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Thursday  
October 27, 1994

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# Federal Register

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

## WASHINGTON, DC

### (TWO BRIEFINGS)

- WHEN:** November 21 at 9:00 am and 1:30 pm
- WHERE:** Office of the Federal Register Conference Room, 800 North Capitol Street NW, Washington, DC (3 blocks north of Union Station Metro)
- RESERVATIONS:** 202-523-4538



# Contents

Federal Register

Vol. 59, No. 207

Thursday, October 27, 1994

## Agency for International Development

### NOTICES

Housing guaranty program:

Israel, 53958

Privacy Act:

Systems of records, 53958-53959

## Agricultural Marketing Service

### RULES

Raisins produced from grapes grown in California, 53927-53929

## Agriculture Department

See Agricultural Marketing Service

See Animal and Plant Health Inspection Service

See Rural Electrification Administration

## Animal and Plant Health Inspection Service

### NOTICES

Environmental statements; availability, etc.:

Genetically engineered organisms; field test permits—  
Canola plants, 53959-53960

## Antitrust Division

### NOTICES

National cooperative research notifications:

Corporation for Open Systems International, 54011

Precision Laser Machining Technology Reinvestment  
Project, 54011-54012

Spinal Implant Manufacturers Group, 54012

## Arms Control and Disarmament Agency

### NOTICES

Senior Executive Service:

Performance Review Boards; membership, 53960

## Army Department

### NOTICES

Meetings:

Science Board, 53969

## Bipartisan Commission on Entitlement and Tax Reform

### NOTICES

Meetings, 53960

## Commerce Department

See Economic Analysis Bureau

See National Institute of Standards and Technology

See National Oceanic and Atmospheric Administration

See Technology Administration

## Commission of Fine Arts

### NOTICES

Meetings, 53963

## Corporation for National and Community Service

### NOTICES

Grants and cooperative agreements; availability, etc.:

AmeriCorps State and direct, learn and serve America K-  
12, and learn and serve America higher education  
programs, 53963-53969

## Defense Department

See Army Department

## Economic Analysis Bureau

### RULES

International services surveys:

Foreign direct investments in U.S.—

BE-80; transactions between U.S. financial services  
providers and unaffiliated foreign persons, 53934-  
53936

## Education Department

### PROPOSED RULES

Postsecondary education:

Federal family education loan program

Correction, 53951

### NOTICES

Agency information collection activities under OMB  
review, 53969

Grants and cooperative agreements; availability, etc.:

Bilingual education and minority languages affairs—

Bilingual vocational instructor training program,  
54096-54113

Bilingual vocational training program, 54076-54094

## Energy Department

See Federal Energy Regulatory Commission

See Western Area Power Administration

### NOTICES

Environmental statements; availability, etc.:

Hanford Site, WA—

Plutonium finishing plant complex; PFP plutonium-  
bearing materials stabilization and stabilized  
material storage, 53969-53973

## Environmental Protection Agency

### PROPOSED RULES

Hazardous waste:

State underground storage tank program approvals—

Utah, 53955-53956

Water pollution control:

Ocean dumping; site designations—

Miami, FL, 53951-53955

### NOTICES

Confidential business information and data transfer to  
contractors, 53976

Meetings:

Environmental Policy and Technology National Advisory  
Council, 53976-53977Superfund; response and remedial actions, proposed  
settlements, etc.:

Brewer Gold Mine Site, SC, 53977

Norcross Mercury Spill Site, GA, 53977

## Executive Office of the President

See Management and Budget Office

See Presidential Documents

## Farm Credit Administration

### NOTICES

Meetings; Sunshine Act, 54030

**Federal Aviation Administration****RULES**

## Airworthiness directives:

Costruzioni Aeronautiche Giovanni Agusta S.p.A.,  
53933-53934

McDonnell Douglas, 53931-53932

**NOTICES**

## Meetings:

Aviation Rulemaking Advisory Committee, 54024

**Federal Communications Commission****NOTICES**

Rulemaking proceedings; petitions filed, granted, denied,  
etc., 53977

**Federal Election Commission****PROPOSED RULES**

Privacy Act; implementation, 53946-53947

**NOTICES**

Meetings; Sunshine Act, 54030

## Privacy Act:

Systems of records, 53977-53987

**Federal Energy Regulatory Commission****NOTICES**

Electric rate and corporate regulation filings:

PECO Energy Co. et al.; correction, 54032

*Applications, hearings, determinations, etc.:*

Boundary Gas, Inc.; correction, 54032

Great Lakes Gas Transmission L.P., 53973

Natural Gas Pipeline Co. of America, 53973

Pacific Gas Transmission Co., 53974

Southern Natural Gas Co. et al., 53974-53975

Texas Eastern Transmission Corp., 53975

Trunkline Gas Co., 53975

Trunkline LNG Co., 53975-53976

**Federal Highway Administration****NOTICES**

Environmental statements; notice of intent:

Smith County, TX, 54024-54025

**Federal Maritime Commission****NOTICES**

Investigations, hearings, petitions, etc.:

South Carolina State Ports Authority, 53987

**Federal Reserve System****NOTICES**

*Applications, hearings, determinations, etc.:*

Commerzbank Aktiengesellschaft, 53987-53988

Massee, James D., et al., 53988

Whitney Holding Corp. et al., 53988-53989

**Fine Arts Commission**

See Commission of Fine Arts

**Fish and Wildlife Service****PROPOSED RULES**

Importation, exportation, and transportation of wildlife:

Polar bear trophy importation permit issuances, 53956-  
53957

**Food and Drug Administration****RULES**

Biological products:

Adverse experience reporting requirements, 54034-54044

**PROPOSED RULES**

Human drugs and biological products:

Adverse experience reporting requirements, 54046-54064

**NOTICES**

Advisory committee information hotline; establishment,  
53992-53993

Biological products:

Adverse experience reporting guideline, 53994

Medical devices; premarket approval:

Ciba Corning Corp; ASC PSA+D, 53994-53995

Meetings:

Advisory committees, panels, etc., 53995-53996

**General Services Administration****NOTICES**

Environmental statements; availability, etc.:

Sacramento, CA; U.S. Courthouse-Federal Building,  
53989-53991

Interagency Committee for Medical Records:

Medical record-group muscle strength, joint R.O.M. girth  
and length measurements (SF 527); form stocking  
change and revision, 53991

**Health and Human Services Department**

See Food and Drug Administration

See Health Resources and Services Administration

See National Institutes of Health

See Public Health Service

See Social Security Administration

**NOTICES**

Grants and cooperative agreements; availability, etc.:

Electronic initiative for disseminating and sharing grant  
information (GrantsNet), 53992

**Health Resources and Services Administration**

See Public Health Service

**NOTICES**

Grants and cooperative agreements; availability, etc.:

National AIDS education and training centers program,  
53996-53999

**Housing and Urban Development Department****NOTICES**

Mortgage and loan insurance programs:

Government National Mortgage Association (Ginnie Mae);  
real estate mortgage investment conduit;  
implementation

Guaranteed multiclass securities, 54009

**Interior Department**

See Fish and Wildlife Service

See Land Management Bureau

See Surface Mining Reclamation and Enforcement Office

**Internal Revenue Service****NOTICES**

Organization, functions, and authority delegations

Deputy Chief Inspector et al., 54027

**International Development Cooperation Agency**

See Agency for International Development

**Interstate Commerce Commission****NOTICES**

Railroad operation, acquisition, construction, etc.:

South Central Florida Express, Inc., 54010-54011

**Justice Department**

See Antitrust Division

See Prisons Bureau

**PROPOSED RULES**

Executive Office for Immigration Review:

Citizenship requirement for employment, 53946

**Land Management Bureau****NOTICES**

- Oil and gas leases:
  - New Mexico, 54009
- Survey plat filings:
  - Arizona, 54009-54010
- Withdrawal and reservation of lands:
  - Oregon, 54010

**Management and Budget Office****NOTICES**

- Budget rescissions and deferrals, 54066-54074

**National Highway Traffic Safety Administration****NOTICES**

- Motor vehicle defect proceedings; petitions, etc.:
  - General Motors Corp., 54025-54026

**National Institute of Standards and Technology****NOTICES**

- Grants and cooperative agreements; availability, etc.:
  - Advanced technology program, 53961-53963

**National Institutes of Health****NOTICES**

- Meetings:
  - National Institute of Environmental Health Sciences, 53999
  - Research Grants Division special emphasis panels, 53999-54000

**National Oceanic and Atmospheric Administration****RULES**

- Fishery conservation and management:
  - Gulf of Alaska groundfish, 53937-53938

**National Science Foundation****NOTICES**

- Grants and cooperative agreements; availability, etc.:
  - Global learning and observations to benefit environment program; meeting, 54012
- Meetings:
  - Geosciences Special Emphasis Panel, 54012
  - Human Resources Development Special Emphasis Panel, 54012-54013
  - Instrumentation and Instrument Development Advisory Panel, 54013
  - Polar Programs Special Emphasis Panel, 54013
- Senior Executive Service:
  - Performance Review Board; membership, 54013

**Nuclear Regulatory Commission****NOTICES**

- Environmental statements; availability, etc.:
  - Baltimore Gas & Electric Co., 54013-54014

**Office of Management and Budget**

See Management and Budget Office

**Presidential Documents****PROCLAMATIONS**

- Bosnia-Herzegovina:
  - Suspension of admission into U.S. of aliens described in U.N. Security Council Resolution 942 (Proc. 6749), 54119-54120

**EXECUTIVE ORDERS**

- Bosnia-Herzegovina
  - Embargo (EO 12934), 54117-54118

**ADMINISTRATIVE ORDERS**

- Government agencies and employees:
  - State Department political appointees; political activity limitation authority; delegation (Memorandum of October 24, 1994), 54121

**Prisons Bureau****RULES**

- Inmate control, custody, care, etc.:
  - Furloughs; transportation costs, 53937

**Public Health Service**

- See Food and Drug Administration
- See Health Resources and Services Administration
- See National Institutes of Health

**NOTICES**

- Organization, functions, and authority delegations:
  - National Institutes of Health, 54000-54002
- Privacy Act:
  - Systems of records, 54002-54004

**Rural Electrification Administration****RULES**

- Rural development:
  - Rural economic development loan and grant program, 53929-53931

**PROPOSED RULES**

- Telephone loans:
  - State telecommunications modernization plan; system planning, design criteria, and procedures, 53939-53946

**Securities and Exchange Commission****RULES**

- Business disposition by seriatim Commission consideration or by delegated authority, 53936-53937

**NOTICES**

- Meetings; Sunshine Act, 54030-54031
- Options price reporting authority, 54014-54015
- Self-regulatory organizations; proposed rule changes:
  - American Stock Exchange, Inc., 54015-54017
  - Boston Stock Exchange, Inc., 54017-54018
  - National Securities Clearing Corp., 54018-54020
  - National Securities Clearing Corp.; correction, 54032
- Applications, hearings, determinations, etc.:
  - Chase Manhattan Bank, N.A., 54020-54021

**Small Business Administration****PROPOSED RULES**

- Small business size standards:
  - Minority small business and capital ownership development assistance, 53947-53948

**NOTICES**

- License surrenders:
  - Rand SBIC, Inc., 54021
- Applications, hearings, determinations, etc.:
  - River Cities Capital Fund L.P., 54021

**Social Security Administration****NOTICES**

- Privacy Act:
  - Systems of records, 54004-54009

**State Department****NOTICES**

- Meetings:
  - International Telecommunications Advisory Committee, 54022

Overseas Security Advisory Council, 54022  
Shipping Coordinating Committee, 54022  
United Nations Framework Convention on Climate Change;  
U.S. climate action report; availability, 54022-54024

#### **Surface Mining Reclamation and Enforcement Office**

##### **PROPOSED RULES**

Permanent program and abandoned mine land reclamation  
plan submissions:  
Texas, 53949-53951

#### **Technology Administration**

##### **NOTICES**

Grants and cooperative agreements; availability, etc.:  
Advanced technology program, 53961-53963

#### **Tennessee Valley Authority**

##### **PROPOSED RULES**

Administrative cost recovery, 53948-53949

#### **Transportation Department**

See Federal Aviation Administration

See Federal Highway Administration

See National Highway Traffic Safety Administration

#### **Treasury Department**

See Internal Revenue Service

#### **United States Information Agency**

##### **NOTICES**

Grants and cooperative agreements; availability, etc.:  
NIS secondary school initiative for school linkages,  
54027-54029

#### **Western Area Power Administration**

##### **NOTICES**

Meetings:

Energy planning and management program, 53976

---

#### **Separate Parts In This Issue**

##### **Part II**

Department of Health and Human Services, Food and Drug  
Administration, 54034-54044

##### **Part III**

Department of Health and Human Services, Food and Drug  
Administration, 54046-54064

##### **Part IV**

Office of Management and Budget, 54066-54074

##### **Part V**

Department of Education, 54076-54094

##### **Part VI**

Department of Education, 54096-54113

##### **Part VII**

The President, 54115-54121

---

#### **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.

---

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numbers, **Federal Register** finding aids, and a list of  
documents on public inspection 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.

**3 CFR**

## Proclamations:

6749.....54119

## Executive Orders:

12808 (See EO

12934).....54117

12934.....54117

## Memorandums:

October 24, 1994.....54121

**7 CFR**

989.....53927

1703.....53929

## Proposed Rules:

1751.....53939

**8 CFR**

## Proposed Rules:

3.....53946

**11 CFR**

## Proposed Rules:

1.....53946

**13 CFR**

## Proposed Rules:

121.....53947

124.....53947

**14 CFR**

39 (2 documents).....53931,

53933

**15 CFR**

801.....53934

**17 CFR**

200.....53936

**18 CFR**

## Proposed Rules:

1310.....53948

**21 CFR**

600.....54034

## Proposed Rules:

20.....54046

310.....54046

312.....54046

314.....54046

600.....54046

**28 CFR**

570.....53937

**30 CFR**

## Proposed Rules:

943.....53949

**34 CFR**

## Proposed Rules:

682.....53951

**40 CFR**

## Proposed Rules:

228.....53951

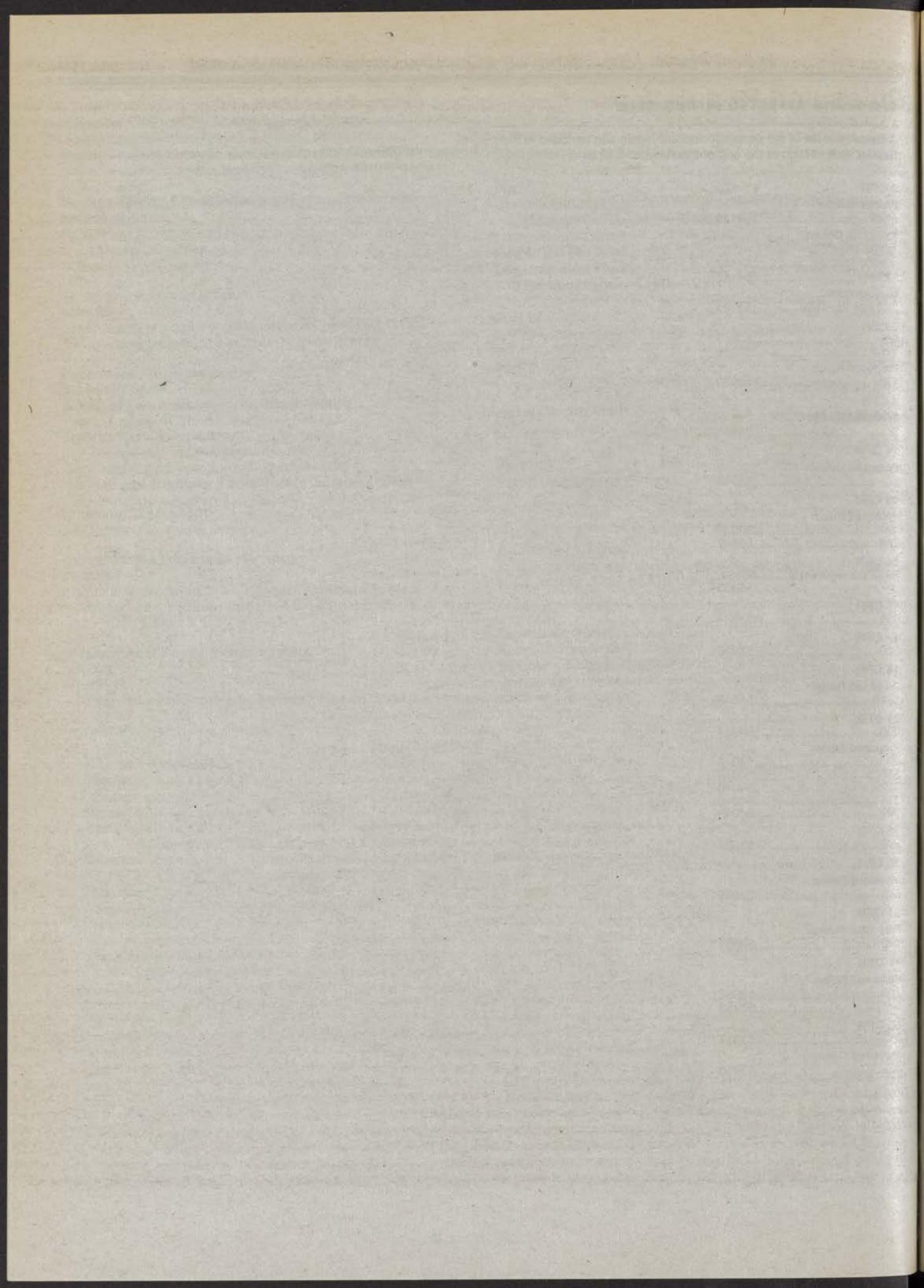
281.....53955

**50 CFR**

672.....53937

## Proposed Rules:

18.....53956



# Rules and Regulations

Federal Register

Vol. 59, No. 207

Thursday, October 27, 1994

This section of the FEDERAL REGISTER contains regulatory documents having general applicability and legal effect, most of which are keyed to and codified in the Code of Federal Regulations, which is published under 50 titles pursuant to 44 U.S.C. 1510.

