish their equivalence. Generic product biobatches are ANDA batches that are compared to the originator/reference product to establish their equivalence. (See Compliance Program 7346.832, Part III, page 2, footnote 2.) Consistent with these definitions, the final rule applies to the following types of bioavailability/bioequivalence studies:

a. *NDA.* (i) If the formulation of the applicant's proposed drug product (test article) is the same as the formulation(s) used in the pivotal clinical studies, the applicant would retain a reserve sample from the batch of the test article used to conduct an in vivo bioavailability study comparing the test article to a reference oral solution, suspension, or injection. A reserve sample of the reference standard (oral solution, suspension, or injection), which is usually made up when needed for a study, would not be retained. If the bioavailability study needs to be repeated, the reference standard would be prepared at the time of the study. For purposes of this rule, pivotal clinical studies are those adequate and well-controlled studies necessary to establish the safety and effectiveness of the test article for its claimed indications.

(ii) If the formulation of the test article differs from the formulation(s) used in conducting the pivotal clinical studies, the applicant would retain a reserve sample of the test article and of the reference standard from the batches used to conduct an in vivo bioequivalence study comparing the test article to the formulation(s) (reference standard) used in the pivotal clinical studies.

(iii) For a new formulation, new dosage form, or a new salt or ester of an active drug ingredient or therapeutic moiety that has been approved for marketing, a reserve sample of the test article and of the reference standard would be retained from the batches used to conduct an in vivo bioequivalence study comparing the test article to a marketed product (reference standard) that contains the same active drug ingredient or therapeutic moiety.

For an NDA, test article means the drug product for which the applicant is seeking approval. Reference standard has the same meaning as the term reference material in § 320.25.

b. *ANDA.* Reserve samples of the test article and reference standard would be retained from those batches used to conduct an in vivo bioavailability or an in vitro study comparing the test article to the approved drug product upon which the applicant relies for approval of its proposed product to establish their equivalence.

For an ANDA, test article means the drug product for which the applicant is seeking approval. Reference standard means an approved drug product identified by FDA as the drug product upon which an applicant relies in seeking approval of its ANDA and is usually the innovator product.

The agency has revised the final rule at §§ 312.57(c) and 320.38 (§ 320.32 in the interim rule) to clarify the in vivo bioavailability studies from which reserve samples are to be retained. With

[1] Compliance Program 7346.832 is available at cost from the Freedom of Information Staff (HFI–35), Food and Drug Administration, rm. 12A–30, 5600 Fishers Lane, Rockville, MD 20857.

respect to the reference to in vitro studies in § 320.63, but not in § 320.32 of the interim rule, FDA included the two new sections such that they would conform to the then existing structure of 21 CFR part 320. Former subpart B of part 320 addressed procedures for determining the in vivo bioavailability of drug products whereas former subpart C of part 320 addressed bioequivalence requirements, which may be an in vivo or an in vitro test. Section 505(j) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355(j)) requires that an ANDA include information to show that the drug product for which the applicant is seeking approval is bioequivalent to the approved drug product upon which the applicant relies in seeking approval of its abbreviated application. Bioequivalence may be demonstrated by in vivo or in vitro bioequivalence methods as determined by the agency. Thus, the reference to an in vitro study in § 320.63 was necessary to accommodate ANDA's submitted under section 505(j) of the act. Because the rule applies to bioavailability and bioequivalence studies required for approval of an NDA and an ANDA, § 320.63 has been revised to delete the wording "or submitted in support of the approval of." Section 320.63 also has been revised to remove the reference to a full application which is covered by § 320.38.

Section 320.31 exempts from the requirements of part 312 many bioequivalence and bioavailability studies. The interim rule added as a condition for such an exemption that the sponsor, or any contract research organization to whom the sponsor delegates responsibility to conduct a bioequivalence or bioavailability study, retain reserve samples of the test article and reference standard and release them upon request to FDA (55 FR 47034 at 47036 and 47038). In finalizing the new subpart B structure of 21 CFR part 320, FDA inadvertently omitted this provision. Therefore, FDA has revised § 320.31 to retain the requirements set forth in the interim rule and to clarify the in vivo bioavailability studies from which reserve samples are to be retained.

2. One comment requested that the regulations at §§ 314.125(b)(17) and 320.63 be revised to clarify that the regulations apply only to a pivotal bioequivalence study. The comment also asserted that § 320.32 (§ 320.38 in this final rule) be deleted because a "pivotal" bioavailability study is technically a bioequivalence study and retention of samples from this study is discussed in § 320.63.

The agency agrees with the comment regarding § 314.125(b)(17) and has revised the final rule accordingly. The agency's conclusions on the types of bioavailability and bioequivalence studies for which the requirements apply and its revisions to §§ 320.38 and 320.63 are discussed in section II.A.1.

3. One comment suggested that, in the case of multiple "biostudies" usually conducted in sequence for a single NDA or ANDA (i.e., a sustained release product) using the same lot of a product, the regulations specify that one supply of retention samples be provided to the testing facility in sufficient quantity for all studies. The comment also asked whether, if additional supplies of the product are needed, the full amount of retention samples also must be supplied again.

FDA believes that the comment misunderstood the interim rule with respect to how the reserve sample is obtained by a contract testing facility. If bioavailability or bioequivalence testing is performed under contract, the study sponsor provides the testing facility with a supply of the test article and of the reference standard sufficient for the testing facility to conduct the study or studies and to remove a portion of the test article and of the reference standard for retention as reserve samples. FDA did not intend that the study sponsor separate out the reserve samples of the test article and reference standard prior to sending the batches to the testing facility. This is to ensure that the reserve samples in fact are representative of the same batches provided by the study sponsor for the testing.

The study sponsor should provide to the testing facility batches of the test product and of the reference standard packaged such that the reserve samples can be randomly selected to ensure that they are in fact representative of the batches provided by the study sponsor and that they are retained in the study sponsor's original container. Because a study sponsor may provide a testing facility with a variety of container sizes and packaging, FDA intends to be flexible in applying the representativeness requirement. For example, the following random sampling techniques should be used by the testing facility for the container size and packaging described:

a. If a single container of the test article and of the reference standard is provided to the testing facility, the testing facility should remove a quantity of the test article and of the reference standard from their respective container sufficient to conduct the study; the remainder of each container would be retained as the reserve sample in the original container.

b. If multiple containers of the test article and of the reference standard are provided to the testing facility, the testing facility should randomly select enough containers of the test article and of the reference standard to conduct the study; the remaining containers of the test article and of the reference standard would be retained as the reserve sample in the original containers.

c. If the test article and reference standard are provided to the testing facility in unit dose packaging, the testing facility should randomly select a quantity of unit doses of the test article and of the reference standard sufficient to conduct the study; the remaining unit doses of the test article and of the reference standard would be retained as the reserve samples in the original unit dose packaging. Providing the test article and reference standard in unit dose packaging for conducting the study and in bulk containers for all of the reserve samples would not be acceptable because it prevents the testing facility from randomly selecting the reserve samples. However, as an alternative for the reserve samples, the study sponsor may provide the testing facility with a quantity of unit doses of the test article and of the reference standard equal to at least 24 dose units and the remaining quantity sufficient to retain the "five times quantity" in bulk containers.

d. If the study is to be blinded and the test article and reference standard are provided to the testing facility in unit dose packaging, with each unit dose labeled with a randomization code, the study sponsor must provide the testing facility with a labeled set of the test article and reference standard sufficient to conduct the study and with additional, identically labeled sets sufficient to retain the "five times quantity." The testing facility should randomly select a labeled set to conduct the study; the remaining labeled sets would be retained in their unit dose packaging as the reserve samples. For a blinded study, the study sponsor should also provide to the testing facility a sealed code for use by FDA should it be necessary to break the code.

If the same batches of the test article and of the reference standard initially provided to the testing facility are used in performing more than one study, only one reserve sample of the test article and reference standard in sufficient quantity need be retained. The reserve samples must be identified as having come from the same batches as used in each specific study. However, if additional supplies of the test article

and of the reference standard are needed by a testing facility for performing additional studies, the testing facility must retain the required reserve samples from the subsequent shipment regardless of whether the shipment is from the same batch as that previously provided to the testing facility. This is to ensure that the reserve samples are, in fact, representative of the batch provided by the study sponsor to the testing facility.