The Code of Federal Regulations is sold by the Superintendent of Documents. Prices of new books are listed in the first FEDERAL REGISTER issue of each week.

## DEPARTMENT OF AGRICULTURE

### Agricultural Marketing Service

#### 7 CFR Part 989

[Docket No. FV94-989-4FR]

#### Raisins Produced From Grapes Grown in California; Temporary Suspension of Certain Reserve Tonnage Pricing Provisions

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Final rule.

**SUMMARY:** This final rule temporarily suspends a sentence in § 989.67(j) of the California raisin marketing order dealing with the pricing of reserve raisins offered to handlers for free use. The industry is faced with a large supply of Zante Currant raisins. The suspension will only apply to 1994-95 reserve Zante Currants so that the value of a portion of the free tonnage inventory held by handlers on July 31, 1994, can be adjusted downward toward current market price levels. This adjustment is necessary to help the industry become price competitive and to aid it in marketing Zante Currants. This action was unanimously recommended by the Raisin Administrative Committee (Committee), which is responsible for local administration of the order.

**EFFECTIVE DATE:** October 27, 1994 through July 31, 1995.

#### FOR FURTHER INFORMATION CONTACT:

Richard P. Van Diest, Marketing Specialist, California Marketing Field Office, Fruit and Vegetable Division, AMS, USDA, 2202 Monterey Street, Suite 102B, Fresno, California 93721; telephone: (209) 487-5901, or FAX (209) 487-5906; or Mark A. Slupek, Marketing Specialist, Marketing Order Administration Branch, F&V, AMS, USDA, Room 2523-S, P.O. Box 96456, Washington, DC 20050-6456;

Telephone: (202) 205-2830, or FAX (202) 720-5698.

**SUPPLEMENTARY INFORMATION:** This rule is issued under Marketing Agreement and Order No. 989 [7 CFR Part 989] (order), regulating the handling of raisins produced from grapes grown in California. The order is effective under the Agricultural Marketing Agreement Act of 1937, as amended, [7 U.S.C. 601-674], hereinafter referred to as the "Act."

The Department of Agriculture (Department) is issuing this rule in conformance with Executive Order 12866.

This rule has been reviewed under Executive Order 12778, Civil Justice Reform. This rule will allow the Committee to implement an inventory price adjustment program for Zante Currents during the 1994-95 crop year, which began August 1, 1994. This rule will not preempt any State or local laws, regulations, or policies, unless they present an irreconcilable conflict with this rule.

The Act provides that administrative proceedings must be exhausted before parties may file suit in court. Under section 608c(15)(A) of the Act, any handler subject to an order may file with the Secretary a petition stating that the order, any provision of the order, or any obligation imposed in connection with the order is not in accordance with law and request a modification of the order or to be exempted therefrom. A handler is afforded the opportunity for a hearing on the petition. After a hearing the Secretary would rule on the petition. The Act provides that the district court of the United States in any district in which the handler is an inhabitant, or has his or her principal place of business, has jurisdiction in equity to review the Secretary's ruling on the petition, provided a bill in equity is filed not later than 20 days after the date of entry of the ruling.

Pursuant to requirements set forth in the Regulatory Flexibility Act (RFA), the Administrator of the Agricultural Marketing Service (AMS) has considered the economic impact of this action on small entities.

The purpose of the RFA is to fit regulatory actions to the scale of business subject to such actions in order that small businesses will not be unduly or disproportionately burdened. Marketing orders issued pursuant to the

Act, and rules issued thereunder, are unique in that they are brought about through group action of essentially small entities acting on their own behalf. Thus, both statutes have small entity orientation and compatibility.

There are approximately 20 handlers of California raisins who are subject to regulation under the order, and approximately 5,000 producers in the regulated area. Small agricultural service firms have been defined by the Small Business Administration [13 CFR 121.601] as those having annual receipts of less than \$5,000,000, and small agricultural producers are defined as those whose annual receipts are less than \$500,000. A minority of handlers and a majority of producers of California raisins may be classified as small entities.

Under the order, seasonal volume regulations can be established. The free percentages prescribe the portion of the crop that can be shipped at any time to any market. The reserve percentages prescribe the portion of the crop that must be held for delayed shipment. Reserve raisins are held in a reserve pool by handlers for the account of the Committee. Funds generated from the sale of reserve pool raisins are distributed equally to equity holders (growers).

This final rule will suspend the penultimate sentence in § 989.67(j) of the order for the 1994-95 crop year. That sentence provides that: "However, such raisins shall not be sold at a price below that which the committee concludes reflects the average price received by producers for free tonnage of the same varietal type purchased by handlers during the current crop year up to the time of any offer for sale of reserve tonnage by the committee, to which shall be added the costs to the equity holders incurred by the committee on account of receiving, inspecting, storing, fumigating, insuring, and holding of said raisins, and including costs of taxes and interest. *Provided*, That, where the outlook for the next crop year or other factors have caused a downward trend in the prices received by producers for free tonnage raisins or in the prices received by handlers for free tonnage packed raisins, reserve tonnage may be sold to handlers at the currently prevailing or the approximate computed field price for

free tonnage raisins, as determined by the committee."

Limited volumes of Zante Currants are produced in California. The 1993-94 California production of Zante Currants was 5,643 tons, which is 32 percent larger than the prior four-year average of 4,279 tons. The estimated 1994-95 production is greater than 6,500 tons or over 50 percent more than the 1989-92 four-year average. It is anticipated that the production of Zante Currants will continue to increase in the next one to three years as newly planted acreage begins to produce and/or reach full production.

Greece is the major producer of currants, generally representing at least 85 percent of the annual world production of such raisins. In 1992-93, Greek currants were in short supply and prices rose sharply. As a result, the market for California Zante Currants strengthened significantly and the grower price increased to \$1,600 from \$1,365 per ton the previous season. In 1993-94, the grower price for California Zante Currants was \$1,200 per ton. The 1993-94 Greek currant crop was approximately 50,000 tons, of excellent quality, and prices were very competitive with those quoted for California Zante Currants. This resulted in a significant drop in California Zante Currant shipments here and abroad.

Currently, the California raisin industry is carrying a very large supply (approximately 4,000 tons) of 1992-93 and 1993-94 crop Zante Currants and projects a record production (approximately 6,500 tons) in 1994-95. The trade is aware of this supply problem and forward purchases from handlers have decreased. Sales are not expected to increase until corrective pricing action is taken by handlers. Before that can begin, however, handlers need assurance that the value of some of their free Zante Currant inventories from the 1992-93 and 1993-94 production years can be reduced to the recently established \$980 per ton 1994-95 free tonnage Zante Currant field price, thus reducing their potential losses on existing free raisin inventory. Suspending the penultimate sentence in § 989.67(j) can assure this protection, as it will allow the Committee to sell 1994 crop reserve tonnage to handlers for free use at a lower price than the established field price.

The Committee plans to offer handlers one ton of 1994-95 crop Zante Currant reserve raisins at \$100 per ton for every four tons of free Zante Currants held by them on July 31, 1994. Purchasing free tonnage 1994-95 crop Zante Currants at \$980 per ton and reserve Zante Currants at \$100 per ton in accordance with this

formula will allow handlers' inventories to achieve an approximate net value of \$980 per ton. In the absence of the suspension, these price adjustments could not be accomplished. In the absence of such adjustments, the industry could not compete effectively with foreign-produced currants without substantial losses on the part of packers and producers. Moreover, a significant loss in foreign markets could result. A loss of domestic markets to foreign imports could also result.

In recommending its action, the Committee recognized that it would be selling a portion of the reserve raisins at a price well below the cost of producing raisins, and that the net proceeds to equity holders would be quite low. In the absence of this action, open price contracting between producers and handlers on 1994-95 crop Zante Currant deliveries was a possibility because of the excess supplies and inflated value of the inventory. On the basis of the Committee's recommendation, handlers did not use open price contracting but instead in negotiations with the Raisin Bargaining Association (Association) agreed to pay producers the aforementioned \$980 per ton price for free tonnage Zante Currants. Without the inventory adjustment program, very low prices for all 1994-95 crop Zante Currants were likely. The Association is a cooperative which bargains sales terms with independent handlers on behalf of its producer members.

It is recognized that the effects of this action on individual entities will vary depending on their financial conditions and their equities in the reserve pool. However, the impact is not expected to be significant. In the long term, the benefits of becoming more competitive under current marketing conditions should outweigh any adverse short-term impact and result in benefits to all industry entities. The domestic inventory price adjustment accomplished through this action will permit an overall price reduction for handlers' sales of Zante Currants, enabling the industry to compete more effectively with lower-priced foreign-produced currants, and to more aggressively market Zante Currants in the interest of maintaining and expanding existing domestic and foreign markets and in developing new markets. The net result of this action is likely to be positive as a result of increased marketings of Zante Currants at reduced prices. On the basis of all of the foregoing, the Administrator of the AMS has determined that the issuance of this rule will not have a significant economic impact on a substantial number of small entities.

After consideration of all relevant matter presented, including the information and recommendations submitted by the Committee, it is determined that: (1) There has been a change of economic or marketing conditions to warrant the sale of Zante Currant reserve raisins to handlers to provide them with raisins to sell as free tonnage, pursuant to section 989.67(j), and (2) under the conditions presently existing in the raisin industry, the penultimate sentence in section 989.67(j) does not now tend to effectuate the declared policy of the Act and is hereby suspended with regard to Zante Currants pursuant to section 989.91(b). However, such suspension shall continue only through July 31, 1995, at which time it shall terminate and the suspended sentence will become operative again beginning August 1, 1995.

Pursuant to 5 U.S.C. 553, it is also found and determined that, upon good cause, it is impracticable, unnecessary, and contrary to the public interest to give preliminary notice prior to putting this rule into effect, and that good cause exists for not postponing the effective date of this action until 30 days after publication in the *Federal Register* because: (1) Producers and handlers have been conducting their marketing operations on the premise that the value of the 1992-93 and 1993-94 Zante Currants carried into the 1994-95 season would be averaged down to the 1994-95 negotiated free tonnage price; (2) the Committee met on October 5, 1994, and computed and announced preliminary free and reserve tonnage percentages for Zante Currant raisins; (3) prompt implementation of this action is necessary to prevent disruption in the marketplace; and (4) the industry is aware of this action, which was unanimously recommended by the Committee at a public meeting.

#### List of Subjects in 7 CFR Part 989

Grapes, Marketing agreements, Raisins, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, 7 CFR part 989 is amended as follows:

#### PART 989—RAISINS PRODUCED FROM GRAPES GROWN IN CALIFORNIA

1. The authority citation for 7 CFR part 989 continues to read as follows:

Authority: 7 U.S.C. 601-674.

**§ 989.67 [Suspended in Part]**

2. In § 989.67(j) the penultimate sentence is suspended effective October 27, 1994 through July 31, 1995.

Dated: October 20, 1994.

Patricia Jensen,

Acting Assistant Secretary, Marketing and Regulatory Programs.

[FR Doc. 94-26638 Filed 10-26-94; 8:45 am]

BILLING CODE 3410-02-P

## Rural Electrification Administration

### 7 CFR Part 1703

RIN 0572-AB04

#### Rural Economic Development Loan and Grant Program: Empowerment Zones

AGENCY: Rural Electrification Administration, USDA.

ACTION: Final rule.

**SUMMARY:** The Rural Electrification Administration (REA) hereby amends its regulation for the Rural Economic Development Loan and Grant Program by adding a provision which will enhance the potential of funding for applications from areas that: Were recently designated by the President as natural disaster areas; have experienced severe economic dislocation due to the loss, removal, or closing of a major source of employment; have experienced long-term and severe economic deterioration, demonstrated by severe unemployment or a high percentage of population out-migration; or have been designated as a Rural Empowerment Zone or Rural Enterprise Community.

**EFFECTIVE DATE:** This regulation is effective on November 28, 1994.

**FOR FURTHER INFORMATION CONTACT:** Lawrence L. Bryant, Jr., Chief, Planning Branch, Rural Development Assistance Staff, Rural Electrification Administration, Room 2237, South Building, U.S. Department of Agriculture, 14th and Independence Avenue, SW., Washington, DC 20250-1500 (202) 690-3594.

**SUPPLEMENTARY INFORMATION:** This rule has been determined to be not significant for purposes of Executive Order 12866 and therefore has not been reviewed by the Office of Management and Budget. This rule has been reviewed under Executive Order 12778, Civil Justice Reform. This rule: (1) Will not preempt any State or local laws, regulations, or policies; (2) Will not have any retroactive effect; and (3) Will not require administrative proceedings

before parties may file suit challenging the provisions of this rule.

In compliance with the Regulatory Flexibility Act, the Administrator certifies that this action would not have a significant economic impact on a substantial number of small entities as defined in the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*). Based on current and historical funding levels for this program and a projected average size loan and/or grant in the range of \$300,000 to \$400,000, it is estimated that 50 to 60 loans and/or grants will be made nationwide each year under the existing rule. Applicants whose rural development projects are enhanced by this action are projected to be less numerous, and therefore, the rule will have a limited impact upon small businesses. Since credit will be channeled to areas which are generally underdeveloped and financially depressed, job creation and economic development resulting from newly emerging businesses and community facilities funded by REA will not pose undue competition or other adverse effects upon existing businesses. Therefore, this rule will have no effect upon businesses or entities other than those to be funded through this program.

In compliance with the Office of Management and Budget (OMB) regulations (5 CFR part 1320) implementing the Paperwork Reduction Act of 1980 (Pub. L. 96-511) and Section 3504 of that Act, the information collection and recordkeeping requirements contained in this rule have been approved by OMB under control number 0572-0090. Comments concerning these requirements should be directed to the Office of Information and Regulatory Affairs of OMB, Attention: Desk Officer for USDA, room 10102, NEOB, Washington, DC, 20503.

The Administrator has determined that this rule will not significantly affect the quality of the human environment as defined by the National Environmental Policy Act of 1969 (42 U.S.C. 4321 *et seq.*). Therefore, this action does not require an environmental impact statement or assessment.

The program is subject to the provisions of Executive Order 12372, which requires intergovernmental consultation with State and local officials, with the exception of applications for Project Feasibility Studies.

This program is listed in the Catalog of Federal Domestic Assistance under No. 10.854, Rural Economic Development Loans and Grants. This

catalog is available on a subscription basis from the Superintendent of Documents, United States Government Printing Office, Washington, DC 20402-9325.

#### Background

On February 15, 1989, REA published the final rule, 7 CFR 1709, subpart B, in the *Federal Register* (54 FR 6867) that implemented the Rural Economic Development Loan and Grant Program, also known as the Cushion of Credit Payments Program, established by Section 313 of the Rural Electrification Act of 1936, as amended (Act). This program provides funds to Act borrowers for the promotion of rural economic development and job creation projects. On September 27, 1990, REA changed the designation of this rule from 7 CFR part 1709 to part 1703 (55 FR 39393) and on September 25, 1992, published an amendment (57 FR 44314) to refine and improve the structure of the rule. On March 14, 1994, REA published a final rule (59 FR 11702) establishing procedures to approve and administer grants and grants in conjunction with zero-interest loans.

On July 28, 1994, a proposed rule was published (59 FR 38378) to amend the rule to enhance the funding potential of Rural Economic Development Loan and Grant Program (REDLGP) applications from economically devastated areas. This constitutes the finalization of that proposed rule.

#### Synopsis

This rule amends the Rural Economic Development Loan and Grant Program as follows:

- The Administrator will have the discretion to designate special economic status under the REDLGP selection factors, adding up to 25 points to an applicant's score if at least one of the four conditions outlined in § 1703.46(g)(7) has occurred.
- The prohibition on funding community antenna television systems or facilities has been reinstated except in special cases as outlined in § 1703.17(d).
- The provision for disbursement of grant funds has been revised to allow REA Borrowers with limited financial resources, or for other reasons, to receive funds based on invoices from project owners rather than committing their own funds under the reimbursement provision. This arrangement will require prior REA approval. See § 1703.22(e).
- The definition of "Rural economic development" has been revised to clarify REA policy on funding projects located outside rural areas as defined in

Section 13 of the Rural Electrification (RE) Act but which provide significant benefits to rural areas.

#### Comments

REA received seven comments regarding this regulation, which were taken into consideration in preparing this final rule. Comments were received from the following:

- (1) Minnesota Rural Electric Association.
- (2) Riverside County Economic Development Agency, Riverside, California.
- (3) City of Hollister, California.
- (4) Maine Ambulatory Care Coalition, Manchester, Maine.
- (5) Crown Economic Development Corporation, Hanford, California.
- (6) Merced County Board of Supervisors, Merced, California.
- (7) Community Development Division, Fresno, California.

Of the comments received, one commenter suggested that REA accept "local" unemployment data, if available, instead of county-wide data because of significant variances in larger counties. We recognize that large geographical counties are at a disadvantage if only countywide data is accepted. Therefore the use, where appropriate, of State-published information, would be a reasonable alternative and have amended § 1703.46(g)(7)(iii) is hereby amended to allow the REA Administrator to consider State-published statistics, provided by the applicant, in those situations where the Census material is clearly not representative of the project location. However, the data must be verifiable and part of a recognized database which reflects information for other areas within the State.

One community expressed concern that requiring disbursement of funds up front and awaiting reimbursement could be a hardship on small rural communities. However, this requirement does not actually impact community government entities because the reimbursement policy is applicable only in cases where REA Borrowers receive grants to establish revolving loan funds. This final rule provides special arrangements only for REA Borrowers establishing revolving loan funds, who are unable to fund projects using the reimbursement method.

Another comment was that REA's definition of "rural" in this rule was too broad and would allow reviewers to fund projects not directly benefiting rural communities. The commenter suggested that the funds either be restricted to the 2500 population limit or controlled by organizations from such

communities, that at least 70 percent of the funds be spent in communities under 2500 and that the urban entity provide at least 60 percent in matching funds. All REDLGP applications are reviewed by the REA staff and selected based on the evaluation criteria outlined in § 1703.46, much of which is based on benefit to rural areas. Moreover, REA borrowers serve primarily rural areas, and they are well-suited to determine that the final benefits are directed toward the local community. As discussed previously in this preamble, the rule has been revised to allow projects which are not located in rural areas. However, those projects must result in significant benefit to rural areas.

Another recommendation was to assign bonus points to areas "nominated" by State and local governments for designation as Rural Empowerment Zones or Rural Enterprise Communities as well as those areas primarily designated by USDA as Rural Empowerment Zones or Rural Enterprise Communities. It was suggested that these communities be rewarded for the development of the plans and partnerships required by the nominating process and receive a portion of the points they would have received if actually designated as Rural Empowerment Zones or Rural Enterprise Communities. REA recognizes that community strategic planning is a key component of the Empowerment initiative, however, this additional planning aspect will directly benefit the communities in other ways such as allowing them to realize and unlock their own potential to partnership with the private sector and other federal and state entities. The strategic planning process also improves the applicant's overall REDLGP application which should be reflected under the normal evaluation criteria.

#### List of Subjects in 7 CFR Part 1703

Community development, Grant programs—housing and community development, Loan programs—housing and community development, Reporting and recordkeeping requirements, Rural areas.

For the reasons set out in the preamble, chapter XVII of title 7 of the Code of Federal Regulations is amended as follows:

#### PART 1703—RURAL DEVELOPMENT

1. The authority citation for 7 CFR part 1703 continues to read as follows:

**Authority:** 7 U.S.C. 901 *et seq.* and 950aaa *et seq.*

#### Subpart B—Rural Economic Development Loan and Grant Program

2. In § 1703.12 of this subpart B, the following definition is revised to read as follows:

#### § 1703.12 Definitions.

\* \* \* \* \*

*Rural economic development*—job creation or preservation or community facilities improvement projects that clearly demonstrate significant benefits to rural areas.

\* \* \* \* \*

3. In § 1703.17, paragraph (d) is added to read as follows:

#### § 1703.17 Uses of zero-interest loans and grants.

\* \* \* \* \*

(d) Zero-interest loans and grants may be used for community antenna television systems or facilities. The borrower will document that such facilities provide a tangible economic benefit to the proposed service area in accordance with § 1703.46 of this subpart. Notwithstanding this, the Administrator reserves the right to deny any proposal for community antenna television systems or facilities. Community antenna television systems or facilities will be considered for funding in accordance with § 1703.46 of this subpart and this section only when all of the following conditions exist:

(1) The proposed community antenna television system or facility is established in cooperation with a local educational and/or medical entity(ies) to provide educational and/or medical programming which addresses specific needs of rural residents;

(2) Services to be provided by the proposed community antenna television systems or facilities are not available in the area to be served, or services are not being provided by the existing television programming carrier at an affordable cost to residents; and

(3) Such community antenna systems or facilities will not present undue competition for existing television programming carriers in the area.

4. In § 1703.20, paragraphs (a)(10) and (a)(11) are redesignated as paragraphs (a)(11) and (a)(12) and a new paragraph (a)(10) is added to read as follows:

#### § 1703.20 Ineligible uses of zero-interest loans and grants.

(a) \* \* \*

(10) For community antenna television systems or facilities except as provided in § 1703.17(d) of this subpart;

\* \* \* \* \*

5. In § 1703.22, paragraphs (e) introductory text, (e)(1), (e)(3) and (e)(4) are revised to read as follows:

## § 1703.22 Revolving loan program.

## (e) Disbursement of grant funds.

Borrowers are not authorized to commence projects to be funded under this section until those projects have been submitted for authorization in accordance with paragraph (c)(1) of this section, or the projects have been submitted for authorization subsequent to grant approval in accordance with paragraph (e)(2) of this section. REA grant funds will be disbursed on a reimbursement basis. However, upon written justification by borrowers and approval by the Administrator, borrowers unable to fund projects under reimbursement provisions, for financial or other extraordinary reasons, may receive grant funds under the special disbursement method by submitting unpaid invoices from project owners, and grant funds will be disbursed to borrowers and passed directly to project owners. In either case, REA grant funds will be disbursed in accordance with the provisions of 7 CFR Part 3015, Uniform Federal Assistance Regulations, the applicable requirements of this subpart, the administrative provisions outlined in paragraph (g) of this section, and the following requirements:

(1) Only projects authorized by REA in accordance with paragraphs (c)(1) and (e)(2) of this section, for which adequate documentation is submitted, including receipts for expenditures under the reimbursement method or unpaid invoices under the special disbursement method, as applicable, and certification of approved purposes, will be considered for disbursement;

(3) Under the reimbursement method, grant funds requisitioned for individual projects in increments of less than \$100,000, or less than 25 percent of the amount approved for the revolving loan fund, whichever is less, may be disbursed semi-annually. Submission periods for requisitioning grant funds on a semi-annual disbursement basis will be 14 days commencing from the 6-month anniversary date of grant approval. Grant funds under the special disbursement method will be requisitioned in accordance with the applicable provision in paragraph (e)(4) of this section;

(4) For the reimbursement method, grant funds requisitioned for individual projects in increments of \$100,000 or greater, or at least 25 percent of the amount approved for the revolving loan fund, whichever is less, may be submitted for disbursement at any time. Under the special disbursement method,

grant funds of less than \$100,000 may be requisitioned for disbursement at any time. However, the minimum requisition will be \$50,000, or the total grant award, whichever is less.

6. In § 1703.46, the period at the end of paragraph (h)(10)(iii) is removed and a semicolon is added in its place, and paragraphs (g)(7) and (h)(11) are added to read as follows:

## § 1703.46 Documenting the evaluation and selection of applications for zero-interest loans and grants.

## (g) Other selection factors. \* \* \*

(7) *Special economic status.* The Administrator has the discretion to designate special economic status (up to 25 points) to applications submitted by borrowers that have documented one or more of the following four conditions in one or more county(ies) to be served by the proposed project:

(i) A designation of disaster area by the President of the United States which has been so designated within three years prior to applying to REA;

(ii) The loss, removal, or closing of a major source or sources of employment in the last 3 years which causes an increase of 2 percentage points or more in the area's most recent unemployment rate compared with the period immediately before the dislocation;

(iii) Chronic or long-term economic deterioration, documented by one or both of the following conditions:

(A) An unemployment level equal to or greater than 1.5 times the National average unemployment percentage from 4 out of the last 5 years, starting with the most current statistics available. The applicant, when calculating recent years' unemployment percentages, should compare county statistics with the National Average unemployment for the corresponding year. Statistics on unemployment will be based on figures provided by the U.S. Bureau of Labor Statistics. However, the Administrator may, at his discretion, also consider verifiable, published State statistical data provided by the applicant in situations where county-wide statistical data is not representative of local conditions. Such statistical data must be part of a recognized database which reflects information for other areas within the State;

(B) A 15% loss of population due to out-migration over the most recent 10-year decennial census, based on the U.S. Bureau of the Census decennial data;

(iv) A designation as a Rural Empowerment Zone or Rural Enterprise Community by the Empowerment Zone

Program authorized by Section 13301 of the Omnibus Reconciliation Act of 1993, Public Law 103-66 (107 Stat. 312), 26 U.S.C. 1391-1393.

(h) \* \* \*  
(11) *Special economic status*—25 points.

Dated: October 19, 1994.

Bob J. Nash,

Under Secretary, Small Community and Rural Development.

[FR Doc. 94-26418 Filed 10-26-94; 8:45 am]

BILLING CODE 3410-15-P

## DEPARTMENT OF TRANSPORTATION

## Federal Aviation Administration

## 14 CFR Part 39

[Docket No. 94-NM-22-AD; Amendment 39-9050; AD 94-22-01]

## Airworthiness Directives; McDonnell Douglas Model DC-10 Series Airplanes

AGENCY: Federal Aviation Administration, DOT.

ACTION: Final rule.

**SUMMARY:** This amendment supersedes an existing airworthiness directive (AD), applicable to all McDonnell Douglas Model DC-10-10, -10F, -30, and -30F series airplanes, that currently requires inspections to detect ice or snow accumulation on top of the fuselage and in the inlet of the number 2 engine, and removal of ice and snow accumulation. This amendment adds certain airplanes to the applicability of the rule and limits the inspection requirement to only a certain group of airplanes. This amendment is prompted by the development of improved fan blades on certain engines and the identification of additional airplanes that are subject to the unsafe condition. The actions specified by this AD are intended to minimize damage to the number 2 engine due to ingestion of ice and snow.

**EFFECTIVE DATE:** November 28, 1994.

**ADDRESSES:** Information related to this rule may be examined at the Federal Aviation Administration (FAA), Transport Airplane Directorate, Rules Docket, 1601 Lind Avenue, SW., Renton, Washington; or at the FAA, Transport Airplane Directorate, Los Angeles Aircraft Certification Office, 3229 East Spring Street, Long Beach, California.

**FOR FURTHER INFORMATION CONTACT:** Raymond Vakili, Aerospace Engineer, Propulsion Branch, ANM-141L, FAA, Transport Airplane Directorate, Los Angeles Aircraft Certification Office,

3229 East Spring Street, Long Beach, California 90806-2425; telephone (310) 988-5262; fax (310) 988-5210.

**SUPPLEMENTARY INFORMATION:** A proposal to amend part 39 of the Federal Aviation Regulations (14 CFR part 39) by superseding AD 75-04-11, amendment 39-2094, which is applicable to all McDonnell Douglas Model DC-10-10, -10F, -30, and -30F series airplanes, was published in the *Federal Register* on July 18, 1994 (59 FR 36375). The action proposed to supersede AD 75-04-11, which currently requires inspections to detect ice and snow accumulation on top of the fuselage and in the inlet of the number 2 engine, and removal of ice and snow. The action proposed to add Model DC-10-15 series airplanes to the applicability of the rule, and to limit the inspection requirement to only a certain group of airplanes.

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

The commenter supports the proposed rule.

After careful review of the available data, including the comment noted above, the FAA has determined that air safety and the public interest require the adoption of the rule as proposed.

There are approximately 379 McDonnell Douglas Model DC-10-10, -10F, -30, -30F, and -15 series airplanes and Model KC-10A (military) airplanes of the affected design in the worldwide fleet. The FAA estimates that 226 airplanes of U.S. registry will be affected by this AD. (Currently, there are no Model DC-10-15 series airplanes of U.S. registry that will be affected by this AD.)

The inspections that were previously required by AD 75-04-11, and retained in this AD take approximately 1 work hour per airplane to accomplish the required actions, and that the average labor rate is \$55 per work hour. Based on these figures, the total cost impact of the inspection requirement on U.S. operators is estimated to be \$12,430, or \$55 per airplane, per inspection. This AD will only add the cost of inspections for the operators of Model KC-10A (military) airplanes.

For operators of Model DC-10-10, -10F, -30, and -30F series airplanes having all solid fan blades in the number 2 engine position, the economic burden will be reduced since the previous requirement to inspect these airplanes in accordance with the existing AD will be eliminated by this AD. However, this does not relieve

operators of the responsibility to comply with the requirements of §§ 91.527 ("Operating in icing conditions") and 121.629 ("Operation in icing conditions"—air carriers) of the Federal Aviation Regulations (14 CFR 91.527 and 121.629).

The total cost impact figure discussed above is based on assumptions that no operator has yet accomplished any of the requirements of this AD action, and that no operator would accomplish those actions in the future if this AD were not adopted.

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

For the reasons discussed above, I certify that this action (1) is not a "significant regulatory action" under Executive Order 12866; (2) is not a "significant rule" under DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and (3) will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act. A final evaluation has been prepared for this action and it is contained in the Rules Docket. A copy of it may be obtained from the Rules Docket at the location provided under the caption ADDRESSES.

#### List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Safety.

#### Adoption of the Amendment

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

#### PART 39—AIRWORTHINESS DIRECTIVES

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

**Authority:** 49 U.S.C. App. 1354(a), 1421 and 1423; 49 U.S.C. 106(g); and 14 CFR 11.89.

#### § 39.13 [Amended]

2. Section 39.13 is amended by removing amendment 39-2094, and by adding a new airworthiness directive

(AD), amendment 39--, to read as follows:

**94-22-01 McDonnell Douglas:** Amendment 39-9050. Docket 94-NM-22-AD. Supersedes AD 75-04-11, Amendment 39-2094.

**Applicability:** Model DC-10-10, -10F, -30, -30F, and -15 series airplanes, and Model KC-10A (military) airplanes, on which the number 2 engine is a General Electric Model CF6 series turbofan engine having one or more gundrilled fan blades installed, including but not limited to part numbers 9010M33 and 9137M39; certificated in any category.

**Compliance:** Required as indicated, unless accomplished previously.

To prevent possible damage to the number 2 engine due to ingestion of ice and snow, accomplish the following:

(a) As of the effective date of this AD, prior to starting the number 2 engine on any airplane that has been parked during icing conditions (freezing rain, snow, sleet) for any period of time during which ice or snow may have accumulated on the airplane in the area of the number 2 engine, inspect to detect ice and snow accumulation on top of the fuselage and in the inlet of the number 2 engine. If ice or snow accumulation is found, prior to further flight, remove the ice or snow accumulation.

**Note 1:** Guidelines for inspection and safeguarding the aircraft are contained in these documents:

Douglas All Operators Letter (AOL) 10-546, dated January 11, 1974

Douglas AOL 10-673, dated August 7, 1974  
DC-10 Airplane Maintenance Manual,  
Chapter 12-31-01

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

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

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

(d) This amendment becomes effective on November 28, 1994.

Issued in Renton, Washington, on October 13, 1994.

**Darrell M. Pederson,**

*Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.*

[FR Doc. 94-25846 Filed 10-26-94; 8:45 am]

BILLING CODE 4910-13-U

## 14 CFR Part 39

[Docket No. 92-ASW-03; Amendment 39-9053; AD 94-22-04]

**Airworthiness Directives; Costruzioni Aeronautiche Giovanni Agusta S.p.A. Model A109A and A109AII Series Helicopters**

AGENCY: Federal Aviation Administration, DOT.

ACTION: Final rule.

**SUMMARY:** This amendment supersedes an existing airworthiness directive (AD), applicable to Costruzioni Aeronautiche Giovanni Agusta S.p.A. Model A109A and A109AII series helicopters, that currently imposes a calendar life limit of 10 years and 6 months on the main rotor retention strap assemblies (strap assemblies). This amendment requires reducing the calendar life limit to 8 years. This amendment is prompted by additional service experience and analyses, that show the current life limit needs to be reduced from 10 years and 6 months to 8 years to prevent deterioration and subsequent failure of the strap assemblies. The actions specified by this AD are intended to prevent failure of the strap assemblies, loss of a main rotor blade, and subsequent loss of control of the helicopter.

**EFFECTIVE DATE:** December 1, 1994.

**ADDRESSES:** This AD and any related information may be examined in the Rules Docket at the Federal Aviation Administration (FAA), Office of the Assistant Chief Counsel, 2601 Meacham Blvd., Room 663, Fort Worth, Texas.

**FOR FURTHER INFORMATION CONTACT:** Mr. Mike Mathias, Aerospace Engineer, Rotorcraft Standards Staff, FAA, Rotorcraft Directorate, 2601 Meacham Blvd., Fort Worth, Texas 76137, telephone (817) 222-5123, fax (817) 222-5961.

**SUPPLEMENTARY INFORMATION:** A proposal to amend part 39 of the Federal Aviation Regulations (14 CFR part 39) by superseding AD 87-15-10, Amendment 39-5681, (52 FR 27787, July 24, 1987), which is applicable to Costruzioni Aeronautiche Giovanni Agusta S.p.A. Model A109A and A109AII series helicopters, was published in the *Federal Register* on August 21, 1992 (57 FR 37914). That action proposed to require an 8-year calendar life instead of a 10 years and 6 months life limit on the strap assemblies, part numbers 2601521 and 109-0101-95-1, -3, and -105.

Interested persons have been afforded an opportunity to participate in the

making of this amendment. No comments were received on the proposal or the FAA's determination of the cost to the public. However, the words "since installation" have been removed and the word "total" has been added to paragraph (a)(2) to further clarify that the TIS and the calendar years relate to the total time on the strap assemblies and not to the time since they were installed on the helicopter. Also, the terms "calendar year" and "calendar month" have now been defined in paragraph (a)(3). Finally, the average labor rate was raised from \$55 to \$60. The FAA has determined that air safety and the public interest require the adoption of the rule as proposed with the noted changes. The FAA has determined that these changes will neither increase the economic burden on any operator nor increase the scope of the AD.

The FAA estimates that 46 helicopters of U.S. registry will be affected by this AD, that it will take approximately 4 work hours per helicopter to accomplish the required actions, and that the average labor rate is \$60 per work hour. Required parts will cost approximately \$1,931 per helicopter. Based on these figures, the total cost impact of the AD on U.S. operators is estimated to be \$99,866.

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

For the reasons discussed above, I certify that this action (1) is not a "significant regulatory action" under Executive Order 12866; (2) is not a "significant rule" under DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and (3) will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act. A final evaluation has been prepared for this action and it is contained in the Rules Docket. A copy of it may be obtained from the Rules Docket at the location provided under the caption **ADDRESSES**.

**List of Subjects in 14 CFR Part 39**

Air transportation, Aircraft, Aviation safety, Safety.

**Adoption of the Amendment**

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

**PART 39—AIRWORTHINESS DIRECTIVES**

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

**Authority:** 49 U.S.C. App. 1354(a), 1421 and 1423; 49 U.S.C. 106(g); and 14 CFR 11.89.

**§ 39.13 [Amended]**

2. Section 39.13 is amended by removing Amendment 39-5681 (52 FR 27787, July 24, 1987), and by adding a new airworthiness directive (AD), Amendment 39-9053, to read as follows:

**AD 94-22-04 Costruzioni Aeronautiche Giovanni Agusta S.p.A.: Amendment 39-9053.** Docket Number 92-ASW-03. Supersedes AD 87-15-10, Amendment 30-5681.

**Applicability:** Model A109A and A109AII series helicopters, certificated in any category.

**Compliance:** Required as indicated, unless accomplished previously.

To prevent failure of the main rotor retention strap assemblies (strap assemblies), accomplish the following:

(a) Replace the strap assemblies, part numbers (P/N) 2061521 and 109-0101-95-1, -3, and -105, with airworthy strap assemblies in accordance with the applicable maintenance manual and the following:

(1) For strap assemblies that have 7½ or more calendar years time-in-service (TIS) on the effective date of this AD, replace the strap assemblies within the next 6 calendar months or before accumulating 5,000 hours total TIS on the strap assemblies, whichever occurs first.