4. One comment stated that FDA may request additional "biostudies" after submission of an ANDA and a firm may want to use the same lot of test and reference products as was used in conducting the original study. The comment argued that under the strict retention sample requirement, the firm could not conduct these biostudies without depletion of the retention samples.

In the situation described by the comment, the study sponsor would need to use a different batch of the test and reference products to conduct additional studies if supplies of the batches used to conduct the original studies are depleted. The regulations do not permit a study sponsor or contract research organization to use its reserve samples to conduct the additional studies.

5. Several comments requested clarification of the regulations about who is responsible for reserve sample retention. One comment argued that the logical responsible party for long-term retention of samples should be the applicant because the applicant is responsible for the manufacture, packaging, testing, and release of the sample of the test article and minimally the packaging, identification testing, and release of the reference standard. The comment stated that it is not practical to sufficiently control the conditions of storage, sample stability, and sample retention at a contract facility after the completion of a study. One comment argued that some outside testing facilities such as universities, hospitals, and clinics do not have the space or proper environment to hold the reserve samples at all or to hold them at the study location, and many do not have the authority to hold certain reserve samples such as controlled substances. Another comment suggested that the regulations provide for the use of independent, third party organizations for the storage of reserve samples. Still another comment stated that the applicant should have the option of storing reserve samples at a company facility rather than at a contract laboratory.

The agency reaffirms that reserve sample retention is the responsibility of the entity performing the bioavailability or bioequivalence study. If the study sponsor performs the study, it is responsible for reserve sample retention for that study; if a study is performed under contract, the contract research organization retains the reserve samples. The purpose of this requirement is to eliminate the possibility for sample substitution by the study sponsor or to preclude a study sponsor from altering a reserve sample from a study conducted by a contract research organization prior to release of the reserve sample to FDA. In several instances, FDA has found that a study sponsor provided the contract testing facility with disguised innovators' products rather than its own proposed product as the test product in certain bioequivalence studies. The reserve samples collected by FDA must have come from the batches provided by the study sponsor to the testing facility for performing a bioavailability or bioequivalence study.

The agency advises that a contract research organization may contract with an independent, third party to provide storage for reserve samples if the contract research organization does not have facilities to store the samples under conditions consistent with product labeling. In this situation, the contract research organization shall provide to the study sponsor, for submission in the bioavailability or bioequivalence study data, the name and address of the facility at which the reserve samples will be stored. A new paragraph (h) is added to § 320.38 to include this provision. The agency notes that hospitals and clinics may wish to consider using their pharmacies for storage of the reserve samples.

With respect to retention of reserve samples that are controlled substances, the burden is on the person who is responsible for retaining the samples to comply with all applicable requirements of the Controlled Substances Act (21 U.S.C. 801) and its implementing regulations.

6. One comment asked who had responsibility for reserve sample retention when a contract research organization administers the drug and collects biological samples, but the biological samples are then returned to the applicant for analysis.

For purposes of this regulation, the agency would consider the contract research organization to have conducted the study and to be responsible for retaining the reserve samples. Similarly, if one contract research organization administers the drug and another contract research organization performs an analysis of the biological samples, the contract research organization that administers the drug would retain the reserve samples.

B. Reserve Sample Retention Period

7. Numerous comments addressed the length of the sample retention period. The interim rule requires that reserve samples be retained for a period of at least 5 years following the date on which the application or supplemental application is approved, or, if such application or supplemental application is not approved, at least 5 years following the date of completion of a bioavailability or bioequivalence study. The interim rule specifically requested comment on the appropriateness of the retention period.

Most of the comments expressed concern that most reserve samples would not exhibit the stability necessary to maintain strength, quality, and purity over such a prolonged period of time, and, therefore, there could be no guarantee that the samples would be appropriate for evaluation by FDA as intended by the interim rule. Requiring special storage conditions, e.g., refrigeration or dehumidification, to prolong a product's stability beyond its normal shelf life would result in a significant expenditure to the applicant or contract research organization responsible for sample retention. Some comments noted that the 5-year period only begins when the application is approved and, in terms of real time, this could be 6 to 8 years for a generic drug product and 7 to 12 years for a new chemical entity. One comment suggested 3 years rather than 5 years as an appropriate retention period; another comment suggested 2 years past submission of an application or supplement, or until the application is approved, whichever occurs first. One comment suggested that FDA make the sample retention period consistent with the good laboratory practice regulations in 21 CFR 58.195(b) and (c). Another comment suggested a retention period of 5 years from the date the bioavailability or bioequivalence study was completed, arguing that NDA and ANDA approval dates are not routinely communicated to a contract testing facility due to potential conflicts of interest.

The 5-year reserve sample retention period is intended to permit flexibility by FDA in its collection and testing of retention samples. Ordinarily, the reserve samples, or a portion of the reserve samples, will be collected by FDA personnel directly from the study sponsor or contract research organization at the storage site during a

preapproval inspection. FDA's priorities for preapproval inspection and sample collection include narrow therapeutic range drugs, new chemical entities, and generic versions of the 200 most prescribed drugs. For drug products not represented in one of these priority categories, a preapproval inspection would be triggered when the applicant's manufacturing facility is new or has not been recently inspected, and when the NDA or ANDA is the initial application for the applicant. In those cases where preapproval inspections were not conducted and reserve samples were not collected prior to approval of an application or abbreviated application, retention of the reserve samples for the 5-year period would permit their availability for collection and testing after approval. Thus, any retention period that would not continue beyond the approval date of an application, as suggested by some comments, would be unacceptable because it would not provide for the availability of the samples in those situations where a preapproval inspection and sample collection were not conducted or where questions arose after approval about a study sponsor's bioequivalence or bioavailability data.

The agency recognizes that a product retained beyond its normal shelf life may not exhibit the stability necessary to maintain its identity, strength, quality, and purity. However, certain types of analyses can be performed on a product to determine that the test article was indeed used in performing a bioavailability or bioequivalence study and that there was no substitution of the reference standard for the test article. Generally, the formulation of the test article and reference standard will differ. For example, different excipients such as binders, fillers, and lubricants may be used; and products may contain tracer ingredients that are unique to the identification of a particular product. Appropriate analyses can be performed on a product retained beyond its expiration date to detect these differences.

8. One comment asked that FDA clarify in the rule that the retention samples may be kept in any appropriate container and need not necessarily duplicate the containers for the products used in the "biostudy." The comment stated that, in many studies, the drug supplied is packaged in individual unit doses or small bottles containing a single day's supply for each study participant. In such cases, if 500 doses are needed for the retention sample, an appropriately packaged bottle of 500 should be allowed, i.e., not 500 unit doses. Another comment recommended that solution dosage forms, parenterals, inhalation aerosols, biologicals, and other specialized delivery devices where storage, stability, and security could be problematic be excluded from retention status.

FDA does not agree that retention samples be kept in any appropriate container. The reserve samples should be retained in the same container/closure system in which the study sponsor provides to the testing facility the supplies of the test article and reference standard. This will provide to FDA evidence as to how the supplies of the test article and reference standard were received by the testing facility. As noted in section II.A.3, the study sponsor should provide to the testing facility supplies of the test article and of the reference standard packaged such that the reserve samples can be randomly selected by the testing facility and retained in the study sponsor's container/closure system.

The agency disagrees with the comment suggesting that certain dosage forms be excluded from the reserve sample retention requirement. The agency must have adequate assurance that the bioavailability and bioequivalence results upon which FDA bases approval of an application are reliable. Therefore, reserve samples of all products used to conduct the types of bioavailability or bioequivalence studies described in this rule must be available for later examination/analysis by FDA.

9. One comment suggested that reserve samples be stored according to the approved labeling and that this be clarified in the rule. Another comment stated that, for new development compounds, appropriate storage information is not always available during the early stages of development, or if it is, such storage conditions are usually limited or restricted. In such a case, storage is usually in accordance with the sponsor's storage requirements.

The agency did not intend that special storage conditions be provided to prolong a product's stability beyond its normal shelf life. All reserve samples are to be retained and stored under conditions consistent with product labeling. The agency believes that, for the types of bioavailability and bioequivalence studies described above for which reserve samples are to be retained, appropriate storage information will be available in the product's labeling. Section 320.38(e) of this final rule (§ 320.32(c) of the interim rule) has been revised to require storage under conditions consistent with product labeling.

10. One comment argued that, for a contract research organization, determining the starting date for sample retention is often a problem because the contract research organization does not have direct knowledge or control over such events as discontinuance of a compound's development, submission of an application for approval, or approval of an application for marketing, which initiates the 5-year retention period.

The agency believes that a contract research organization can make arrangements with a study sponsor regarding notification of the status of the application for which a bioavailability or bioequivalence study has been conducted, and that it is the responsibility of the contract research organization to obtain such information in order to comply with the sample retention requirements of this rule. There is nothing in the regulations that prevents the inclusion, in the contract between a study sponsor and a contract research organization, of a condition requiring the study sponsor to notify the contract research organization of those regulatory actions about a test article that are necessary for a contract research organization to comply with this rule, e.g., discontinuance of the development of a drug, submission of an application for approval, or date of approval of an application for the test article. Thus, the agency recommends that all contract research organizations insist on the inclusion of such a condition in their contract with the study sponsor.

11. One comment stated that the reference standard used for determining bioavailability is usually a solution or suspension that is made up especially for the study, which would rarely be expected to be stable for more than 6 years. The comment suggested an exemption from the sample retention requirements for these reference standards.

As discussed under section II.A.1.a.(i), a reserve sample of the reference standard from the batch used to conduct a bioavailability study comparing the test product to a reference oral solution, suspension, or injection need not be retained. If the study needs to be repeated, the reference standard would be prepared at the time of the study.

12. One comment asked if the 5-year sample retention requirement would apply if, after receiving a not approvable letter from the agency, the applicant decides to withdraw the NDA.

The final rule, like the interim rule, requires that if an application or supplemental application is not approved, reserve samples be retained at least 5 years following the date of

completion of the bioavailability or bioequivalence study in which the sample, from which the reserve sample was obtained, was used. A decision by the applicant to withdraw its application in response to a not approvable letter is without prejudice to refiling. Therefore, because an applicant may resubmit its application, data from previously conducted bioavailability studies could be used for approval of the resubmitted application. Thus, in the situation described by the comment, the reserve samples must be retained for the required time period. The agency believes, however, that in some cases, given the time that may elapse between the conduct of a study and the completion of FDA's review of an application, the 5-year period following the date of completion of a bioavailability study will have expired.

13. One comment asked if the agency would grant a waiver reducing the reserve sample amounts if sufficient quantities of a drug product were not available due to production restrictions such as high product costs or high potency compounds.

The agency does not intend to grant waivers from the requirements of this rule. FDA must be assured that the bioavailability and bioequivalence results upon which FDA bases approval are reliable. Therefore, samples of the products used to conduct the types of bioavailability and bioequivalence studies described in this rule must be available for FDA's analysis. An applicant should consider the requirements of this rule in determining its production quantities.

C. Quantity of Reserve Samples

14. The interim rule required that a sufficient quantity of the reserve samples be retained to permit FDA to perform five times all of the release tests required in the application or supplemental application.

Several comments argued that the quantity of both the test article and reference standard seemed excessive, and asked the agency to reconsider the retention sample size requirement in light of the intended uses for the retained samples. Some comments suggested that the regulations be modified to reflect either the requirement of twice the quantity needed for release testing under the current good manufacturing practice (CGMP) regulations, or the NDA methods validation requirement in 21 CFR 314.50(e) of three times the quantity necessary to perform each test. Two comments argued that samples of the reference standard usually are obtained from the marketplace, and it can be extremely difficult to find in large quantities a single lot of a product sufficient to conduct the study and to retain a portion for the reserve sample. One of the comments suggested retention of two intact bottles of the reference standard sample for identification of lot number, expiry, strength, etc., for 3 years.

One comment asserted that acquiring large quantities of material, if available, for no purpose other than satisfying an excessive retention requirement is an unnecessary economic cost. In addition, the comment suggested that, in assessing potential uses, the agency consider that: (1) the materials to be tested may have been well into their anticipated shelf life at the time of the bioavailability or bioequivalence testing, and (2) the materials will inevitably continue to deteriorate over time such that many potential tests of the retained material (e.g., rerun of release tests or of the "biostudy" itself) could well be meaningless even if those retests are conducted during the application review process. Another comment asserted that the regulation will cause an economic impact in that additional storage space will need to be obtained and existing space modified in order to meet unique and long-term storage requirements. One comment stated that it may not be practical to retain the five times quantity for special dosage forms in limited supply such as early development lots for bioavailability studies.

FDA's experience in the testing of reserve samples of drug products used in a bioavailability or bioequivalence study is that the five times quantity required for the test article and the reference standard is needed to perform necessary testing. Although the interim rule required a "sufficient quantity to permit FDA to perform five times all of the release tests required in the application or supplemental application," FDA does not intend to perform release tests on the reserve samples. The five times quantity standard is intended to provide a yardstick for the retention of a sufficient quantity of the samples by all study sponsors and contract research organizations. The reserve samples of the test article and of the reference standard are used by FDA to conduct a chemical and physical examination of the samples to assure the identity and composition of the test article and reference standard. This is necessary to detect fraudulent substitution of the reference standard for the test article in conducting a bioavailability or bioequivalence study. Although generic drugs are expected to be functionally equivalent to their brand-name counterparts, they are not expected to be identical in all physical and chemical aspects because of differences in, for example, identity and proportions of excipients. These differences are used by FDA to determine if fraudulent substitution has occurred. Any remaining reserve sample is held by FDA in the event that additional testing is necessary. For example, FDA may need to repeat the bioavailability or bioequivalence testing or to perform other appropriate analyses such as content uniformity and dissolution testing on the samples.

The agency agrees that, for some reference standards, only limited quantities may be available in the marketplace. However, FDA believes that sufficient quantities are available to conduct the necessary "biostudies" and to provide the required reserve samples.

The agency continues to believe that the five times quantity standard is an appropriate standard for the reserve sample of the test article and of the reference standard and is retaining that standard in this final rule. However, a study sponsor or contract research organization may consult with the agency if it believes certain dosage forms present unreasonable storage problems. If a contract research organization is unsure of what quantity constitutes the five times quantity, it should contact the study sponsor.

15. One comment asked if the requirement to retain a sufficient quantity of reserve sample to allow FDA to perform five times all of the release tests required in the application or supplemental application provides enough sample for FDA to repeat the bioavailability or bioequivalence testing or perform other appropriate testing, if necessary. Another comment asked if the required retention sample size included sufficient material to allow for a so-called "split" sample so that the applicant could independently verify any tests conducted by the agency on the retained material.

The quantity of sample required to be retained is sufficient for all testing by FDA including a repeat of a bioavailability or bioequivalence study, if necessary. No additional samples beyond the five times quantity need be retained by the study sponsor or contract research organization. However, the required retention sample size does not provide sufficient material for independent testing by the study sponsor.

16. One comment asked for clarification of the sample retention requirement with respect to products that are manufactured in a dry form and

need to be reconstituted just prior to use in a study.

For purposes of the sample retention requirement in this rule, the reserve sample would consist of the product in the dry form, not the reconstituted form.

17. Two comments requested clarification of the effective date of the interim rule with respect to ongoing studies. One comment argued that testing programs already underway as of November 8, 1990, the effective date of the interim rule, should not have to be restarted because insufficient material is available to satisfy the sample retention requirement in addition to that necessary to conduct the required tests. The comment further stated that even if additional material from the same product lots were available, it could not be "representative" of the material submitted for the "biostudies" unless it had been submitted to the testing laboratory at the same time as the original material. One comment argued that, at a minimum, the new requirements should be deemed to be satisfied, in the case of ongoing studies, by the retention of as much material as is available after the testing is complete. This would also apply to study programs which commenced prior to November 8, 1990, if subsequent studies were planned to use the same limited lots of test or reference drugs.