(2) For strap assemblies that have less than 7½ calendar years TIS on the effective date of this AD, replace the strap assemblies before accumulating 8 calendar years TIS or before accumulating 5,000 hours total TIS on the strap assemblies, whichever occurs first.

(3) For the purposes of this AD, the calendar compliance times begin on the day the strap assemblies are installed on any helicopter. Additionally, a calendar year is a 365-day period of time. Also, a calendar month is a 30-day period of time.

(b) An alternative method of compliance or adjustment of the compliance time that provides an acceptable level of safety may be used when approved by the Manager, Rotorcraft Standards Staff, FAA, Rotorcraft Directorate, or by the Manager, Brussels Aircraft Certification Office, AEU-100, FAA, Europe, Africa, and Middle East Office, c/o American Embassy, Brussels, Belgium. Operators shall submit their requests through an FAA Principal Maintenance Inspector, who may concur or comment and then send it to the Manager, Rotorcraft Standards Staff.

**Note:** Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the Rotorcraft Standards Staff or the Brussels Aircraft Certification Office.

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

(d) This amendment becomes effective on December 1, 1994.

Issued in Fort Worth, Texas, on October 21, 1994.

Eric Bries,

Acting Manager, Rotorcraft Directorate,  
Aircraft Certification Service.

[FR Doc. 94-26599 Filed 10-26-94; 8:45 am]

BILLING CODE 4910-13-P

## DEPARTMENT OF COMMERCE

### Bureau of Economic Analysis

#### 15 CFR Part 801

[Docket No. 940797-4294]

RIN 0691-AA24

#### International Services Surveys: BE-80 Benchmark Survey of Financial Services Transactions Between U.S. Financial Services Providers and Unaffiliated Foreign Persons

AGENCY: Bureau of Economic Analysis,  
Commerce.

ACTION: Final rule.

**SUMMARY:** These final rules institute a new international services survey, the BE-80, Benchmark Survey of Financial Services Transactions Between U.S. Financial Services Providers and Unaffiliated Foreign Persons, to be conducted by the Bureau of Economic Analysis (BEA), U.S. Department of Commerce. The survey will, for the first time, collect comprehensive information on trade in financial services between U.S. financial services providers and unaffiliated foreign persons. It is intended to cover the universe of such transactions by type and by country. The information is needed to support trade policy initiatives, including trade negotiations, on financial services and to compile the U.S. balance of payments and national income and product accounts. The survey will be conducted once every 5 years under the International Investment and Trade in Services Survey Act and the Omnibus Trade and Competitiveness Act of 1988. The first survey will cover 1994.

**DATES:** These rules will be effective November 28, 1994.

**FOR FURTHER INFORMATION CONTACT:**

Betty L. Baker, Chief, International Investment Division (BE-50), Bureau of Economic Analysis, U.S. Department of Commerce, Washington, DC 20230; phone (202) 606-9805.

**SUPPLEMENTARY INFORMATION:** In the July 28, 1994 Federal Register, volume 59, No. 144, 59 FR 38387, BEA published a notice of proposed rulemaking setting forth reporting requirements for a new survey, the BE-80, Benchmark Survey of Financial Services Transactions Between U.S. Financial Services Providers and Unaffiliated Foreign Persons. No comments on the proposed rules were received. As a result, the final rules are the same as the proposed rules.

These final rules amend existing 15 CFR 801.9 and add new 15 CFR 801.11 to implement the new survey. The survey will be conducted by BEA under the International Investment and Trade in Services Survey Act (P.L. 94-472, 90 Stat. 2059, 22 U.S.C. 3101-3108, as amended) and the Omnibus Trade and Competitiveness Act of 1988 (P.L. 100-418, 15 U.S.C. 4908(b)). Section 4(a) of the International Investment and Trade in Services Survey Act provides that "The President shall, to the extent he deems necessary and feasible—\* \* \*(4) conduct \* \* \* benchmark surveys with respect to trade in services between unaffiliated United States persons and foreign persons \* \* \*" In Section 3 of Executive Order 11961, as amended by Executive Order 12518, the President delegated the authority under the Act as concerns international trade in services to the Secretary of Commerce, who has redelegated it to BEA.

The Omnibus Trade and Competitiveness Act of 1988 directs that "The Secretary (of Commerce) shall ensure that \* \* \* there is included in the Data Bank information on service sector activity that is as complete and timely as information on economic activity in the merchandise sector. The Secretary shall undertake a new benchmark survey of services transactions, including transactions with respect to \* \* \* banking services; (and) brokerage services."

The major purposes of the survey are to provide the information on financial services needed in monitoring U.S. services trade, analyzing its effects on the U.S. economy, formulating U.S. international trade policy, supporting bilateral and multilateral trade negotiations, compiling the U.S. balance of payments and national income and product accounts, developing U.S. international price indexes for services, assessing U.S. competitiveness in international trade in services, and

improving the ability of U.S. businesses to identify and evaluate market opportunities.

The BE-80 survey will be conducted once every 5 years, and the first survey will be for 1994. The survey covers the universe of financial services transactions between U.S. financial services providers and unaffiliated foreign persons. Reporting is required from U.S. financial services providers who have sales to or purchases from unaffiliated foreign persons in all covered financial services combined in excess of \$1 million during the reporting year. Those financial services providers meeting this criteria must supply data on the amount of their sales or purchases of each covered type of service, disaggregated by country. U.S. financial services providers that have covered transactions of less than \$1 million during the reporting year are asked to provide, on a voluntary basis, estimates only of their total sales or purchases of each type of financial service. The survey is scheduled to be mailed to potential respondents in February 1995, and completed reports are due May 31.

It is anticipated that the information from the benchmark survey will be updated in nonbenchmark years by an annual follow-on survey that is more limited in scope and that will cover only a sample of the companies reporting in the BE-80 survey.

#### Executive Order 12612

These final rules do not contain policies with Federalism implications sufficient to warrant preparation of a Federalism assessment under E.O. 12612.

#### Executive Order 12866

These final rules have been determined to be not significant for purposes of E.O. 12866.

#### Paperwork Reduction Act

The collection of information requirement in these final rules has been approved by OMB (OMB No. 0608-0062).

Public reporting burden for this collection of information is estimated to vary from 4 to 150 hours, with an overall average burden of 7.5 hours. This includes time for reviewing the instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Comments from the public regarding the burden estimate or any other aspect of this collection of information should be addressed to: Director, Bureau of Economic Analysis (BE-1), U.S.

Department of Commerce, Washington, DC 20503; and to the Office of Management and Budget, Washington, DC 20503, Attention: Desk Officer for the Department of Commerce.

#### Regulatory Flexibility Act

The General Counsel, Department of Commerce, has certified to the Chief Counsel for Advocacy, Small Business Administration, under the provisions of the Regulatory Flexibility Act (5 U.S.C. 605(b)), that these final rules will not have a significant economic impact on a substantial number of small entities. The exemption level for the survey excludes most small businesses from mandatory reporting. Reporting is required only if total sales or total purchases transactions in financial services with unaffiliated foreign persons by U.S. persons who are financial services providers, or by U.S. persons whose consolidated enterprise includes a separately organized subsidiary or part that is a financial services provider, exceed \$1 million during the year. In addition, international business tends to be conducted mainly by the larger companies in a given industry; in the financial services industry, this is particularly true, because of the high degree of consolidation occurring in that industry in the United States during the past several years. In any event, small businesses tend to have specialized operations and activities, so those with reportable transactions will likely not have significant amounts of data to report; therefore, the burden on them will be relatively small.

#### List of Subjects in 15 CFR Part 801

Economic statistics, Balance of payments, Foreign trade, Penalties, Reporting and recordkeeping requirements.

Dated: October 11, 1994.

Carol S. Carson,

Director, Bureau of Economic Analysis.

For the reasons set forth in the preamble, BEA amends 15 CFR Part 801 as follows:

#### PART 801—[AMENDED]

1. The authority citation for 15 CFR Part 801 is revised to read as follows:

**Authority:** 5 U.S.C. 301, 15 U.S.C. 4908(b), 22 U.S.C. 3101–3108, and E.O. 11961 (3 CFR, 1977 Comp., p. 86) as amended by E.O. 12013 (3 CFR, 1977 Comp., p. 147) E.O. 12318 (3 CFR, 1981 Comp., p. 173), and E.O. 12518 (3 CFR, 1985 Comp., p. 348).

2. Section 801.9 is amended by revising paragraph (a) to read as follows:

#### § 801.9 Reports required.

(a) *Benchmark surveys.* Section 4(a)(4) of the Act (22 U.S.C. 3103) provides that benchmark surveys of trade in services between U.S. and unaffiliated foreign persons be conducted, but not more frequently than every 5 years. General reporting requirements, exemption levels, and the year of coverage of the BE-20 survey may be found in § 801.10, and general reporting requirements, exemption levels, and the year of coverage of the BE-80 survey may be found in § 801.11. More detailed instructions are given on the forms themselves.

\* \* \* \* \*

3. Section 801.11 is added to read as follows:

#### § 801.11 Rules and regulations for the BE-80, Benchmark Survey of Financial Services Transactions Between U.S. Financial Services Providers and Unaffiliated Foreign Persons.

A BE-80, Benchmark Survey of Financial Services Transactions Between U.S. Financial Services Providers and Unaffiliated Foreign Persons, will be conducted covering companies' 1994 fiscal year and every fifth year thereafter. All legal authorities, provisions, definitions, and requirements contained in § 801.1 through § 801.9 are applicable to this survey. Additional rules and regulations for the BE-80 survey are given in paragraphs (a) through (d) of this section. More detailed instructions are given on the report form itself.

(a) *Who must report.*—(1) *Mandatory reporting.* Reports are required from each U.S. person who is a financial services provider or intermediary, or whose consolidated U.S. enterprise includes a separately organized subsidiary or part that is a financial services provider or intermediary, and who had transactions (either sales or purchases) directly with unaffiliated foreign persons in all financial services combined in excess of \$1,000,000 during its fiscal year covered by the survey. The \$1,000,000 threshold should be applied to financial services transactions with unaffiliated foreign persons by all parts of the consolidated U.S. enterprise combined that are financial services providers or intermediaries. Because the \$1,000,000 threshold applies separately to sales and purchases, the mandatory reporting requirement may apply only to sales, only to purchases, or to both sales and purchases.

(i) The determination of whether a U.S. financial services provider or intermediary is subject to this mandatory reporting requirement may

be judgmental, that is, based on the judgment of knowledgeable persons in a company who can identify reportable transactions on a recall basis, with a reasonable degree of certainty, without conducting a detailed manual records search.

(ii) Reporters who file pursuant to this mandatory reporting requirement must provide data on total sales and/or purchases of each of the covered types of financial services transactions and must disaggregate the totals by country.

(2) *Voluntary reporting.* If, during the fiscal year covered, sales or purchases of financial services by a firm that is a financial services provider or intermediary, or by a firm's subsidiaries or parts combined that are financial services providers or intermediaries, are \$1,000,000 or less, the U.S. person is requested to provide an estimate of the total for each type of service. Provision of this information is voluntary. Because the \$1,000,000 threshold applies separately to sales and purchases, this voluntary reporting option may apply only to sales, only to purchases, or to both sales and purchases.

(b) *BE-80 definition of financial services provider.* The definition of financial services provider used for this survey is analogous in coverage to the finance and insurance part of Division H of the 1987 Standard Industrial Classification Manual (SIC major groups 60 through 64, and major group 67). More specifically, companies and/or subsidiaries and other separable parts of companies in the following industries are defined as financial services providers: Depository institutions (including commercial banks and thrifts); nondepository credit institutions; security and commodity futures brokers, dealers, exchanges, traders, underwriters, and services providers (including investment bankers and providers of securities custody services); credit card companies, insurance carriers, agents, brokers and services providers; investment advisors and managers; mutual funds; pension funds; trusts; holding companies; investors; oil royalty traders; etc.

(c) *Covered types of services.* The BE-80 survey covers the following types of financial services transactions (purchases and/or sales) between U.S. financial services providers and unaffiliated foreign persons: Brokerage, except foreign exchange brokerage services; private placement services; underwriting services; financial management services; credit-related services, except credit card services; credit card services; financial advisory and custody services; securities lending

services; foreign exchange brokerage services; and other financial services.

(d) *What to file.* (1) The BE-80 survey consists of Forms BE-80(A) and BE-80(B). Before completing a Form BE-80(B), a consolidated U.S. enterprise (including the top parent and all of its subsidiaries and parts combined) must complete Form BE-80(A) to determine its reporting status. If the enterprise is subject to the mandatory reporting requirement, or if it is exempt from the mandatory reporting requirement but chooses to report data voluntarily, either a separate Form BE-80(B) may be filed for each separately organized financial services subsidiary or part of the consolidated U.S. enterprise, or a single BE-80(B) may be filed, representing the sum of covered transactions by all financial services subsidiaries or parts of the enterprise combined.

(2) Reporters that receive the BE-80 survey from BEA, but that are not reporting data in either the mandatory or voluntary section of any Form BE-80(B), must return the Exemption Claim, attached to Form BE-80(A), to BEA.

[FR Doc. 94-26596 Filed 10-26-94; 8:45 am]  
BILLING CODE 3510-EA-M

## SECURITIES AND EXCHANGE COMMISSION

### 17 CFR PART 200

[Release No. 34-34871]

#### Disposition of Business by Seriatim Commission Consideration or by Delegated Authority

**ACTION:** Final rule.

**SUMMARY:** The Securities and Exchange Commission ("Commission") is amending its rules on disposition of Commission business to formalize current practice regarding procedures for seriatim and delegated consideration of business.

**EFFECTIVE DATE:** October 27, 1994.

**FOR FURTHER INFORMATION CONTACT:** C. Hunter Jones, Office of the General Counsel, (202) 942-0877, or Anne Sullivan, Office of the General Counsel, (202) 942-0954.

**SUPPLEMENTARY INFORMATION:** The Commission is modifying 17 CFR 200.41-200.42 concerning seriatim consideration of business and actions by individual Commissioners on a delegated basis in order to formalize current practice and clarify that any member of the Commission may schedule a matter for joint deliberation, regardless of the number of Commissioners who have voted to

approve it, and that a member of the Commission who is serving as duty officer is authorized to approve a formal order of private investigation.

The Commission has determined that these amendments and additions to its procedural rules relate solely to the agency's organization, procedure or practice. Therefore, the provisions of the Administrative Procedure Act ("APA") regarding notice of proposed rulemaking, opportunities for public participation, and prior publication<sup>1</sup> are not applicable. Similarly, the provisions of the Regulatory Flexibility Act,<sup>2</sup> which apply only when notice and comment are required by the APA or other laws, are not applicable.

#### Effects on Competition

Section 23(a)(2) of the Securities Exchange Act of 1934 ("Exchange Act")<sup>3</sup> requires the Commission, in adopting rules under the Exchange Act, to consider the anti-competitive effects of such rules, if any, and to balance any impact against the regulatory benefits gained in furthering the purposes of the Exchange Act. The Commission has considered the changes adopted in this release in light of the standards cited in section 23(a)(2) and believes that their adoption would not impose any burden on competition not necessary or appropriate in furtherance of the Exchange Act.

#### Statutory Basis of Rule

The amendments to the Commission's rules are adopted pursuant to the authorities set forth therein.

#### List of Subjects in 17 CFR Part 200

Administrative practice and procedure, Authority delegations (Government agencies).

#### Text of Amendments

For the reasons set out in the preamble, Title 17, Chapter II, Part 200 of the Code of Federal Regulations is amended as follows:

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

##### Subpart B—Disposition of Commission Business

1. The authority citation for Part 200, Subpart B, continues to read as follows:

**Authority:** 5 U.S.C. 552b.

2. Section 200.41 is amended by revising paragraph (a) to read as follows:

<sup>1</sup> 5 U.S.C. 553.

<sup>2</sup> 5 U.S.C. 601-612.

<sup>3</sup> 15 U.S.C. 78w(a)(2).

#### § 200.41 Disposition of business by seriatim Commission consideration.

(a) Whenever the Commission's Chairman, or the Commission member designated as duty officer pursuant to § 200.42, is of the opinion that joint deliberation among the members of the Commission upon any matter is unnecessary in light of the nature of the matter, impracticable, or contrary to the requirements of agency business, but is of the view that such matter should be the subject of a vote of the Commission, such matter may be disposed of by circulation of any relevant materials concerning the matter among all Commission members. Each participating Commission member shall report his or her vote to the Secretary, who shall record it in the Minute Record of the Commission. Any matter circulated for disposition pursuant to this subsection shall not be considered final until each Commission member has reported his or her vote to the Secretary or has reported to the Secretary that the Commissioner does not intend to participate in the matter.

\* \* \* \* \*

3. Section 200.42 is amended by redesignating paragraph (b)(2) as paragraph (b)(3) and adding a new paragraph (b)(2) to read as follows:

#### § 200.42 Disposition of business by exercise of authority delegated to individual Commissioner.

\* \* \* \* \*

(b) \* \* \*

(2) The duty officer may, when in his or her opinion it would be proper and timely, exercise the authority delegated in this section to initiate by order a nonpublic formal investigative proceeding pursuant to section 19(b) of the Securities Act of 1933 (15 U.S.C. 77s(b)), section 21(b) of the Securities Exchange Act of 1934 (15 U.S.C. 78u(b)), section 18(c) of the Public Utility Holding Company Act of 1935 (15 U.S.C. 79r(c)), section 42(b) of the Investment Company Act of 1940 (15 U.S.C. 80a-41(b)), section 209(b) of the Investment Advisers Act of 1940 (15 U.S.C. 80b-9(b)), and Part 203 (Rules Relating to Investigations) of this title (17 CFR part 203). After consideration of a staff recommendation for initiation by order of a nonpublic formal investigative proceeding, the duty officer shall forthwith report his or her action thereon to the Secretary.

\* \* \* \* \*

By the Commission.

Dated: October 21, 1994.

Jonathan G. Katz,

Secretary.

[FR Doc. 94-26582 Filed 10-26-94; 8:45 am]

BILLING CODE 8010-01-P

## DEPARTMENT OF JUSTICE

### Bureau of Prisons

#### 28 CFR Part 570

[BOP-1005-F]

RIN 1120-AA10

#### Furloughs; Transportation Costs

AGENCY: Bureau of Prisons, Justice.

ACTION: Final rule.

**SUMMARY:** In this document the Bureau of Prisons is amending its rule on furloughs. Section 570.33(c) contained provisions governing the choice of transportation for transfers to community corrections centers. As revised, these provisions have been simplified to indicate that an inmate may choose the means of transportation if all transportation costs are to be borne by the inmate. The intended effect of the amendment is to reduce costs to the Bureau.

**EFFECTIVE DATE:** November 28, 1994.

**ADDRESSES:** Office of General Counsel, Bureau of Prisons, HOLC Room 754, 320 First Street, NW., Washington, DC 20534.

**FOR FURTHER INFORMATION CONTACT:** Roy Nanovic, Office of General Counsel, Bureau of Prisons, phone (202) 514-6655.

**SUPPLEMENTARY INFORMATION:** The Bureau of Prisons is amending its regulations on furloughs. A final rule on this subject was published in the *Federal Register* July 1, 1981 (46 FR 34552) and was amended September 30, 1983 (48 FR 45051) and January 21, 1994 (59 FR 3510).

A proposed rule was published in the *Federal Register* January 21, 1994 (59 FR 3512) for the purpose of amending the provisions in § 570.33(c) which state that the Warden may allow an inmate scheduled for transfer to a community corrections center (CCC) to choose the means of transportation to the CCC. Under these provisions, the inmate paid all costs when the distance travelled was not over 150 miles, but the inmate merely paid the difference in cost when the distance was over 150 miles and the inmate preferred to travel by plane rather than by public ground transportation. As proposed for revision, paragraph (c) was simplified to indicate

that an inmate may choose the means of transportation if all transportation costs are to be borne by the inmate.

The comment period closed on March 22, 1994. The Bureau received no comment on this rulemaking, and the Bureau is therefore adopting the proposed amendment as a final rule without change.

The Bureau of Prisons has determined that this rule is not a significant regulatory action for the purpose of E.O. 12866, and accordingly this rule was not reviewed by the Office of Management and Budget. After review of the law and regulations, the Director, Bureau of Prisons has certified that this rule, for the purpose of the Regulatory Flexibility Act (Pub. L. 96-354), does not have a significant impact on a substantial number of small entities.

#### List of Subjects in 28 CFR Part 570

Prisoners.

Kathleen M. Hawk,

Director, Bureau of Prisons.

Accordingly, pursuant to the rulemaking authority vested in the Attorney General in 5 U.S.C. 552(a) and delegated to the Director, Bureau of Prisons in 28 CFR 0.96(p), part 570 in subchapter D of 28 CFR, chapter V is amended as set forth below.

#### SUBCHAPTER D—COMMUNITY PROGRAMS AND RELEASE

#### PART 570—COMMUNITY PROGRAMS

1. The authority citation for 28 CFR part 570 continues to read as follows:

**Authority:** 5 U.S.C. 301; 18 U.S.C. 751, 3621, 3622, 3624, 4001, 4042, 4081, 4082 (Repealed in part as to offenses committed on or after November 1, 1987), 4161-4166, 5006-5024 (Repealed October 12, 1984 as to offenses committed after that date), 5039; 28 U.S.C. 509, 510; 28 CFR 0.95-0.99.

2. In § 570.33, paragraph (c) is revised to read as follows:

#### § 570.33 Expenses of furlough.

\* \* \* \* \*

(c) The Warden may allow an inmate scheduled for transfer to a community corrections center (CCC) to choose the means of transportation to the CCC if all transportation costs are borne by the inmate. An inmate traveling under these provisions is expected to go directly as scheduled from the institution to the CCC.

[FR Doc. 94-26671 Filed 10-26-94; 8:45 am]  
BILLING CODE 4410-05-P

## DEPARTMENT OF COMMERCE

### National Oceanic and Atmospheric Administration

#### 50 CFR Part 672

[Docket No. 931199-4042; I.D. 102494A]

#### Groundfish of the Gulf of Alaska

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

ACTION: Closure.

**SUMMARY:** NMFS is closing the directed fishery for Pacific ocean perch in the Eastern Regulatory Area of the Gulf of Alaska (GOA). This action is necessary to prevent exceeding the Pacific ocean perch total allowable catch (TAC) in this area.

**EFFECTIVE DATE:** 12 noon, Alaska local time (A.l.t.), October 24, 1994, until 12 midnight, A.l.t., December 31, 1994.

**FOR FURTHER INFORMATION CONTACT:** Andrew N. Smoker, 907-586-7228.

**SUPPLEMENTARY INFORMATION:** The groundfish fishery in the GOA exclusive economic zone is managed by the Secretary of Commerce according to the Fishery Management Plan for Groundfish of the Gulf of Alaska (FMP) prepared by the North Pacific Fishery Management Council under authority of the Magnuson Fishery Conservation and Management Act. Fishing by U.S. vessels is governed by regulations implementing the FMP at 50 CFR parts 620 and 672.

In accordance with § 672.20(c)(1)(ii)(B), the Pacific ocean perch TAC for the Eastern Regulatory Area was established by the final 1994 specifications of groundfish (59 FR 7647, February 16, 1994) as 1,265 metric tons (mt).

The Director, Alaska Region, NMFS (Regional Director), established in accordance with § 672.20(c)(2)(ii) a directed fishing allowance for Pacific ocean perch of 1,165 mt, with consideration that 100 mt would be taken as incidental catch in directed fishing for other species in this area. The Regional Director has determined that this directed fishing allowance has been reached. Consequently, NMFS is prohibiting directed fishing for Pacific ocean perch in the Eastern Regulatory Area effective from 12 noon, A.l.t., October 24, 1994, until 12 midnight, A.l.t., December 31, 1994.

Directed fishing standards for applicable gear types may be found in the regulations at § 672.20(g).

**Classification**

This action is taken under 50 CFR 672.20 and is exempt from review under E.O. 12866.

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

**Dated:** October 24, 1994.

**David S. Crestin,**

*Acting Director, Office of Fisheries  
Conservation and Management, National  
Marine Fisheries Service.*

[FR Doc. 94-26659 Filed 10-24-94; 1:46 pm]

BILLING CODE 3510-22-F

# Proposed Rules

Federal Register

Vol. 59, No. 207

Thursday, October 27, 1994

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

## DEPARTMENT OF AGRICULTURE

### Rural Electrification Administration

#### 7 CFR Part 1751

RIN 0572-AB07

#### Telecommunications System Planning and Design Criteria, and Procedures

AGENCY: Rural Electrification Administration, USDA.

ACTION: Proposed rule.

**SUMMARY:** The Rural Electrification Administration (REA) proposes to amend its interim rule regarding the State Telecommunications Modernization Plan requirements. The proposed changes are in response to comments received from the public regarding the interim rule. All Telephone Borrowers will be affected by this proposed rule.

**DATES:** Comments concerning this proposed rule must be received by REA or bear a postmark or its equivalent no later than November 28, 1994.

**ADDRESSES:** Submit written comments to Matthew P. Link, Director, Rural Telephone Bank Management Staff, U.S. Department of Agriculture, Rural Electrification Administration, 14th & Independence Avenue, SW., Room 2832-S, Washington, DC 20250-1500. REA requests an original and three copies of all comments (7 CFR part 1700). All comments received will be made available for public inspection at Room 2238-S, at the address listed above, between 8:30 a.m. and 5 p.m. (7 CFR 1.27(b)).

**FOR FURTHER INFORMATION CONTACT:** Robert Peters, Assistant Administrator, Telephone Program, at the address listed above, telephone number (202) 720-9554.

#### SUPPLEMENTARY INFORMATION:

##### Executive Order 12866

This proposed rule has been determined to be significant and was reviewed by the Office of Management

and Budget (OMB) under Executive Order 12866.

##### Executive Order 12778

This proposed rule has been reviewed under Executive Order 12778, Civil Justice Reform. If adopted, this proposed rule will not: (1) Preempt any State or local laws, regulations, or policies, unless they present an irreconcilable conflict with this rule; (2) Have any retroactive effect; and (3) Require administrative proceedings before parties may file suit challenging the provisions of this rule.

##### Regulatory Flexibility Act Certification

REA has determined that this proposed rule will not have a significant economic impact on a substantial number of small entities, as defined in the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*). The REA program provides loans to REA Borrowers at interest rates and terms that are more favorable than those generally available from the private sector. REA Borrowers, as a result of obtaining federal financing, receive economic benefits which ultimately offset any direct economic costs associated with complying with REA regulations and requirements. Moreover, this action is in response to the Rural Electrification Loan Restructuring Act of 1993.

##### Information Collection and Recordkeeping Requirements

The reporting and recordkeeping requirements contained in the proposed rule have been submitted to OMB for approval in accordance with the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 *et seq.*). Send comments regarding this collection of information to: Department of Agriculture, Clearance Office, Office of Information Resources Management, Room 404-W, Washington, DC 20250, and Regulatory Affairs of OMB, Attention: Desk Officer for USDA, Room 3201, New Executive Office Building, Washington, DC 20503.

##### National Environmental Policy Act Certification

REA has determined that this proposed rule will not significantly affect the quality of the human environment as defined by the National Environmental Policy Act of 1969 (42 U.S.C. 4321 *et seq.*). Therefore, this action does not require an

environmental impact statement or assessment.

##### Catalog of Federal Domestic Assistance

The program described by this proposed rule is listed in the Catalog of Federal Domestic Assistance Programs under 10.851, Rural Telephone Loans and Loan Guarantees, and 10.852, Rural Telephone Bank Loans. This catalog is available on a subscription basis from the Superintendent of Documents, the United States Government Printing Office, Washington, DC 20402-9325.

##### Executive Order 12372

This proposed rule is excluded from the scope of Executive Order 12372, Intergovernmental Consultation. A Notice of Final Rule entitled Department Programs and Activities Excluded from Executive Order 12372 (50 FR 47034) exempts REA and RTB loans and loan guarantees to governmental and nongovernmental entities from coverage under this Order.

##### Background

On December 20, 1993, REA published an interim rule (58 FR 66250) to incorporate changes to telephone loan policies required by the Rural Electrification Loan Restructuring Act of 1993 (RELRA) (107 Stat. 1356). RELRA amended several provisions of the Rural Electrification Act of 1936, as amended (7 U.S.C. 901 *et seq.*) (RE Act), and mandated a restructuring of the telephone loan program.

On April 13, 1994, REA adopted its interim rule as a final rule (59 FR 17460) with one exception, 7 CFR part 1751, Telecommunications System Planning and Design Criteria, and Procedures. Because of the overwhelming response and concerns regarding the requirements of the State Telecommunications Modernization Plan (Modernization Plan), REA is proposing to amend 7 CFR part 1751, subpart B.

As revised, this Rule would require that Modernization Plans, at a minimum, apply to all REA borrowers. If a Modernization Plan is developed by the PUC or the State Legislature, REA encourages, but does not require, that the Modernization Plan's requirements apply to the rural service areas of all Telecommunications Providers. A State's decision not to include non-REA borrowers will not prejudice REA approval of their Plan. The PUC or the State Legislature may also, at its option, extend coverage of the Modernization

Plan to all service areas of all Telecommunications Providers in the State. In addition, while requirements contained in § 1751.106 apply only to wireline services, the State Legislature or PUC, at its discretion, may extend coverage of Modernization Plans to wireless or other communications services in a State as it deems appropriate.

It is REA's policy that every State have a Modernization Plan which provides for the improvement of the State's Public Switched Network. If the Plan Developer is either the State Legislature or the PUC, such entity must submit for REA approval its Modernization Plan by a date one year from issuance of the Final Rule. After this date, if a State or its PUC declines or fails to submit for REA approval its Modernization Plan, eligibility to develop the Plan passes to a numeric majority of the Borrowers within the State. While there is no time limit requiring States to have an approved plan in place, REA, as required by RELRA, will not approve any direct loans in States without such a plan.

During the comment period, REA received 81 comments regarding the interim rule, and these comments were taken into consideration in preparing the proposed amendments. Comments were received from the following:

- (1) Alaska Public Utilities Commission.
- (2) Arkansas Public Service Commission.
- (3) California Public Utilities Commission.
- (4) Joint comments from the Colorado Office of Consumer Counsel, Texas Office of Public Utility Counsel, Iowa Office of Consumer Advocate, and D.C. Office of the People's Counsel.
- (5) Colorado Public Utilities Commission Staff.
- (6) Florida Public Service Commission.
- (7) Idaho Public Utilities Commission.
- (8) Illinois Commerce Commission.
- (9) Indiana Utility Regulatory Commission.
- (10) Iowa Utilities Board.
- (11) Michigan Public Service Commission Staff.
- (12) Minnesota Public Utilities Commission.
- (13) Missouri Public Service Commission.
- (14) Nebraska Public Service Commission.
- (15) New England Conference of Public Utilities Commissioners, Inc.
- (16) New Hampshire Office of the Consumer Advocate.
- (17) New York State Department of Public Service.

- (18) North Carolina Public Staff Utilities Commission.
- (19) North Dakota Public Service Commission.
- (20) Pennsylvania Office of Consumer Advocate.
- (21) Pennsylvania Public Utility Commission.
- (22) Tennessee Public Service Commission.
- (23) Texas Public Utility Commission.
- (24) Utah Department of Commerce Division of Public Utilities.
- (25) Virginia State Corporation Commission.
- (26) Wisconsin Public Service Commission.
- (27) ALLTEL Service Corporation.
- (28) Century Telephone Enterprises, Inc.
- (29) Golden West Telecommunications Cooperative, Inc.
- (30) Great Plains Communications, Inc.
- (31) GTE Service Corporation.
- (32) Hiawatha Telephone Company.
- (33) Hills Telephone Company, Inc.
- (34) Interstate Telecommunications Cooperative, Inc.
- (35) James Valley Cooperative Telephone Company.
- (36) Kingdom Telephone Company.
- (37) Mark Twain Rural Telephone Company Group.
- (38) Martin and Associates, Inc., submitted comments on behalf of 16 local exchange carriers located in South Dakota.
- (39) Matanuska Telephone Association, Inc.
- (40) MEBTEL Communications.
- (41) Pacific Telecom, Inc.
- (42) Project Mutual Telephone Company.
- (43) Rochester Telephone Corporation.
- (44) Sioux Valley Telephone Company.
- (45) Steelville Telephone Exchange, Inc.
- (46) TDS Telecom.
- (47) United and Central Telephone Companies.
- (48) Young, Van Assenderp, Varnadoe & Pennon, P.A., submitted comments on behalf of 7 REA Telephone Borrowers located in Florida and Alabama.
- (49) Association of Communications Engineers.
- (50) Eastern REA Borrowers Association.
- (51) Idaho Telephone Association.
- (52) Illinois Independent Telephone Association.
- (53) Illinois Telephone Association.
- (54) Iowa Telephone Association.
- (55) Missouri Telephone Association.
- (56) Montana Telephone Association.
- (57) Joint comments from the National Rural Telecom Association, and the Western Rural Telephone Association.

- (58) Nebraska Telephone Association
- (59) New York State Telephone Association, Inc.
- (60) North Dakota Association of Telephone Cooperatives.
- (61) National Telephone Cooperative Association.
- (62) Joint comments from the Oklahoma Rural Telephone Coalition, Rural Arkansas Telephone Systems, and Texas Statewide Telephone Cooperative, Inc.
- (63) Organization for the Protection and Advancement of Small Telephone Companies.
- (64) Oregon Independent Telephone Association.
- (65) Pennsylvania Telephone Association.
- (66) Telecommunications Industry Association.
- (67) Texas Telephone Association.
- (68) United States Telephone Association.
- (69) Washington Independent Telephone Association.
- (70) Ameritech Operating Companies.
- (71) Bell Atlantic Telephone Companies.
- (72) BellSouth Telecommunications, Inc.
- (73) NYNEX (New York Telephone Company and New England Telephone and Telegraph Company).
- (74) Pacific Bell and Nevada Bell.
- (75) Southwestern Bell Corporation.
- (76) U.S. West Communications, Inc.
- (77) MCI Telecommunications Corporation.
- (78) Central Associated Engineers, Inc.
- (79) Fred Williamson & Associates, Inc.
- (80) Hastad Engineering Company.
- (81) Hicks & Ragland Engineering Co., Inc.

1. *Comment Summary:* REA should not specify specific technologies.

*Response:* This was a nearly unanimous comment and one with which REA concurs. REA's intent is to specify information carrying capability, i.e., bit rate. References to specific technologies, like ISDN, have been removed.

2. Many commenters asserted that REA exceeded its statutory authority in one or more of the following ways:

a. *Comment Summary:* Congress intended State Telecommunications Modernization Plans to be guidelines.

*Response:* Many commenters believe that the use of the word "objectives" in RELRA implies non-binding guidelines. REA believes the commenters are taking the word out of context. The entire provision is as follows:

"REQUIREMENTS.—For purposes of subparagraph (A), a telecommunications

modernization plan must, at a minimum, meet the following objectives."

REA believes that an objective that must be met is mandatory. In the interim regulation (7 CFR part 1751, published December 20, 1993), REA set forth both "requirements" and "objectives" to be contained in the Modernization Plan. Requirements were to be binding while objectives were only goals or targets. This may have led to confusion because both words are used in RELRA. In the proposed rule, REA has included only requirements.

*b. Comment Summary:* REA went beyond the intent of RELRA by establishing timeframes for modernization.

*Response:* REA set timeframes because a requirement with no due date is not a requirement.

REA believes that advanced telecommunications services should be available to the public within a reasonable time after they are developed. Broad experience in bringing modern telephone service to rural America teaches the value of caution and reflection before imposing binding requirements on future business activities. Varying construction schedules, economic conditions and rates of technological innovation affect even the most careful projections. REA conservatively projected the reasonably expected growth of both the public's need for telecommunications services and the ability of Telecommunications Providers and equipment manufacturers to provide those services.