The requirements established in the interim rule apply only to bioavailability and bioequivalence studies that were initiated on or after November 8, 1990.

18. One comment addressed the provisions of §§ 314.125(b)(17) and 314.150(b)(9), which state that FDA may refuse to approve, or to withdraw approval of, an application if an applicant or contract research organization refuses to permit an inspection of its facilities or records, or refuses to submit to FDA reserve samples when requested. The comment asked that when a contract research organization, without the knowledge or approval of the applicant, refuses to permit an FDA inspection of facilities or records relevant to a study or to submit to FDA reserve samples of drug products used in the study, the rule provide for notification to the applicant with an opportunity to intervene before any agency action to refuse to approve, or to withdraw the approval of, an application.

The agency advises that the regulations concerning FDA's action to refuse to approve an application or to withdraw the approval of an application are set forth under §§ 314.120 and 314.150, respectively. Thus, an applicant will have an opportunity to respond to any agency action by the procedures for denying or withdrawing the approval of an application. The agency emphasizes that, because actions or inactions of a contract research organization may affect the status of an applicant's application, the applicant may well wish to assure that the obligation to permit inspection and to release or submit to FDA reserve samples is included in any contract.

19. One comment suggested that the written assurance that the reserve samples came from the same samples as used in the specific bioavailability or bioequivalence study required under § 320.32(e) of the interim rule be modeled after 21 CFR 10.20(j), which requires that submissions to the Dockets Management Branch include a statement that, to the best of the knowledge, information, and belief of the person making the submission, the statements made in the submission are true and accurate. The comment argued that due to the extended period of time that samples must be retained and potential personnel turnover during that time, the person executing the written assurance may not have firsthand knowledge of the history of the sample being released to the agency, and may have to rely on company documentation. The comment further argued that an assurance provided under the interim rule would subject an individual to potential criminal liability under 18 U.S.C. 1001, based upon whether the statement is true or not, even though the person may not have direct personal knowledge of its falsity. Another comment asked in what form the written assurance should be. One comment asserted that both the sponsor and testing laboratory should certify that the reserve samples are those used in the specific bioavailability or bioequivalence studies submitted to FDA, and that copies of the certification statements should be held by both parties and be made available to FDA upon request.

The agency agrees that the person executing the written assurance may not have firsthand knowledge of the history of the samples and may have to rely on records of the applicant or contract research organization. Therefore, FDA has revised § 320.38(g) (§ 320.32(e) in the interim rule) to require that the applicant or contract research organization provide a written assurance that, to the best knowledge and belief of the individual executing the assurance, the reserve samples came from the same samples as used in the specific bioavailability or bioequivalence study identified by the agency. The written assurance may be in the form of a certification or other appropriate form. Because it is the contract research organization that separates out the reserve samples from the supplies of the test article and reference standard provided by the study sponsor rather than the study sponsor, FDA does not believe that the study sponsor can assure that the reserve samples came from the same batch as used in a specific bioavailability or bioequivalence study. Therefore, FDA does not agree with the assertion that both the study sponsor and testing laboratory certify with respect to the reserve sample.

20. Two comments asked that the requirement in § 320.32(b) of the interim rule, which requires that samples be positively identified as having come from the same sample as used in the specific bioavailability or bioequivalence study, be more specific as to what is expected.

The agency believes that specific ways to identify reserve samples and the study in which they were used should be left to the study sponsor or contract research organization responsible for retaining the samples. Therefore, the agency declines to provide specificity in the regulation. Appropriate identification may, however, consist of, but not be limited to, including on the sample container and in the study report, the product name, lot number, and study number.

21. One comment suggested that for inhalants that require exhaustive number of dosage units to be tested for release and require large storage space, a definitive number of retention samples, for example, 10 to 20 units, should be sufficient.

As discussed in section II.C.14, FDA does not intend to perform release testing on the reserve samples. Nevertheless, the agency does not agree that 10 to 20 units of an inhalant dosage form are sufficient for FDA's analysis and testing. As also discussed in section II.C.14, the reserve samples ordinarily will be used by FDA to perform a chemical and physical examination of the samples. The agency may also need to perform analyses such as content uniformity and dissolution for solid oral dosage forms and may need to repeat the bioavailability or bioequivalence testing. The agency concludes that the quantity of the reserve sample of an inhalant test article and of the reference standard needed for testing and analyses must be at least 50 units.

D. Need For Additional Requirements

22. In the preamble to the interim rule, FDA stated it was considering whether additional requirements were

necessary to ensure the integrity of the reserve samples and invited comment on questions relating to storage area, need for a sample custodian, and packaging of the reserve samples. Seventeen comments responded to the agency's questions or otherwise addressed the issue of the need for additional requirements.

Two comments recommended that, under CGMP regulations, applicants be required to adopt written procedures for selection of samples from drug lots used in bioavailability or bioequivalence testing and for secure transmission of these samples to internal facilities or contract research organizations for "biotesting" and storage. Additional written procedures should establish the security measures to be followed for retained samples, including requirements for the storage area, sample custodian, and packaging of the samples to ensure that sample integrity is not compromised. Most of the comments recommended that the reserve samples be stored in an area where access is controlled and that is separate from the testing area. One comment, however, asked for a clarification of the wording "separate from" arguing that it is not necessary to require separation from the testing area so long as the storage area is segregated and access is controlled. A majority of the comments suggested that the need for a sample custodian should be left up to the applicant or testing facility and not be required by regulation. Responses to the questions of how the reserve samples should be packaged during the retention period to ensure that sample integrity is not compromised and to prevent tampering varied among the responders. Some comments recommended that the packaging of the reserve samples be in the same container/closure as that provided to the testing facility or a normal marketed package; other comments suggested using tamper-resistant packaging, using a sealed protective container such as glass, taking appropriate measures to prevent tampering, or that there is no need for specific packaging requirements if there is appropriate documentation based on written operating procedures.

FDA agrees with those comments recommending that reserve samples be stored in an area separate from the testing area and with controlled access. Accordingly, § 320.38(e) [§ 320.32(c) in the interim rule) has been revised to require that each reserve sample be stored in an area segregated from the area where testing is conducted and with access limited to authorized personnel. The agency has used the phrase "segregated from" rather than "separate from" because it is not intended that the storage area necessarily be in a different room, building, or facility. The requirement is intended to ensure that enough physical separation be employed by the study sponsor or contract research organization as is necessary to ensure that the integrity of the reserve sample is not compromised during the retention period.

The agency is not including other additional requirements at this time. If, based on FDA's inspectional experience and collection of reserve samples, the agency believes additional requirements are needed to ensure the integrity of the samples, it will propose appropriate revisions to this rule. The rule does not preclude study sponsors from adopting written procedures for the selection and transmission to the testing facility or contract research organization of the test article and reference standard for testing and storage of the reserve samples.

E. Other Comments

23. One comment noted that the interim rule did not address the situation where a contract testing laboratory goes out of business or is otherwise not in a position to continue to meet its obligations under the rule. The comment suggested that, under such circumstances, the sponsor should be allowed to recover from the contractor any retained samples from the studies it sponsored because sponsors are already required under the interim rule to maintain samples for studies conducted in-house. This would obviate the need for special procedures to deal with the insolvency of contractors or other potential problems with third party custodians, and would greatly simplify FDA's ability to obtain the samples because they would be readily available from the sponsor even for studies conducted by contract testing laboratories in foreign countries.

The agency agrees that the rule should provide for the transfer of reserve samples if a contract research organization goes out of business, but does not agree that the samples should be transferred to the sponsor or applicant for whom the contract research organization conducted the bioavailability or bioequivalence study. Rather, to preclude the possibility for sample substitution by a study sponsor or to preclude a study sponsor from altering a reserve sample, FDA concludes that the reserve samples should be transferred to an appropriate, independent third party, e.g., a commercial storage facility or a university. Therefore, a new paragraph (i) is added to § 320.38 (§ 320.32 in the interim rule), which states that when a contract research organization conducting a bioavailability or bioequivalence study requiring reserve sample retention goes out of business, it shall transfer its reserve samples to an appropriate, independent third party and shall notify in writing the sponsor of the study and provide the sponsor with the name and address of the facility to which the reserve samples have been transferred. Because the comment did not describe the circumstances in which a contract research organization "is otherwise not in a position to continue to meet its obligations under the rule," no further revision of the rule has been made.

24. One comment suggested that after the retention period is up, samples should be returned to the sponsor for proper accountability and destruction as required under CGMP's.

The agency advises that this final rule, like the interim rule, does not preclude such an approach. The study sponsor may wish to include in the contractual agreement with the contract research organization provisions for handling of the reserve samples after the retention period has expired. It should be noted, however, that the CGMP regulations do not address disposition of outdated reserve samples required to be retained under those regulations.

25. One comment suggested using a standardized photographic archiving procedure to show the drug product at the time of dosing for the bioavailability or bioequivalence study. This photographic record could be retained beyond the expiration date of the product, and would demonstrate the product's physical appearance.

The agency does not intend to require a photographic archiving procedure in this final rule; however, this does not preclude a testing facility from adopting such a procedure. FDA intends, as part of its physical analysis of a product that is a solid oral dosage form, to photograph each strength of each product to clearly document its shape, color, and distinctive markings. These photographs will be retained by FDA for later use in comparing subsequent batches of the test article or in comparing the test article to the reference standard.

26. Several comments addressed a statement in the preamble to the interim rule that states "in vitro and animal in vivo bioequivalence and bioavailability studies are within the scope of the good laboratory practice regulations." The comments argued that animal bioequivalence and bioavailability studies have not previously been

considered within the scope of 21 CFR part 58 except when conducted as part of a toxicology protocol or when conducted to directly support a toxicology protocol. The comments asked that FDA further clarify the scope of the preamble statement and this rule.

The agency believes the regulations at 21 CFR part 58 are ambiguous with respect to in vitro and animal in vivo bioavailability and bioequivalence studies required for approval of an NDA or ANDA; however, it is understood that no one considers those regulations to apply to the types of studies subject to this rule. Therefore, the requirements of this rule do not affect the reserve sample retention requirements under 21 CFR part 58.

III. Economic Impact

FDA has examined the economic consequences of the changes implemented by the final rule in accordance with Executive Order 12291 and the Regulatory Flexibility Act (Pub. L. 96–354). This final rule more clearly defines the types of in vivo bioavailability studies for which reserve samples are to be retained. Although this rule has been in place as an interim regulation, the agency is not aware that it has imposed any undue costs. Nevertheless, because several comments to the record alluded to potential costs, the agency has conducted a Threshold Assessment of the final rule, which is on file with the Dockets Management Branch (HFA–305), rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857.

The agency's assessment presents costs of retaining samples for an estimated 360 marketing applications per year. The study addressees both the additional storage costs and the acquisition costs of the test articles and reference standards. Storage costs were estimated on the basis of each sample requiring 0.5 square feet of storage for 5 years, and amounted to about $2,800. These costs would be roughly proportionate to the duration of the retention period. Acquisition costs of about $94,000 for reference samples were obtained from a survey of average retail prices of 16 well-prescribed medicines. Although individual circumstances may arise where storage or acquisition costs for a particular sample could rise substantially above these estimates, the agency believes that, on average, the annual costs of this rule will be about $100,000. FDA believes that these costs will likely be more than offset by the societal benefits of this rule, i.e., the added assurance that FDA's drug approval process functions effectively to ensure that only safe and effective drug products enter the marketplace. Accordingly, the agency concludes that this final rule is not a major rule as defined by Executive Order 12291, and certifies that the final rule will not have a significant impact on a substantial number of small entities, as defined by the Regulatory Flexibility Act.

Notwithstanding the above agency assessment, FDA believes that it would be desirable to have available specific data with respect to various sample retention periods and quantities of samples to be retained. Therefore, the agency is soliciting information on the following areas:

(1) The incremental costs of retention of samples for 3 years relative to 4 years, and 4 years relative to 5 years;

(2) The incremental costs of retention of a "4 times quantity" of samples relative to a "5 times quantity"; and

(3) Any information on the incremental benefits of either retaining greater quantities of samples, or of retaining samples for greater periods of time.

Interested persons may, on or before May 28, 1993 submit to the Dockets Management Branch (address above) information on these areas. Two copies of any information should be submitted, except that individuals may submit one copy. Information submitted is to be identified with the docket number found in brackets in the heading of this document. Information received may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

IV. Environmental Impact

The agency has determined under 21 CFR 25.24(a)(8) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

List of Subjects

21 CFR Part 312

Drugs, Exports, Imports, Investigations, Labeling, Medical research, Reporting and recordkeeping requirements, Safety.

21 CFR Part 314

Administrative practice and procedure, Confidential business information, Drugs, Reporting and recordkeeping requirements.

21 CFR Part 320

Drugs, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act, the Public Health Service Act, and authority delegated to the Commissioner of Food and Drugs, 21 CFR parts 312, 314, and 320 are amended as follows:

PART 312—INVESTIGATIONAL NEW DRUG APPLICATION

1. The authority citation for 21 CFR part 312 continues to read as follows:

Authority: Secs. 201, 301, 501, 502, 503, 505, 506, 507, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 351, 352, 353, 355, 356, 357, 371); sec. 351 of the Public Health Service Act (42 U.S.C. 262).

2. Section 312.57 is amended by revising paragraph (c) to read as follows:

§ 312.57 Recordkeeping and record retention.

* * * * *

(c) A sponsor shall retain reserve samples of any test article and reference standard identified in, and used in any of the bioequivalence or bioavailability studies described in, § 320.38 or § 320.63 of this chapter, and release the reserve samples to FDA upon request, in accordance with, and for the period specified in § 320.38.

* * * * *

PART 314—APPLICATIONS FOR FDA APPROVAL TO MARKET A NEW DRUG OR AN ANTIBIOTIC DRUG

3. The authority citation for 21 CFR part 314 continues to read as follows:

Authority: Secs. 201, 301, 501, 502, 503, 505, 506, 507, 701, 706 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 351, 352, 353, 355, 356, 357, 371, 376).

4. Section 314.125 is amended by revising paragraph (b)(17) to read as follows:

§ 314.125 Refusal to approve an application or abbreviated antibiotic application.

* * * * *

(b) * * *

(17) The applicant or contract research organization that conducted a bioavailability or bioequivalence study described in § 320.38 or § 320.63 of this chapter that is contained in the application or abbreviated antibiotic application refuses to permit an inspection of facilities or records relevant to the study by a properly authorized officer or employee of the Department of Health and Human Services or refuses to submit reserve samples of the drug products used in the study when requested by FDA.

* * * * *

5. Section 314.127 is amended by revising paragraph (b) to read as follows:

§ 314.127 Refusal to approve an abbreviated new drug application.

* * * * *

(b) FDA may refuse to approve an abbreviated application for a new drug if the applicant or contract research organization that conducted a bioavailability or bioequivalence study described in § 320.63 of this chapter that is contained in the abbreviated new drug application refuses to permit an inspection of facilities or records relevant to the study by a properly authorized officer of employee of the Department of Health and Human Services or refuses to submit reserve samples of the drug products used in the study when requested by FDA.

6. Section 314.150 is amended by revising paragraph (b)(9) to read as follows:

§ 314.150 Withdrawal of approval of an application or abbreviated application.

* * * * *

(b) * * *

(9) That the applicant or contract research organization that conducted a bioavailability or bioequivalence study described in § 320.38 or § 320.63 of this chapter that is contained in the application or abbreviated application refuses to permit an inspection of facilities or records relevant to the study by a properly authorized officer or employee of the Department of Health and Human Services or refuses to submit reserve samples of the drug products used in the study when requested by FDA.

* * * * *

PART 320—BIOAVAILABILITY AND BIOEQUIVALENCE REQUIREMENTS

7. The authority citation for 21 CFR part 320 continues to read as follows:

Authority: Secs. 201, 501, 502, 505, 507, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 351, 352, 355, 357, 371).