REA consulted both its past experience and its expectations of future technological development before setting the short-, medium- and long-term deadlines in the regulation. Our experience with new technology such as buried cable, digital switching, and fiber optic systems where the widespread deployment into the telecommunications network took two to five years, lead us to adopt the five year phase-in concept. The timetable is achievable, given the telecommunications services presently available, the resources of the Telecommunications Providers, and the accelerating engineering achievements likely in the next few years.

The regulations phase in the requirements in three steps to provide for an orderly deployment of these telecommunications services. Facilities constructed more than one year after REA approves a Modernization Plan are required to provide those services that can be produced by equipment now in existence. The one year delay allows for construction-in-progress to be

completed before the Modernization Plan requirements go into effect. The requirements for the medium and long terms simply expand the coverage of the requirements so that when the long term period (11-16 years) is reached, all subscribers will have the services deployed during the short term period available to them.

*c. Comment Summary:* RELRA does not require that telecommunications improvements be deployed "concurrently" in rural and nonrural areas but only that "the plan must provide for uniform deployment schedules to ensure that advanced services are deployed at the same time in rural and nonrural areas".

*Response:* Several commenters thought that REA intended all improvements to be made simultaneously throughout a service area. REA understands that there is a logical order to providing improvements and that they will often happen first in nonrural areas. REA intends that they should be deployed and available at approximately the same time in rural and nonrural areas. For example, if digital switching technology is being deployed in a nonrural area, replacement switches in rural areas would also employ digital technology. This does not mean that if a switch was replaced in a nonrural area, a switch would have to be replaced in the rural area. In the proposed rule, REA has clarified this requirement. See § 1751.106(a).

*d. Comment Summary:* REA has no basis for requiring either the elimination of mileage and/or zone charges or that Telecommunications Providers adopt flexible tariffs. These issues concern rates and are not "service standards".

*Response:* The stated requirement in RELRA is the elimination of party line service. REA's experience has been that imposing zone and mileage charges on one-party service creates a large disincentive for subscribers to choose this service. However, REA will not require the Modernization Plan contain a provision to eliminate zone and mileage charges.

RELRA provides that the Modernization Plan "must provide for the availability of telecommunications services for improved business, educational, and medical services." Rigid rate structures have served as the primary impediment to the provision of distance learning and medical link services. REA has seen cases where states have set wideband rates in direct proportion to the voiceband rate resulting in, for example, rates for schools far beyond what they can afford.

REA has clarified its intent on this subject in § 1751.106(e).

*e. Comment Summary:* It is not always practical to build only non-loaded twisted pair plant.

*Response:* REA concurs and has given the Plan Developer some discretion in this matter. Section 1751.106(g)(2)(ii) has been revised to allow a Telecommunications Provider to request additional time from the Plan Developer in the case of a PUC or State Legislature developed plan, or from the REA in the case of a REA Borrower developed plan. The Plan Developer or REA, as the case may be, must consider each request separately and can grant additional time only if either the best available telecommunications technology lacks the capability to enable the Telecommunications Provider to comply with the non-loaded requirement or complying with the requirement would impose prohibitive cost on the Telecommunications Provider.

*f. Comment Summary:* Nothing in the law suggests the need for 150 Mb/sec transmission rate for video. Many compression technologies are available which allow video to be transmitted over ordinary telephone lines.

*Response:* In the interim rule, all references to provision of 150 Mb/sec service were non-binding "objectives", see paragraph 2a. REA focused on the requirement in RELRA that telephone lines be capable of carrying at least 1,000,000 bits per second. REA adjusted this to the standard North American rate of 1.544 Mb/sec. Such a rate allows for both the transmission of at least 1 million bits per second and for the transmission of modest quality, highly compressed video. A higher rate is not required by the proposed rule.

*3. Comment Summary:* Many radio based services such as cellular and BETRS will be unable to meet REA bandwidth requirements.

*Response:* REA interprets the Modernization Plan requirements of RELRA to apply to service provided by telephone lines, i.e., "Wireline Service", the basic service most Americans receive. This interpretation has been clarified in the proposed rule.

*4. Comment Summary:* REA has not defined "Public Switched Network" or "Telecommunications Providers".

*Response:* REA has defined these terms in the proposed regulation.

*5. Comment Summary:* The interim rule violates section 202 of the RE Act which states that nothing in the RE Act shall be construed to deprive any State commission of jurisdiction to regulate telephone service, including the rates for such service.

*Response:* REA believes there is no conflict between RELRA and section 202 of the RE Act. The PUC is neither required to develop a Modernization Plan nor to approve REA loans that are consistent with a Modernization Plan whoever is the Plan Developer. Therefore the PUC's jurisdiction to regulate telephone service is not impaired. No change has been made to the regulation based on this comment.

6. *Comment Summary:* REA has not considered how the proposed services can be offered at affordable rates. The regulation could result in an REA Borrower-developed Modernization Plan which requires investments that a PUC would not approve.

*Response:* The requirements included in the proposed regulation apply almost entirely to new construction. New construction has to be economically justified to receive either REA financing or PUC approval for inclusion in the rate base. REA believes strongly in universal service and would not issue a regulation which it believed to be an impediment to that goal. No change has been made to the regulation based on these comments.

7. *Comment Summary:* REA should include a requirement that other interested parties be notified of intent to develop a Modernization Plan.

*Response:* REA concurs with this comment and has changed the wording on notification to include other interested parties. See § 1751.102 (b) and (c)(2).

8. *Comment Summary:* A Modernization Plan should cover only REA Borrowers or should cover all Telecommunications Providers only if developed by the PUC or a State Legislature.

*Response:* As redrafted, the Modernization Plan must apply only to REA Borrowers unless a PUC or a State Legislature decides, at its option, to apply the Modernization Plan to non-REA Borrower Telecommunications Providers. The REA does, however, encourage the PUCs and State Legislatures to apply the Modernization Plans to all Telecommunications Providers in the State.

9. *Comment Summary:* REA requires integration of PCS when it doesn't exist.

*Response:* REA intended that a Modernization Plan should encourage integration of new technologies into the network. REA has substituted "emerging technologies" for PCS and clarified its intent. See § 1751.106(d).

10. *Comment Summary:* Modernization Plans should be based on market principles.

*Response:* The modern telecommunications system envisioned

by RELRA and the Modernization Plan requirements can succeed only if it is supported by market demand. REA's electric and telecommunications programs have repeatedly demonstrated how quickly rural America takes advantage of new utility services. RELRA and the Modernization Plans lead the way for today's nonrural and rural subscribers to receive the modern telecommunications services they want and need. REA believes that the Modernization Plan requirements of this regulation rest on a sound economic basis. True to its statutory mandate, REA will finance projects only if it believes there is adequate security and the loan will be repaid within the time agreed.

11. *Comment Summary:* It is untimely for REA to develop a rule when other laws concerning telecommunications have been introduced in Congress. It is inappropriate for REA to develop rules for telecommunications. That should be the responsibility of the FCC.

*Response:* REA, as the agency responsible for promoting rural telecommunications, has long experience in setting the engineering and technical standards for service in rural areas and is ideally suited for the responsibility it was given by Congress. REA is working to ensure that Modernization Plan requirements and the Proposed Rule governing their preparation are flexible enough to accommodate evolving national policies promoting the National Information Infrastructure.

REA will revise, within our statutory constraints, these regulations and approve amendments to Modernization Plans if the National Information Infrastructure develops along lines not presently envisioned. However, the legislative imperative of RELRA and rural America's urgent need for modern telecommunications services require that the regulations not be delayed.

12. *Comment Summary:* The rule is not clear on Plan Developer eligibility as related to time. The law says the one year period starts after publication of the final rule. Can Borrowers submit a Modernization Plan before the end of the year if the PUC or State Legislature does not intend to? What if a PUC or State Legislature submits a Modernization Plan on the last day? Won't loans be delayed if a PUC or State Legislature does not develop a plan and an REA Borrower-developed one has not been approved?

*Response:* RELRA sets forth the method of determining Plan Developer eligibility. With regard to the specific points mentioned above:

a. The one year period starts with publication of the final rule developed in response to comments on this proposed rule.

b. Modernization Plans developed by REA Borrowers will not be accepted until a PUC's and State Legislature's eligibility has expired, unless the PUC and State Legislature officially reject eligibility.

c. A Modernization Plan submitted on the last day will be approved by REA if it meets the minimum requirements without alteration. The proposed rule includes language which recommends that to ensure a PUC or a State Legislature has sufficient time to respond to any REA comments on its proposed Modernization Plan, the PUC or State Legislature should submit its plan at least 90 days in advance of the expiration of its eligibility. See § 1751.104(b)(2).

d. Loans will not be made between the end of a PUC's and State Legislature's eligibility and the approval of a Borrower-developed Modernization Plan.

13. *Comment Summary:* The regulation should allow for waivers to a Modernization Plan.

*Response:* REA has changed the regulation to allow the Modernization Plan developer the authority to grant time extensions necessitated by the state of technology as long as the extensions are granted on a case-by-case basis, do not exceed five years, and the circumstances for which extensions are granted are spelled out in the Modernization Plan. See § 1751.106(b).

14. *Comment Summary:* What is a generic design for Broadband service? How can this be done without local power?

*Response:* REA believes that the lack of consensus on how to bring wider band switched service to the home and small business, particularly in rural areas, means that Telecommunications Providers continue to build and rebuild their systems essentially for traditional voiceband service. In many cases this plant can not be adapted to wider band services.

In the interim rule (dated December 20, 1993) REA had required a "generic design" for broadband service. Since REA is no longer including non-binding goals in the proposed regulation, the requirement for a generic design has been changed to a requirement for the developer to provide a strategic development proposal which provides the Plan Developer's vision of a State telecommunications structure for the future.

With regard to local power, REA retains a concern over system reliability.

The proposed rule requires that no matter what level of service is being offered, sufficient system power must be available to provide voice service during electric utility outages. See § 1751.106(h)(2)(ii) and (i)(2)(iv).

**General Summary:** It is REA's belief that national telecommunications "highways" will not and cannot be fully utilized unless improvements are made to what might be called the telecommunications "driveways", the local loops. Most loops cannot transmit information over 9600 bits per second (b/s). Consequently, many advanced telecommunications services are not available on the Public Switched Network or, where available, operate only on short loops. This limits use of these advanced services to densely populated areas.

RELRA requires that telephone lines be capable of transmitting: (1) Information at no less than 1,000,000 bits per second (1Mb/s) and (2) video images. REA believes both requirements can be satisfied by telephone lines which can transmit and receive 1.544 Mb/s, the North American standard digital transmission rate. This rate is sufficient to carry both 1 million bits per second and highly compressed, modest quality video.

To carry 1.544 Mb/sec, the capacity of ordinary telephone loops must be increased by several orders of magnitude. The other requirements in the law are more easily met. Therefore, improving the loop has been REA's focus in preparing minimum Modernization Plan requirements.

REA believes that the requirements and time limits set forth in this section will achieve the service standards of RELRA.

However, REA is concerned about coordination between States. REA recommends that Modernization Plan Developers should work with Plan Developers in other States both before and after their Modernization Plans are approved to coordinate proposed improvements.

REA recommends that Modernization Plan Developers give consideration to planning for outside plant which can ultimately provide future broadband Wireline Service with a bandwidth equivalent to a digital rate on the order of 150 Mb/sec. Such facilities could carry one or more channels of conventional video with the quality depending on the modulation technique.

#### List of Subjects in 7 CFR Part 1751

Loan programs—communications, Telecommunications, Telephone.

For reasons set forth in the preamble, chapter XVII of Title 7 of the Code of Federal Regulations is proposed to be amended by revising part 1751 to read as follows:

### PART 1751—TELECOMMUNICATIONS SYSTEM PLANNING AND DESIGN CRITERIA, AND PROCEDURES

#### Subpart A—[Reserved]

Sec.  
1751.1–1751.99 [Reserved]

#### Subpart B—State Telecommunications Modernization Plan

- 1751.100 Definitions.  
1751.101 General.  
1751.102 Modernization Plan developer—eligibility.  
1751.103 Loan requirements.  
1751.104 Obtaining REA approval of a proposed Modernization Plan.  
1751.105 Amending a Modernization Plan—  
1751.106 Modernization Plan—requirements.

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

#### Subpart A—[Reserved]

§§ 1751.1–1751.99 [Reserved]

#### Subpart B—State Telecommunications Modernization Plan

##### § 1751.100 Definitions.

As used in this subpart:

**Bit rate.** The rate of transmission of telecommunications signals or intelligence in binary (two state) form in bits per unit time, e.g., Mb/s (megabits per second), kb/s (kilobits per second), etc.

**Borrower.** Any organization which has an outstanding telephone loan made by REA or the Rural Telephone Bank, or guaranteed by REA, or which has a completed loan application with REA.

**Emerging technologies.** New or not fully developed methods of telecommunications.

**Hardship loan.** A loan made by REA under section 305(d)(1) of the RE Act bearing interest at a rate of 5 percent per year.

**Local power.** Electrical source, provided by someone other than the telecommunications utility, used for powering a subscriber's station equipment.

**Loop.** A dedicated facility which connects the customer's station to the Public Switched Network. The loop may consist of twisted pair copper wire, coaxial cable, fiber optic cable, radio, or a combination of these. It may also include dedicated electronic or lightwave transmission equipment.

**Modernization Plan (State Telecommunications Modernization Plan).** A plan, which has been approved

by REA, for improving the Public Switched Network of a State. The Modernization Plan must conform to the provisions of this subpart.

**Plan Developer.** The PUC, State Legislature, or a numeric majority of the REA borrowers within the State that have the responsibility for creating the Modernization Plan.

**Public Switched Network.** The network intended for public use furnished by Telecommunications Providers on a switched basis.

**PUC (Public Utilities Commission).** The public utilities commission, public service commission or other State body with such jurisdiction over rates, service areas or other aspects of the services and operation of providers of telecommunications services as vested in the commission or other body authority, to the extent provided by the State, to guide development of telecommunications services in the State.

**RE Act.** The Rural Electrification Act of 1936, as amended (7 U.S.C. 901 *et seq.*).

**REA cost-of-money loan.** A loan made under section 305(d)(2) of the RE Act bearing an interest rate as determined under 7 CFR 1735.31(c). REA cost-of-money loans are made concurrently with RTB loans.

**RTB loan.** A loan made by the Rural Telephone Bank (RTB) under section 408 of the RE Act bearing an interest rate as determined under 7 CFR 1610.10. RTB loans are made concurrently with REA cost-of-money loans.

**State.** Each of the 50 states of the United States, the District of Columbia, and the territories and insular possessions of the United States. This does not include countries in the Compact of Free Association.

**Telecommunications.** The transmission or reception of voice, data, sounds, signals, pictures, writings, or signs of all kinds, by wire, fiber, radio, light, or other visual or electromagnetic means.

**Telecommunications Providers.** Local exchange carriers, competitive access providers, and interexchange carriers which provide telecommunications service in the State covered by the Modernization Plan and such other entities providing telecommunications services as the developer of the Modernization Plan (See § 1751.102) may determine.

**Wireline Service.** Telecommunications service provided over telephone lines. It is characterized by a wire or wirelike connection carrying electricity or light between the subscriber and the Public Switched

Network. Wireline Service implies a physical connection. Although radio may form part of the circuit, it is not the major method of transmission as in radiotelephone.

**§ 1751.101 General.**

(a) It is the policy of REA that every State have a Modernization Plan which provides for the improvement of the State's Public Switched Network.

(b) A proposed Modernization Plan must be submitted to REA for approval. REA will approve the proposed Modernization Plan if it conforms to the provisions of this subpart. Once obtained, REA's approval of a Modernization Plan cannot be rescinded.

(c) The Modernization Plan shall not interfere with REA's authority to issue such other telecommunications standards, specifications, requirements, and procurement rules as may be promulgated from time to time by REA including, without limitation, those set forth in 7 CFR part 1755.

(d) The Modernization Plan must, at a minimum, apply to all REA borrowers. If a Modernization Plan is developed by the PUC or the State Legislature, REA encourages, but does not require, that the Modernization Plan's requirements apply to the rural service areas of all Telecommunications Providers. A State's decision not to include non-REA borrowers will not prejudice REA approval of their Plan. The PUC or the State Legislature may also, at its option, extend coverage of the Modernization Plan to all service areas of all Telecommunications Providers in the State. In addition, while requirements contained in § 1751.106 apply only to wireline services, the State Legislature or PUC, at its discretion, may extend coverage of Modernization Plans to wireless or other communications services in a State as it deems appropriate.

**§ 1751.102 Modernization Plan developer—eligibility.**

(a) Each State, either by statute or through its Public Utility Commission, is eligible until one year after publication of the final rule in the **Federal Register** to develop a proposed Modernization Plan and deliver it to REA. REA will review and consider for approval all PUC or State Legislature-developed Modernization Plans received by REA within this one year period. The review and approval, if any, may occur after the one year period ends even though the PUC or State Legislature is no longer eligible to submit a proposed Modernization Plan.

(b) The PUC must notify all Telecommunications Providers in the State that are part of the Public Switched Network and other interested parties of its intent to develop a proposed Modernization Plan. The PUC is encouraged to consider all such Providers' and interested parties' views and incorporate these views in the Modernization Plan.

(c) If the State Legislature or PUC is no longer eligible to develop a Modernization Plan, as described in paragraph (a) of this section, eligibility to develop the Modernization Plan passes to a numeric majority of the Borrowers within the State. In this case, the following apply:

(1) All Borrowers shall be given reasonable notice of and shall be encouraged to attend and contribute to all meetings and other proceedings relating to the development of the Modernization Plan; and

(2) Borrowers developing a Modernization Plan are encouraged to solicit the views of other Telecommunications Providers and interested parties in the State.

(3) There is no time limit placed on the REA Borrowers to develop a Modernization Plan, however, REA, as required by the Rural Electrification Loan Restructuring Act of 1993 (107 Stat. 1356), will not approve any direct loans in States that do not have an approved Modernization Plan. See § 1751.103 of this subpart.

**§ 1751.103 Loan requirements.**

For information about loan eligibility requirements in relation to the Modernization Plan, see 7 CFR part 1735. In particular, one year after publication of the final rule, REA will make hardship loans, REA cost-of-money loans, and RTB loans for facilities and other RE Act purposes for Telephone Borrowers in a State only if:

(a) The State has an REA approved Modernization Plan; and

(b) The Borrower is participating in the Modernization Plan for the State. A Borrower is considered to be participating if, in REA's opinion, the purposes of the loan requested by the Borrower are consistent with the Borrower achieving the requirements stated in the Modernization Plan within the timeframe stated in the Modernization Plan unless REA has determined that achieving the requirements is not technically or economically feasible.

**§ 1751.104 Obtaining REA approval of a proposed Modernization Plan.**

(a) To obtain REA approval of a proposed Modernization Plan, the Plan

Developer must submit the following to REA:

(1) A certified copy of the statute or PUC order, if the State is the Plan Developer, or a written request for REA approval of the proposed Modernization Plan signed by an authorized representative of the Plan Developer, if a majority of Borrowers is the Plan Developer; and

(2) Three copies of the proposed Modernization Plan.

(b) Generally, REA will review the proposed Modernization Plan within (30) days and either:

(1) Approve the Modernization Plan if it conforms to the provisions of this subpart in which case REA will return a copy of the Modernization Plan with notice of approval to the Plan Developer; or,

(2) Not approve the proposed Modernization Plan if it does not conform to the provisions of this subpart. In this event, REA will return the proposed Modernization Plan to the Plan Developer with specific written comments and suggestions for modifying the proposed Modernization Plan so that it will conform to the provisions of this subpart. If the Plan Developer remains eligible, REA will invite the Plan Developer to submit a modified proposed Modernization Plan for REA consideration. This process can continue until the Plan Developer gains approval of a proposed Modernization Plan unless the Plan Developer is a PUC or State Legislature whose eligibility has expired. If the PUC's or State Legislature's eligibility has expired, REA will return the proposed Modernization Plan unapproved. Because REA does not have authority to extend a PUC's or State Legislature's eligibility, REA recommends that a PUC or State Legislature submit a proposed Modernization Plan at least 90 days in advance of one year after publication of the final rule to allow time for this process.

**§ 1751.105 Amending a Modernization Plan.**

(a) REA understands that changes in standards, technology, regulation, and the economy could indicate that an REA-approved Modernization Plan should be amended.

(b) The Plan Developer of the Modernization Plan may amend the Modernization Plan if REA finds the proposed changes continue to conform to the provisions of this subpart.

(c) The procedure for requesting approval of an amended Modernization Plan is identical to the procedure for a proposed Modernization Plan except

that there are no time limits on the eligibility of the Plan Developer.

(d) The existing Modernization Plan remains in force until REA has approved the proposed amended Modernization Plan.

(e) REA may from time to time revise these regulations to incorporate newer technological and economic standards that REA believes represent more desirable goals for the future course of telecommunications services. Such revisions will be made in accordance with the Administrative Procedure Act. These revisions shall not invalidate Modernization Plans approved by REA but shall be used by REA to determine whether to approve amendments to Modernization Plans presented for REA approval after the effective date of the revision.

**§ 1751.106 Modernization Plan—requirements.**

(a) A Modernization Plan must set service requirements for improving the Public Switched Network and must at a minimum meet the following requirements:

(1) The Modernization Plan must provide for the elimination of party line service.

(2) The Modernization Plan must provide for the availability of telecommunications services for improved business, educational, and medical services.

(3) The Modernization Plan must encourage and improve computer networks and information highways for subscribers in rural areas.

(4) The Modernization Plan must provide for:

(i) Subscribers in rural areas to be able to receive through telephone lines:

- (A) Conference calling;
- (B) Video images; and
- (C) Data at a rate of at least 1,000,000 bits of information per second; and

(ii) The proper routing of information to subscribers.

(5) The Modernization Plan must provide for uniform deployment schedules to ensure that advanced services are deployed at the same time in rural and nonrural areas.

(b) In addition to the requirements set forth in paragraph (a) of this section, minimum requirements are described in paragraphs (g) through (i) of this section and are grouped by timeframe, i.e., short-term, medium-term, and long-term. The Modernization Plan shall provide that such requirements be implemented as set forth in this section of the regulation except that the Modernization Plan may authorize the Plan Developer to approve extensions if the required investment is not

economically reasonable or if the best available telecommunications technology lacks the capability to enable the Telecommunications Provider receiving the extension to comply with the Modernization Plan. Extensions shall be granted only on a case-by-case basis and shall not exceed a total of five years from the first extension except under unusual circumstances.

(c) Each State's Modernization Plan shall include a strategic development proposal for rebuilding the Public Switched Network within the State. The strategic development proposal shall provide all Telecommunications Providers in the State the Plan Developer's vision of a State telecommunications structure for the future. Within the scope of paragraph (d) of § 1751.101 of this subpart, the Modernization Plan shall state whether all Telecommunications Providers in the State are required to construct their systems in a manner consistent with the strategic development proposal.

(d) The Modernization Plan must require that the design of the Public Switched Network allow for the expeditious deployment and integration of such emerging technologies as may from time to time become commercially feasible.

(e) The Modernization Plan must provide guidelines to Telecommunications Providers for the development of affordable tariffs for medical links and distance learning services.

(f) With regard to the uniform deployment requirement set forth in paragraph (a)(5) of this section, if services cannot be deployed at the same time, only the minimum feasible interval of time shall separate availability of the services in rural and nonrural areas.

(g) *Short-term requirements.* (1) The "short-term requirements start date" is the date one year after the date REA approves the Modernization Plan for the State.

(2) All facilities providing Wireline Service wholly or partially constructed or reconstructed after the short-term requirements start date, even if the construction began before such date, shall be constructed so that:

(i) Every subscriber can be provided 1-party service. Existing party line subscribers would be allowed to maintain party line service only if they requested it and approval is granted by the PUC.

(ii) Twisted-pair copper plant is non-loaded, unless the PUC, in the case of a PUC or State Legislature-developed Modernization Plan, or the REA, in the case of a REA Borrower-developed

Modernization Plan, determines, on a case-by-case basis, after written request from a Telecommunications Provider, that the Telecommunications Provider should be granted additional time because either the best available telecommunications technology lacks the capability to enable the Telecommunications Provider to comply with this requirement or complying with this requirement would impose prohibitive cost on the Telecommunications Provider.

(3) All switching equipment installed by a Telecommunications Provider after the short-term requirements start date shall contain the hardware, but not necessarily the software, to be capable of:

- (i) Switching 1.544 Mb/sec. traffic.
- (ii) Providing custom calling features. At a minimum, custom calling features must include call waiting, call forwarding, abbreviated dialing, and three-way calling.

(iii) Providing E911 service when required by any local government for areas served by the Telecommunications Provider.

(h) *Medium-term requirements.* (1) The "medium-term requirements start date" is the date six years after the date REA approves the Modernization Plan for the State, or such earlier date as the Modernization Plan shall provide.

(2) All facilities providing Wireline Service wholly or partially constructed or reconstructed after the medium-term requirements start date, even if the construction began before such date, shall be constructed so that:

(i) Switched 1.544 Mb/sec service is available to any subscriber. Available means the service will be provided on demand after a reasonable waiting period.

(ii) The system does not rely exclusively on local power at the subscriber end. There must be sufficient system power to operate subscriber voice service during electric utility power outages.

(3) No later than the medium-term start date, all switching equipment must be provisioned with the necessary hardware to be capable of providing E911 service when required by any local government for areas served by the Telecommunications Provider.

(i) *Long-term requirements.* (1) The "long-term requirements start date" is the date eleven years after the date REA approves the Modernization Plan for the State, or such earlier date as the Modernization Plan shall provide.

(2) After the long-term requirements start date, the following requirements shall apply to all Wireline Service

provided by Telecommunications Providers:

- (i) Telecommunications Providers shall eliminate party line service.
- (ii) Telephone service shall be available to any subscriber at 1.544 Mb/sec. Available means the service will be provided on demand after a reasonable waiting period.
- (iii) No service lower than one digital voice circuit (56-64 kb/sec) shall be offered as a new service.
- (iv) The system must not rely exclusively on local power at the subscriber end. There must be sufficient system power to operate subscriber voice service during electric utility power outages.

Dated: October 24, 1994.

**Bob J. Nash,**

*Under Secretary, Small Community and Rural Development.*

[FR Doc. 94-26761 Filed 10-26-94; 8:45 am]

BILLING CODE 3410-15-P

## DEPARTMENT OF JUSTICE

### 8 CFR Part 3

[AG Order No. 1928-94]

#### Executive Office for Immigration Review; Citizenship Requirement for Employment

AGENCY: Department of Justice.

ACTION: Proposed rule.

**SUMMARY:** This proposed rule requires that employees hired by the Executive Office for Immigration Review (EOIR or Agency) be citizens of the United States of America. This rule exempts EOIR from the Immigration Reform and Control Act of 1986's general prohibition of discrimination based on citizenship status and supplements Executive Order 11935 which requires United States citizenship for almost all Federal employees in the competitive service.

**DATES:** Written comments must be received on or before November 28, 1994.

**ADDRESSES:** Please submit written comments in triplicate to Gerald S. Hurwitz, Counsel to the Director, Executive Office for Immigration Review, Suite 2400, 5107 Leesburg Pike, Falls Church, Virginia 22041.

**FOR FURTHER INFORMATION CONTACT:** Gerald S. Hurwitz, Counsel to the Director, Executive Office for Immigration Review, Suite 2400, 5107 Leesburg Pike, Falls Church, Virginia 22041, Telephone: (703) 305-0470.

**SUPPLEMENTARY INFORMATION:** This proposed rule authorizes EOIR to

require its employees and volunteers to be citizens of the United States of America. Because the central task of this Agency is adjudicating immigration-related cases, Agency employees and volunteers often have access to sensitive information and handle complex and sensitive immigration issues. It is imperative that individuals who work at EOIR, either as employees or volunteers, demonstrate their allegiance to the United States by being able to document that they are United States citizens. Pursuant to E.O. 11935, 41 FR 37301 (1976), the Executive Branch requires United States citizenship for employees hired in the competitive service. This proposed rule extends the citizenship requirement to all EOIR employees and volunteers. The rule exempts EOIR from the prohibition of discrimination based on citizenship status, pursuant to the procedures established by the Immigration Reform and Control Act of 1986, 8 U.S.C. 1324b(a)(2)(C).

Additionally, this proposed rule allows the Agency to exercise its discretion to hire non-citizens when necessary to accomplish the Agency's mission. For example, this rule would permit the Director of the Agency to authorize hiring an interpreter skilled in the English language and an unusual foreign language when a United States citizen interpreter is not available.

Insertion of this rule requires a slight reorganization of 8 CFR part 3.

This rule does not have a significant adverse economic impact on a substantial number of small entities. 5 U.S.C. 605(b).

This rule has been drafted and reviewed in accordance with E.O. 12866 section 1(b), Principles of Regulation. The Attorney General has determined that this rule is not a "significant regulatory action" under E.O. 12866, section 3(f), Regulatory Planning and Review, and accordingly this rule has not been reviewed by the Office of Management and Budget.

This rule will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, in accordance with E.O. 12612, it is determined that this rule does not have sufficient federalism implication to warrant the preparation of a Federalism Assessment.

#### List of Subjects in 8 CFR Part 3

Administrative practice and procedure, Immigration, Organization and functions (Government agencies).

## PART 3—EXECUTIVE OFFICE FOR IMMIGRATION REVIEW

1. The authority citation for part 3 of title 8 is revised to read as follows:

**Authority:** 5 U.S.C. 301; 8 U.S.C. 1103, 1252 note, 1252b, 1324b, 1362; 28 U.S.C. 509, 510, 1746; sec. 2, Reorg. Plan No. 2 of 1950, 3 CFR 1949-1953 Comp., p. 1002.

2. Section 3.0 is amended by designating the existing text as paragraph (a) and adding a heading and by adding a new paragraph (b) to read as follows:

### § 3.0 Executive Office for Immigration Review.

(a) *Organization.* \* \* \*

(b) *Citizenship Requirement for Employment.* (1) An application to work at the Executive Office for Immigration Review (EOIR or Agency), either as an employee or as a volunteer, must include a signed affirmation from the applicant that he or she is a citizen of the United States of America. Upon the Agency's request, the applicant must document United States citizenship.

(2) The Director of EOIR may, by explicit written determination and to the extent permitted by law, authorize the appointment of an alien to an Agency position when necessary to accomplish the work of EOIR.

Dated: October 18, 1994.

**Janet Reno,**

*Attorney General.*

[FR Doc. 94-26630 Filed 10-26-94; 8:45 am]

BILLING CODE 4410-01-M

## FEDERAL ELECTION COMMISSION

### 11 CFR Part 1

[Notice 1994-15]

#### Privacy Act; Implementation

AGENCY: Federal Election Commission.

ACTION: Proposed rule with request for comments.

**SUMMARY:** The Federal Election Commission ("Commission" or "FEC") is establishing a new system of records under the Privacy Act of 1974, "Inspector General Investigative Files (FEC 12)", to consist of the investigatory files of the Commission's Office of the Inspector General ("OIG"). The Commission proposes to exempt this new system of records from certain provisions of the Privacy Act of 1974 ("Act").

**DATES:** Comments must be received on or before November 28, 1994.

**ADDRESSES:** Comments must be in writing and addressed to: Ms. Susan E.

Propper, Assistant General Counsel, 999 E Street, NW., Washington, DC 20463.

**FOR FURTHER INFORMATION CONTACT:**

Ms. Susan E. Propper, Assistant General Counsel, 999 E Street, NW., Washington, DC 20463, (202) 219-3690 or (800) 424-9530.

**SUPPLEMENTARY INFORMATION:** Elsewhere in today's *Federal Register*, the Commission is publishing a notice to establish a proposed system notice to establish a new system of records, FEC 12, "Office of Inspector General Investigative Files," under the Privacy Act, 5 U.S.C. 552a, as amended. The following proposed amendment of the Commission's Privacy Act regulations at 11 CFR 1.14 is necessary to exempt the new system of records from certain provisions of that Act.

The Privacy Act and the implementing regulations require, among other things, that the Commission provide notice when collecting information, account for certain disclosures, permit individuals access to their records, and allow them to request that the records be amended. These provisions could interfere with the conduct of OIG investigations if applied to the OIG's maintenance of the proposed system of records.

Accordingly, the Commission proposes to exempt FEC 12 from these requirements under sections (j)(2) and (k)(2) of the Act. Section (j)(2), 5 U.S.C. 552a(j)(2), exempts a system of records maintained by "the agency or component thereof which performs as its principal function any activity pertaining to enforcement of criminal laws \* \* \*." Section (k)(2), 5 U.S.C. 552a(k)(2), exempts a system of records consisting of "investigatory materials compiled for law enforcement purposes," where such materials are not within the scope of the (j)(2) exemption pertaining to criminal law enforcement.

The proposed system of records consists of information covered by the (j)(2) and (k)(2) exemptions. The OIG investigatory files are maintained pursuant to official investigational and law enforcement functions of the Commission's Office of Inspector General under authority of the 1988 amendments to the Inspector General Act of 1978. See Public Law 100-504, amending Public Law 95-452, 5 U.S.C. app. The OIG is an office within the Commission that performs as one of its principal functions activities relating to the enforcement of criminal laws. In addition, the OIG is responsible for investigating a wide range of non-criminal law enforcement matters, including civil, administrative, or regulatory violations and similar

wrongdoing. Access by subject individuals and others to this system of records could substantially compromise the effectiveness of OIG investigations, and thus impede the apprehension and successful prosecution or discipline of persons engaged in fraud or other illegal activity.

For these reasons, the Commission is proposing to exempt proposed FEC 12 under exemptions (j)(2) and (k)(2) of the Privacy Act, by adding a new paragraph (b) to 11 CFR 1.14, the section in which the Commission specifies its systems of records that are exempt under the Act. Where applicable, section (j)(2) may be invoked to exempt a system of records from any Privacy Act provision except: 5 U.S.C. 552a(b) (conditions of disclosure); (c) (1) and (2) (accounting of disclosures and retention of accounting, respectively); (e)(4) (A) through (F) (system notice requirements); (e) (6), (7), (8), (10) and (11) (certain agency requirements relating to system maintenance); and (i) (criminal penalties). Section (k)(2) may be invoked to exempt a system of records from: 5 U.S.C. 552a(c)(3) (making accounting of disclosures available to the subject individual); (d) (access to records); (e)(1) (maintaining only relevant and necessary information); (e)(4) (G), (H), and (I) (notice of certain procedures), and (f) (promulgation of certain Privacy Act rules). The proposed language notes these specific exceptions and exemptions.

The Commission welcomes comments on any aspect of this proposed rule.

**Certification of No Effect Pursuant to 5 U.S.C. 605(b) (Regulatory Flexibility Act)**

The Commission certifies that the proposed rules will not, if adopted, have a significant impact on a substantial number of small entities. The basis for this certification is that the Privacy Act applies only to "individuals," and individuals are not "small entities" within the meaning of the Regulatory Flexibility Act.

**List of Subjects in 11 CFR Part 1**

Privacy.

For the reasons set out in the preamble, it is proposed to amend chapter I of title 11 of the Code of Federal Regulations as follows:

**PART 1—PRIVACY ACT**

1. The authority citation for part 1 would continue to read as follows:

**Authority:** 5 U.S.C. 552a.

2. Section 1.14 would be amended by redesignating paragraph (b) as paragraph

(c), and by adding new paragraph (b) to read as follows:

**§ 1.14 Specific exemptions.**

\* \* \* \* \*

(b)(1) Pursuant to 5 U.S.C. 552a(j)(2), records contained in FEC 12, Office of Inspector General Investigative Files, are exempt from the provisions of 5 U.S.C. 552a, except subsections (b), (c) (1) and (2), (e)(4) (A) through (F), (e) (6), (7), (9), (10), and (11), and (i), and the corresponding provisions of 11 CFR part 1, to the extent this system of records relates in any way to the enforcement of criminal laws.