8. Section 320.31 is amended by revising paragraph (c), by adding new paragraph (d), and by removing paragraphs (e) and (f) to read as follows:

§ 320.31 Applicability of requirements regarding an "Investigational New Drug Application."

* * * * *

(c) The provisions of parts 50, 56, and 312 of this chapter are applicable to any bioavailability or bioequivalence study in humans conducted under an IND.

(d) A bioavailability or bioequivalence study in humans other than one described in paragraphs (a) through (c) of this section is exempt from the requirements of part 312 of this chapter if the following conditions are satisfied:

(1) If the study is one described under § 320.38(b) or § 320.63, the person conducting the study, including any contract research organization, shall retain reserve samples of any test article and reference standard used in the study and release the reserve samples to FDA upon request, in accordance with, and for the period specified in, § 320.38; and

(2) An in vivo bioavailability or bioequivalence study in humans shall be conducted in compliance with the requirements for institutional review set forth in part 56 of this chapter, and informed consent set forth in part 50 of this chapter.

9. Section 320.38 is revised to read as follows:

§ 320.38 Retention of bioavailability samples.

(a) The applicant of an application or supplemental application submitted under section 505 or 507 of the Federal Food, Drug, and Cosmetic Act, or, if bioavailability testing was performed under contract, the contract research organization shall retain an appropriately identified reserve sample of the drug product for which the applicant is seeking approval (test article) and of the reference standard used to perform an in vivo bioavailability study in accordance with and for the studies described in paragraph (b) of this section that is representative of each sample of the test article and reference standard provided by the applicant for the testing.

(b) Reserve samples shall be retained for the following test articles and reference standards and for the studies described:

(1) If the formulation of the test article is the same as the formulation(s) used in the clinical studies demonstrating substantial evidence of safety and effectiveness for the test article's claimed indications, a reserve sample of the test article used to conduct an in vivo bioavailability study comparing the test article to a reference oral solution, suspension, or injection.

(2) If the formulation of the test article differs from the formulation(s) used in the clinical studies demonstrating substantial evidence of safety and effectiveness for the test article's claimed indications, a reserve sample of the test article and of the reference standard used to conduct an in vivo bioequivalence study comparing the test article to the formulation(s) (reference standard) used in the clinical studies.

(3) For a new formulation, new dosage form, or a new salt or ester of an active drug ingredient or therapeutic moiety that has been approved for marketing, a reserve sample of the test article and of the reference standard used to conduct an in vivo bioequivalence study comparing the test article to a marketed product (reference standard) that contains the same active drug ingredient or therapeutic moiety.

(c) Each reserve sample shall consist of a sufficient quantity to permit FDA to perform five times all of the release tests required in the application or supplemental application.

(d) Each reserve sample shall be adequately identified so that the reserve sample can be positively identified as having come from the same sample as used in the specific bioavailability study.

(e) Each reserve sample shall be stored under conditions consistent with product labeling and in an area segregated from the area where testing is conducted and with access limited to authorized personnel. Each reserve sample shall be retained for a period of at least 5 years following the date on which the application or supplemental application is approved, or, if such application or supplemental application is not approved, at least 5 years following the date of completion of the bioavailability study in which the sample from which the reserve sample was obtained was used.

(f) Authorized FDA personnel will ordinarily collect reserve samples directly from the applicant or contract research organization at the storage site during a preapproval inspection. If authorized FDA personnel are unable to collect samples, FDA may require the applicant or contract research organization to submit the reserve samples to the place identified in the agency's request. If FDA has not collected or requested delivery of a reserve sample, or if FDA has not collected or requested delivery of any portion of a reserve sample, the applicant or contract research organization shall retain the sample or remaining sample for the 5-year period specified in paragraph (e) of this section.

(g) Upon release of the reserve samples to FDA, the applicant or contract research organization shall provide a written assurance that, to the best knowledge and belief of the individual executing the assurance, the reserve samples came from the same samples as used in the specific bioavailability or bioequivalence study identified by the agency. The assurance shall be executed by an individual authorized to act for the applicant or contract research organization in releasing the reserve samples to FDA.

(h) A contract research organization may contract with an appropriate, independent third party to provide storage of reserve samples provided that the sponsor of the study has been notified in writing of the name and address of the facility at which the reserve samples will be stored.

(i) If a contract research organization conducting a bioavailability or bioequivalence study that requires reserve sample retention under this section or § 320.63 goes out of business, it shall transfer its reserve samples to an appropriate, independent third party, and shall notify in writing the sponsor of the study of the transfer and provide the study sponsor with the name and address of the facility to which the reserve samples have been transferred.

10. Section 320.63 is revised to read as follows:

§ 320.63 Retention of bioequivalence samples.

The applicant of an abbreviated application or a supplemental application submitted under section 505 or 507 of the Federal Food, Drug, and Cosmetic Act, or, if bioequivalence testing was performed under contract, the contract research organization shall retain reserve samples of any test article and reference standard used in conducting an in vivo or in vitro bioequivalence study required for approval of the abbreviated application or supplemental application. The applicant or contract research organization shall retain the reserve samples in accordance with, and for the period specified in, § 320.38 and shall release the reserve samples to FDA upon request in accordance with § 320.38.

Dated: March 3, 1993.

Michael R. Taylor,

Deputy Commissioner for Policy.

[FR Doc. 93–9927 Filed 4–27–93; 8:45 am]

BILLING CODE 4160–01–F

Reader Aids

Federal Register

Vol. 58, No. 80

Wednesday, April 28, 1993

INFORMATION AND ASSISTANCE

Federal Register

Index, finding aids & general information	202–523–5227
Public inspection desk	523–5215
Corrections to published documents	523–5237
Document drafting information	523–3187
Machine readable documents	523–3447

Code of Federal Regulations

Index, finding aids & general information	523–5227
Printing schedules	523–3419

Laws

Public Laws Update Service (numbers, dates, etc.)	523–6641
Additional information	523–5230

Presidential Documents

Executive orders and proclamations	523–5230
Public Papers of the Presidents	523–5230
Weekly Compilation of Presidential Documents	523–5230

The United States Government Manual

General information	523–5230

Other Services

Data base and machine readable specifications	523–3447
Guide to Record Retention Requirements	523–3187
Legal staff	523–4534
Privacy Act Compilation	523–3187
Public Laws Update Service (PLUS)	523–6641
TDD for the hearing impaired	523–5229

ELECTRONIC BULLETIN BOARD

Free **Electronic Bulletin Board** service for Public Law numbers, Federal Register finding aids, and a list of Clinton Administration officials. 202–275–1538, or 275–0920

FEDERAL REGISTER PAGES AND DATES, APRIL

17081–17320.....1
17321–17490.....2
17491–17772.....5
17773–17942.....6
17943–18138.....7
18139–18336.....8
18337–19032.....9
19033–19192.....12
19193–19320.....13
19321–19546.....14
19547–19766.....15
19767–21092.....16
21093–21240.....19
21241–21342.....20
21343–21534.....21
21535–21636.....22
21637–21888.....23
21889–25536.....26
25537–25772.....27
25773–25928.....28

CFR PARTS AFFECTED DURING APRIL

At the end of each month, the Office of the Federal Register publishes separately a List of CFR Sections Affected (LSA), which lists parts and sections affected by documents published since the revision date of each title.

3 CFR

Executive Orders:
12842.....17081
12843.....21881
12844.....21885
12845.....21887
12846.....25771
July 2, 1910
(Revoked in part by PLO 6961).....18018
January 4, 1901
(Revoked in part by PLO 6964).....19212

Proclamation:
6179 (See Proc. 6544)
6455 (See Proc. 6544)
6515 (See Proc. 6544)
6517 (See Proc. 6544)
6540.....17773
6541.....19315
6542.....19317
6543.....19319
6544.....19547
6545.....21093
6546.....21341
6547.....25537
6548.....25539
6549.....25541

Administrative Orders:
Presidential Determinations:
No. 92–18 of February 28, 1992
(See No. 93–18 of March 31).....19033
No. 93–17 of March 17.....19193
No. 93–18 of March 31, 1993.....19033
No. 93–19 of April 15, 1993.....21889

4 CFR

Proposed Rules:
27.....25785
28.....25785

5 CFR

330.....18139
335.....18139
870.....18142
890.....18142

7 CFR

16.....18143
29.....21343
110.....19014
400.....17943, 17944
401.....21241
925.....21535
944.....21536
1001.....17946
1002.....17946
1011.....17947
1413.....18304
1477.....19767
1493.....21218
1703.....21637
1944.....21891
1956.....21344
1962.....21344
3401.....21852

Proposed Rules:
301.....21113
1097.....25576
1098.....25577
1099.....25577
1150.....25785
1160.....21512, 25900
1413.....17807
1710.....21661
1735.....21661
1785.....18043
1786.....18043
1788.....25786

9 CFR

Proposed Rules:
94.....17462
112.....25786
113.....21114
317.....19781

10 CFR

2.....17321
50.....21904
52.....21904
72.....17948
1703.....21241

Proposed Rules:
20.....18049, 19784, 25578
50.....18167
61.....25578
72.....19786
73.....21546
170.....21116, 21662
171.....21116, 21662

11 CFR

110.....17967

12 CFR

207.....25543
220.....25543
221.....25543
224.....25543
226.....17083
701.....21642
705.....21642
748.....17491
791.....17492
902.....19195
904.....19197
906.....19202
909.....19204

960.....17968
1627.....18144, 21627
Proposed Rules:
327.....17533
700.....21953
701.....17808, 21953
722.....21953

13 CFR

101.....19321

14 CFR

11.....18138
21.....19553
23.....18958
25.....19553
39.....17972, 18337, 18338, 18340, 18341, 18342, 19049, 19322, 19326, 19327, 19328, 19571, 19768, 21242, 21346, 21537, 21912, 21914, 21916, 21917, 21920, 21922, 21923, 25546, 25548, 25549, 25551, 25552
71.....17322, 17494, 18344, 19152, 19208, 19573, 19574, 19575
73.....17323, 18345, 21249
93.....21095
97.....17324, 17325
Proposed Rules:
Ch. I.....19634, 21274
39.....18051, 18053, 18347, 19068, 19069, 19071, 19073, 19634, 19635, 19787, 19788, 21546, 21692, 21955, 21957, 21959, 25579
71.....17541, 17543, 18054, 18055, 18349, 19214, 19637, 21122, 21123, 21411
73.....18351
121.....21336

15 CFR

303.....21347
775.....25553
799.....21925
Proposed Rules:
946.....18316

16 CFR

400.....21095
Proposed Rules:
305.....18056
306.....25582
400.....25703
404.....21124
410.....21125
418.....21125

17 CFR

1.....17495, 19575, 21776, 22019
3.....19575, 21776
5.....19769
10.....19575
30.....17495, 19209, 22019
33.....17495, 22019
145.....19575
150.....17973
180.....17495, 22019
190.....17495, 22019
200.....17327, 21348, 25773
202.....17327
228.....19598, 21348
229.....17327, 19598, 21348
230.....17327, 18145
232.....21348
239.....17327, 19050, 19330, 21927
240.....17327, 18145, 19330, 19598, 21334, 21348, 25773
249.....17327
250.....17327
259.....17327
270.....17327, 19050, 19330, 21927
274.....17327, 19050, 19330, 21927
Proposed Rules:
12.....17369
150.....18057
200.....18352
230.....19361
239.....19361
270.....18352
274.....19361

18 CFR

101.....17982
154.....25555
201.....17982
271.....19607
365.....21250, 25900
Proposed Rules:
Ch. I.....18185, 19215
141.....17544, 19876
284.....19365, 25583
401.....18352
1301.....17553

19 CFR

10.....18146
12.....19347, 21334
101.....21349, 21350
177.....21538
Proposed Rules:
122.....19366
201.....19638
207.....19638

21 CFR

Ch. I.....17085
1.....17085, 17328, 19876
5.....17091, 17093, 17094, 17095, 17096, 17105, 17341, 18346
12.....17095
14.....17095
20.....17096, 17097
73.....17506, 17508
74.....17098, 17510, 21538
100.....17096, 17097
101.....17085, 17096, 17097, 17099, 17100, 17101, 17102, 17103, 17104, 17328, 17341, 17343, 19876
102.....17102, 17103
104.....17104
105.....17096, 17104
130.....17103, 17105
131.....17105
133.....17105
135.....17103, 17105
136.....17103
137.....17103
139.....17103
145.....17103
146.....17103
150.....17103
152.....17103
155.....17103
156.....17103
158.....17103
160.....17103
161.....17103
163.....17103
164.....17103
166.....17103, 21648
168.....17103, 17105
169.....17103
172.....17098, 19770, 21096, 21097, 21098, 21099
175.....21256, 21257
176.....21100
177.....17098, 21258
178.....17098, 17512, 17512, 17513, 17514
186.....17098
189.....17098
312.....25918
314.....25918
320.....25918
520.....18304
522.....18304
529.....17346
558.....17515, 17516, 17346
579.....18147
630.....19609
1308.....17106
Proposed Rules:
100.....17171
101.....17171, 18057
102.....17171
135.....17172
161.....17171
330.....17553
358.....17554
876.....25902
1308.....25788, 25790

22 CFR

514.....18304

23 CFR

Proposed Rules:
657.....19367
658.....19367
1309.....21649
1313.....21649

24 CFR

50.....17164
215.....21657
236.....21657
574.....17164
813.....21657
905.....17164, 19349, 21657
913.....21657
3500.....17165
Proposed Rules:
125.....17172
290.....21960
576.....17764
886.....21960
3280.....19536
3282.....19536

25 CFR

Proposed Rules:
518.....18353

26 CFR

1.....17166, 17775, 18148, 18448, 19060, 21412, 21417, 21426, 25556
5.....25556
5c.....25556
12.....25556
54.....25556
301.....17516, 17517
602.....25556
Proposed Rules:
1.....17557, 21548, 21692, 25587, 25703
52.....21963, 25791
301.....18185, 21550

27 CFR

7.....21228
22.....19060
24.....19062
Proposed Rules:
7.....21126, 21130, 21233

28 CFR

35.....17520
36.....17521
Proposed Rules:
16.....21963
36.....17558

29 CFR

1400.....18007
1601.....19210
1910.....21778
1915.....21778
1928.....21778
2610.....19609
2622.....19609
2644.....19610
2676.....19611

30 CFR

75.....21103
935.....21658
938.....18149
Proposed Rules:
701.....19215
817.....19215
904.....21552
906.....19367
914.....21693
935.....17173, 17372, 18185, 21274
938.....21965
944.....18187
950.....17811

31 CFR

210.....21634
251.....25774
253.....25774
254.....25775
290.....25775

32 CFR

82.....21927
200.....21927
213.....25776
372a.....25776
390a.....25776

33 CFR

20.....17926
100.....17525, 18008, 18009, 19351, 25558, 25559
110.....21103, 21104
117.....25560
151.....18329
162.....17525
165.....17525
334.....21226

Proposed Rules:
100.....25588
117.....18358
165.....17567, 18189, 19074, 19790, 19791, 21132
168.....25766
334.....17373, 17374

34 CFR
377.....17308
668.....21660
674.....21860
675.....21860
676.....21860
682.....19211, 21860
690.....21860
Proposed Rules:
Ch. VI.....25590
614.....19298
685.....17472
698.....18308
777.....21052
778.....21052
779.....21052

36 CFR
242.....17776
Proposed Rules:
215.....19369
217.....19369
1191.....17175

37 CFR
202.....17778

38 CFR
3.....25561, 25562, 25563, 25564
17.....25565
21.....25565

39 CFR
Proposed Rules:
111.....18190, 19075

40 CFR
50.....21351
52.....17778, 17780, 18010, 18011, 18161, 19066, 21542, 25566, 25776, 25777
60.....18014
61.....18014
80.....19152
81.....17783, 25567
85.....21359
86.....19211, 21359
122.....18014
180.....19352, 19354, 19357, 21402, 25779, 25780, 25782, 25783
185.....19354, 19357
186.....19357
264.....18014
265.....18014
271.....18162
403.....18014
707.....18014
Proposed Rules:
Ch. I.....18062, 21276, 25591
52.....18190, 19075, 21133
80.....17175
82.....19080, 25793
86.....19087
112.....19030
122.....20802, 21046
123.....20802, 21046
131.....20802, 21046
132.....20802, 21046
180.....19357, 19389, 19391, 25792
238.....18062, 21432
260.....18197, 25706
261.....18197, 25706
262.....18197
264.....18197, 25706
265.....18197, 25706
268.....18197
270.....18197, 25706
273.....18197
281.....21135
300.....18197
302.....25706
372.....19308
455.....19392

41 CFR
Proposed Rules:
128–1.....18360

42 CFR
413.....17527
431.....25784
483.....25784

43 CFR
Public Land Order:
6961.....18018
6962.....18163
6963.....19212
6964.....19212
6965.....19612
Proposed Rules:
3400.....18362

44 CFR
64.....19612, 19614, 25568
65.....19617, 19618
67.....19620
Proposed Rules:
67.....19641

45 CFR
96.....21218
1612.....21403
Proposed Rules:
1610.....21434
1611.....21434

46 CFR
174.....17316
252.....17346

47 CFR
0.....19771
1.....17528, 19771, 21405, 25569
2.....25574
15.....25574
21.....19771
22.....21928
61.....17166, 17528, 21407
64.....17167, 21408
73.....17786, 17349, 19359, 21106, 21107, 21259
74.....19771
76.....17530, 17350, 19623, 19626, 19627, 21107, 21929
90.....17787, 21110, 21405
94.....21405
95.....21405
Proposed Rules:
1.....19393
2.....17180, 19644
61.....17813
64.....21434
73.....17816, 17817, 17818, 19216, 19394, 19395, 19396, 21137, 25592, 25593, 25594, 25794
74.....25794
80.....17180, 17568
87.....17568
90.....17819, 19396, 21276
94.....17568
97.....17180, 17375

48 CFR
215.....18448
252.....18448
Proposed Rules:
1816.....19398
9903.....18363

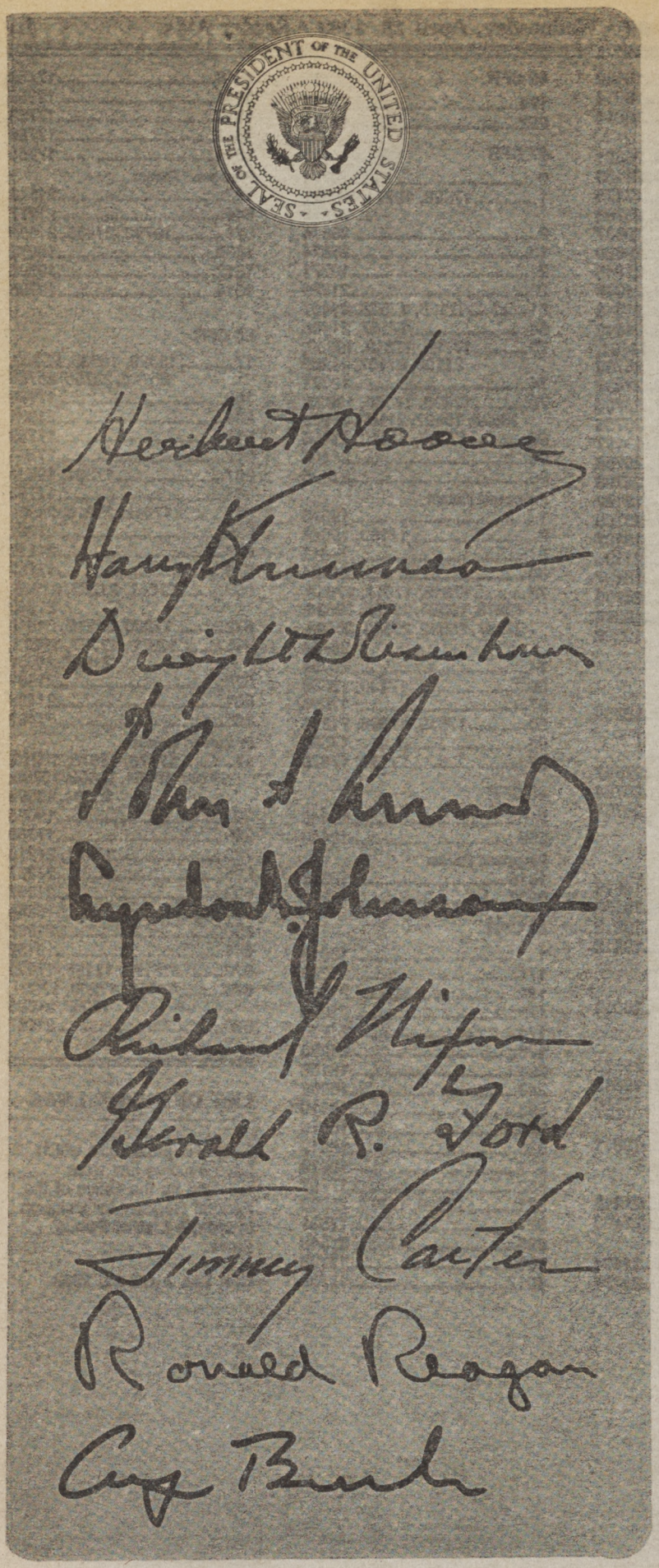
49 CFR
1.....18018
171.....21260
172.....21260
173.....21260
174.....21260
176.....21260
228.....18163
240.....18982
523.....18019
525.....18019
533.....18019
537.....18019
552.....17787
571.....19628, 19776, 25900
821.....17531
826.....17531, 21543
1002.....17788
1017.....17788
1018.....17788
1141.....19359
1312.....17788
1313.....17788
1314.....17788
Proposed Rules:
192.....21512
544.....21277
571.....19792, 21435, 21553
1039.....18072
1312.....19795
1314.....19795

50 CFR
17.....18029, 18035, 25742, 25746, 25755, 25758
100.....17776
204.....21931
216.....17789
217.....17364
227.....17364, 19631
301.....17791
611.....17642, 21218, 21931
625.....21261
646.....21111
658.....17169
663.....21261, 21263, 21265, 21949
672.....17806, 21218, 21545
675.....17366, 17367, 19213, 21627, 21951
678.....21931
681.....21409
685.....17462
Proposed Rules:
17.....17376, 18073, 19216, 19220, 19401, 19402, 19795, 25594, 25595
20.....19008
216.....17569
226.....17181, 21218
285.....21967
602.....21967
625.....18365
630.....21967
641.....19152
672.....17193, 17196, 17821
675.....17196, 17200, 17821, 19087, 21695
678.....21967

LIST OF PUBLIC LAWS

Note: No public bills which have become law were received by the Office of the Federal Register for inclusion in today's List of Public Laws.

Last List April 21, 1993



Public Papers of the Presidents of the United States

Annual volumes containing the public messages and statements, news conferences, and other selected papers released by the White House.

Volumes for the following years are available; other volumes not listed are out of print.

Ronald Reagan

1983
(Book I) $31.00

1983
(Book II) $32.00

1984
(Book I) $36.00

1984
(Book II) $36.00

1985
(Book I) $34.00

1985
(Book II) $30.00

1986
(Book I) $37.00

1986
(Book II) $35.00

1987
(Book I) $33.00

1987
(Book II) $35.00

1988
(Book I) $39.00

1988–89
(Book II) $38.00

George Bush

1989
(Book I) $38.00

1989
(Book II) $40.00

1990
(Book I) $41.00

1990
(Book II) $41.00

1991
(Book I) $41.00

1991
(Book II) $44.00

Published by the Office of the Federal Register, National Archives and Records Administration

Mail order to:
New Orders, Superintendent of Documents
P.O. Box 371954, Pittsburgh, PA 15250–7954

Printed on recycled paper