(2) Pursuant to 5 U.S.C. 552a(k)(2), FEC 12, Office of Inspector General Investigative Files, is exempt from 552a (c)(3), (d), (e)(1), (e)(4) (G), (H), and (I), and (f), and the corresponding provisions of 11 CFR part 1, to the extent the system of records consists of investigatory material compiled for law enforcement purposes, except for material that falls within the exemption included in paragraph (b)(1) of this section.

\* \* \* \* \*

Dated: October 24, 1994.

**Trevor Potter,**

*Chairman.*

[FR Doc. 94-26614 Filed 10-26-94; 8:45 am]

BILLING CODE 6715-01-M

**SMALL BUSINESS ADMINISTRATION**

**13 CFR Parts 121 and 124**

**Small Business Size Regulations; Minority Small Business and Capital Ownership Development Assistance**

**AGENCY:** Small Business Administration.

**ACTION:** Proposed rule; extension of comment period.

**SUMMARY:** The Small Business Administration (SBA) extends the comment period on its proposed rule that would amend both eligibility requirements for and contractual assistance provisions within the SBA's section 8(a) program, and that was published in the *Federal Register* on August 30, 1994, 59 FR 44652.

**DATES:** The date for the receipt of comments pertaining to the proposed rule published at 59 FR 44652 has been extended from September 29, 1994. Comments must now be submitted on or before November 28, 1994.

**ADDRESSES:** Written comments should be addressed to Herbert L. Mitchell, Associate Administrator, Office of Minority Enterprise Development, U.S. Small Business Administration, 409 3rd Street, SW, Washington, DC 20416.

**FOR FURTHER INFORMATION CONTACT:**  
Office of Minority Enterprise  
Development, (202) 205-6410.

**SUPPLEMENTARY INFORMATION:** On August 30, 1994, SBA published a proposed rule to, among other things, (1) make several clarifications of the eligibility requirements for admission to SBA's 8(a) program, the need for which has been identified by SBA through the practical experience gained in operating the program and in defending the agency's actions in 8(a) eligibility appeals brought before SBA's Office of Hearings and Appeals, (2) authorize participation by business concerns owned by Community Development Corporations in the 8(a) program in accord with 42 U.S.C. 9815, and (3) make several changes to the 8(a) contractual assistance requirements, including eliminating 8(a) support levels and the concepts of local buy and national buy 8(a) requirements.

The rule required that comments concerning its proposed provisions be submitted to SBA for review on or before November 28, 1994. SBA has received a number of comments stating that the 30-day comment period was insufficient to properly address all of the proposal, and requesting that the comment period be extended. In light of the fact that the end of the comment period coincided with the end of the Federal fiscal year, a very busy time for any business concerns contracting with the Federal Government, SBA concurs that an extension of the comment period for this rule is appropriate. Thus, SBA is extending the comment period for an additional 30 days from the date this notice is published in the *Federal Register*.

Dated: October 19, 1994.

**Philip Lader,**  
*Administrator.*

[FR Doc. 94-26611 Filed 10-26-94; 8:45 am]

BILLING CODE 8025-01-M

## TENNESSEE VALLEY AUTHORITY

### 18 CFR Part 1310

#### Administrative Cost Recovery

**AGENCY:** Tennessee Valley Authority (TVA).

**ACTION:** Proposed rule.

**SUMMARY:** TVA proposes to amend its administrative cost recovery regulations by: Adding a provision requiring payment to TVA of nonrefundable application processing fees to recover the costs of reviewing plans for the construction, operation, or maintenance of dams, appurtenant works, or other

obstructions affecting navigation, flood control, or public lands or reservations in the Tennessee River system under Section 26a of the TVA Act; eliminating cost recovery exemptions for agricultural licenses; firewood cutting permits; permits for the nonexclusive short-term use of TVA land; conveyance or abandonment of TVA land or landrights to States, municipalities, and political subdivisions and agencies thereof; and use of TVA land for utility line crossings; authorizing the responsible land manager to establish a standard charge for each category of action rather than determining the actual administrative costs for each individual action; increasing the range of fees for certain actions.

The implementation of these regulations would allow TVA to recover more of its administrative costs incurred in processing certain actions from those persons who directly benefit from the actions.

**DATES:** Comments must be submitted on or before November 28, 1994. The proposed effective date is January 31, 1995.

**ADDRESSES:** Comments should be sent to David L. Pack, Manager of Reservoir Land Management, Tennessee Valley Authority, 17 Ridgeway Road, Norris, Tennessee 37828.

**FOR FURTHER INFORMATION CONTACT:** David L. Pack, Manager of Reservoir Land Management, (615) 632-1602.

**SUPPLEMENTARY INFORMATION:** In order to help ensure that TVA land management and permitting activities are self-sustaining to the full extent possible, the agency has determined that its administrative cost recovery regulations should be expanded to include a broader range of use, disposal, and permitting activities. This determination is consistent with the objectives of the current administration to increase government efficiency and to recover the costs of government services from those who most directly benefit from the services.

Persons who wish to construct dams, appurtenant works, or other obstructions in or along the Tennessee River system are required by Section 26a of the TVA Act of 1933, as amended, to obtain TVA's approval of plans for the proposed activity prior to construction. TVA's administrative cost recovery regulations currently provide for recovery of costs of actions taken by TVA to approve obstructions constructed without prior approval of plans. In order to help ensure that the agency's entire Section 26a permitting program is self-sustaining to the full extent possible, TVA now proposes to

recover the costs of processing permits for proposed obstructions as well as after-the-fact permit processing. The proposed amendment would allow the responsible land manager to set a standard permit processing fee, which would be payable upon submission of a permit application and would be nonrefundable, regardless of whether or not the plans are approved by TVA.

It is presently envisioned that the standard application processing fee for private noncommercial Section 26a permit proposals would be \$100, and the standard fee for commercial, industrial, and public Section 26a permit application processing would be \$500. These proposed fees are based in part upon a preliminary review of costs incurred by TVA in processing these permits. In addition, TVA examined prevailing permit application fees by conducting a comparative analysis survey of 40 other agencies and utilities. In adjusting application processing fees and in establishing standard fees for other applicable activities, the responsible land manager will examine average costs incurred in conducting the various activities.

TVA presently charges a \$2 per applicant administrative fee for quota deer hunts and quota turkey hunts at Land Between The Lakes. The purpose of this fee is to recover the cost of processing applications, conducting a computerized drawing, and mailing notification of selection status. TVA proposes the application fee increase from \$2 to a range of \$5 to \$25. This range will allow TVA to recover increasing costs of conducting the drawings and hunts, and allow a range of pricing for special hunts and drawings.

The proposed effective date of this action is January 31, 1995. Applications received prior to this date will be processed under the regulations in effect at the time of receipt of the application.

#### List of Subjects in 18 CFR Part 1310

Government property, Hunting.

For the reasons set out in the preamble, 18 CFR Part 1310 is proposed to be revised to read as follows:

#### PART 1310—ADMINISTRATIVE COST RECOVERY

- Sec.  
1310.1 Purpose.  
1310.2 Application.  
1310.3 Assessment of administrative charge.

Authority: 16 U.S.C. 831-831dd; 31 U.S.C. 9701.

**§ 1310.1 Purpose.**

The purpose of the regulations in this part is to establish a schedule of fees to be charged in connection with the disposition and uses of, and activities affecting, real property in TVA's custody or control; approval of plans under Section 26a of the Tennessee Valley Authority Act of 1933, as amended (16 U.S.C. 831y-1); and certain other activities in order to help ensure that such activities are self-sustaining to the full extent possible.

**§ 1310.2 Application.**

(a) *General.* TVA will undertake the following actions only upon the condition that the applicant pay to TVA such administrative charge as the Vice-President of Land Management or the Manager of Power Properties (hereinafter "responsible land manager"), as appropriate, shall assess in accordance with § 1310.3; provided, however, that the responsible land manager may waive payment where he/she determines that there is a corresponding benefit to TVA or that such waiver is otherwise in the public interest:

(1) Conveyance and abandonment of TVA land or landrights.

(2) Licenses and other uses of TVA land not involving the disposition of TVA real property or interests in real property.

(3) Actions taken to suffer the presence of unauthorized fills and structures over, on, or across TVA land or landrights, and including actions not involving the abandonment or disposal of TVA land or landrights.

(4) Actions taken to approve fills, structures, or other obstructions under Section 26a of the Tennessee Valley Authority Act of 1933, as amended (16 U.S.C. 831y-1), and TVA's regulations issued thereunder at part 1304 of this chapter.

(b) *Exemption.* An administrative charge shall not be made for the following actions:

(1) Conveyances pursuant to section 4(k)(d) of the Tennessee Valley Authority Act of 1933, as amended (16 U.S.C. 831c(k)(d)).

(2) Releases of unneeded mineral right options.

(3) TVA phosphate land and mineral transactions.

(4) Permits and licenses for use of TVA land by distributors of TVA power.

(c) *Quota deer hunt and turkey hunt applications.* Quota deer hunt and turkey hunt permit applications will be processed by TVA if accompanied by the fee prescribed in § 1310.3(d).

**§ 1310.3 Assessment of administrative charge.**

(a) *Range of charges.* Except as otherwise provided in this part, the responsible land manager shall assess a charge which he/she determines in his/her sole judgment to be approximately equal to the administrative costs incurred by TVA for each action including both the direct cost to TVA and applicable overheads. In determining the amount of such charge, the responsible land manager may establish a standard charge for each category of action rather than determining the actual administrative costs for each individual action. The standard charge shall be an amount approximately equal to TVA's actual average administrative costs for the category of action. Charges shall be not less than the minimum or greater than the maximum amount specified herein, except as otherwise provided in paragraph (c) of this section.

(1) Land transfers—\$500–\$10,000.

(2) Use permits or licenses—\$50–\$5,000.

(3) Actions taken to approve plans for fills, structures, or other obstructions under Section 26a of the TVA Act—\$100–\$5,000.

(4) Abandonment of transmission line easements and rights-of-way—\$100–\$1,500.

(5) Quota deer hunt or turkey hunt applications—\$5–\$25.

(b) *Basis of charge.* The administrative charge assessed by the responsible land manager shall, to the extent applicable, include the following costs:

(1) Appraisal of the land or landrights affected;

(2) Assessing applicable rental fees;

(3) Compliance inspections and other field investigations;

(4) Title and record searches;

(5) Preparation for and conducting public auction and negotiated sales;

(6) Mapping and surveying;

(7) Preparation of conveyance instrument, permit, or other authorization or approval instrument;

(8) Coordination of the proposed action within TVA and with other Federal, State, and local agencies;

(9) Legal review; and

(10) Administrative overheads associated with the transaction.

(c) *Assessment of charge when actual administrative costs significantly exceed established range.* When the responsible land manager determines that the actual administrative costs are expected to significantly exceed the range of costs established in paragraph (a) of this section, such manager shall not proceed with the TVA action until agreement is reached on payment of a charge

calculated to cover TVA's actual administrative costs.

(d) *Quota deer hunt and turkey hunt application fees.* A fee for each person in the amount prescribed by the responsible land manager must accompany the completed application form for a quota deer hunt and turkey hunt permit. Applications will not be processed unless accompanied by the correct fee amount. No refunds will be made to unsuccessful applicants, except that fees received after the application due date will be refunded.

(e) *Additional charges.* In addition to the charges assessed under this part, TVA may impose a charge in connection with environmental reviews or other environmental investigations it conducts under its policies or procedures implementing the National Environmental Policy Act. (42 U.S.C. 4321 *et seq.*)

Dated: October 20, 1994.

David L. Pack,

Manager, Reservoir Land Management.

[FR Doc. 94-26669 Filed 10-26-94; 8:45 am]

BILLING CODE 8120-01-M

**DEPARTMENT OF THE INTERIOR****Office of Surface Mining Reclamation and Enforcement****30 CFR Part 943****Texas Permanent Regulatory Program**

**AGENCY:** Office of Surface Mining Reclamation and Enforcement (OSM), Interior.

**ACTION:** Proposed Rule; Reopening and Extension of Public Comment Period on Proposed Amendment.

**SUMMARY:** OSM is announcing receipt of additional explanatory information and revisions pertaining to a previously proposed amendment to the Texas regulatory program (hereinafter, the "Texas program") under the Surface Mining Control and Reclamation Act of 1977 (SMCRA). The additional explanatory information and revisions for Texas' proposed rules and statute pertain to ownership and control. The amendment is intended to revise the Texas program to be consistent with the corresponding Federal regulations and SMCRA.

This document sets forth the times and locations that the Texas program and proposed amendment to that program are available for public inspection and dates and times of the reopened comment period during which interested persons may submit written comments on the proposed amendment.

**DATES:** Written comments must be received by 4:00 p.m., c.s.t., November 14, 1994.

**ADDRESSES:** Written comments should be mailed or hand delivered to James H. Moncrief at the address listed below.

Copies of the Texas program, the proposed amendment, and all written comments received in response to this document will be available for public review at the addresses listed below during normal business hours, Monday through Friday, excluding holidays. Each requester may receive one free copy of the proposed amendment by contacting OSM's Tulsa Field Office.

James H. Moncrief, Director, Tulsa Field Office, Office of Surface Mining Reclamation and Enforcement, 5100 East Skelly Drive, Suite 550, Tulsa, OK 74135, Telephone: (918) 581-6430;

Railroad Commission of Texas, Surface Mining and Reclamation Division, Capitol Station, P.O. Drawer 12967, Austin, TX 78711, Telephone: (512) 463-6900.

**FOR FURTHER INFORMATION CONTACT:** James H. Moncrief, Telephone: (918) 581-6430.

#### SUPPLEMENTARY INFORMATION:

##### I. Background on the Texas Program

On February 16, 1980, the Secretary of the Interior conditionally approved the Texas program. General background information on the Texas program, including the Secretary's findings, the disposition of comments, and the conditions of approval of the Texas program can be found in the February 27, 1980, *Federal Register* (45 FR 12998). Subsequent actions concerning Texas' program and program amendments can be found at 30 CFR 943.15 and 943.16.

##### II. Submission of Proposed Amendment

By letter dated May 24, 1994, (Administrative Record No. TX-576), Texas submitted a proposed amendment to its program pursuant to SMCRA. Texas submitted the proposed amendment in response to required program amendments at 30 CFR 943.16(c) (1) and (2), (d), (f), (j)(1), (2), (3), and (4), (r), and (s) (59 FR 13200, March 21, 1994). The ownership and control provisions of the Texas Coal Mining Regulations (TCMR) at 16 Texas Administrative Code (TAC) § 11.221 and of the Texas Surface Coal Mining and Reclamation Act (TSCMRA) at Article 5920-11 of the Texas Revised Civil Statutes Annotated that Texas proposed to amend were: TCMR § 778.116(m), identification of interests and compliance information; TCMR

§ 786.215(e) and (f), review of permit applications; TCMR 786.216(i) through (n), criteria for permit approval or denial; TCMR § 788.225(f), (g), and (h), commission review of outstanding permits; and section 21(c) of TSCMRA, reporting notices of violations in permit applications.

OSM announced receipt of the proposed amendment in the June 30, 1994, *Federal Register* (59 FR 33705) and invited public comment on its adequacy (Administrative Record No. TX-576.07). The public comment period ended August 1, 1994.

During its review of the amendment, OSM identified concerns relating to the provisions of the rules and statute at TCMR § 778.116(m), identification of interests and compliance information; TCMR § 786.215(e)(1), review of permit applications; TCMR § 788.225(g), commission review of outstanding permits; and section 21(c) of TSCMRA, reporting notices of violations in permit applications. OSM notified Texas of the concerns by letter dated August 11, 1994 (Administrative Record No. TX-576.12). In response to OSM's concerns for these provisions, Texas, in a letter dated October 6, 1994, submitted a revised amendment (Administrative Record No. TX-576.13).

Texas proposes to additionally (1) revise TCMR § 778.116(m) and TCMR § 786.215(e)(1) so that each requires an application to list violations incurred by the applicant under all SMCRA-approved State programs, including the Texas program; (2) recodify the previously proposed second sentence of TCMR § 788.225(g) as (g)(1) and subparagraphs (g) (1) through (4) as (g)(1) (i) through (iv); (3) revise TCMR § 788.225(g) to provide that if the Commission elects to rescind an improvidently issued permit it must serve the permittee with a notice of the proposed rescission and include the reasons under TCMR § 788.225(e) for the Commission's findings; (4) revise TCMR § 788.225(g)(1)(iv) to require the Commission to find that, in addition to severing any ownership or control link with the responsible person, the permittee does not continue to be responsible for the violation, penalty, or fee; and (5) recodify previously proposed TCMR § 788.225(h) and (i), respectively, as TCMR § 788.225(g)(2) and (h).

##### III. Public Comment Procedures

OSM is reopening the comment period on the proposed Texas program amendment to provide the public an opportunity to reconsider the adequacy of the proposed amendment in light of the additional materials submitted. In

accordance with the provisions of 30 CFR 732.17(h), OSM is seeking comments on whether the proposed amendment satisfies the applicable program approval criteria of 30 CFR 732.15. If the amendment is deemed adequate, it will become part of the Texas program.

Written comments should be specific, pertain only to the issues proposed in this rulemaking, and include explanations in support of the commenter's recommendations. Comments received after the time indicated under **DATES** at locations other than the Tulsa Field Office will not necessarily be considered in the final rulemaking or included in the administrative record.

#### IV. Procedural Determinations

##### 1. Executive Order 12866

This rule is exempted from review by the Office of Management and Budget (OMB) under Executive Order 12866 (Regulatory Planning and Review).

##### 2. Executive Order 12778

The Department of the Interior has conducted the reviews required by section 2 of Executive Order 12778 (Civil Justice Reform) and has determined that this rule meets the applicable standards of subsections (a) and (b) of that section. However, these standards are not applicable to the actual language of State regulatory programs and program amendments since each such program is drafted and promulgated by a specific State, not by OSM. Under sections 503 and 505 of SMCRA (30 U.S.C. 1253 AND 12550) and the Federal regulations at 30 CFR 730.11, 732.15, and 732.17(h)(10), decisions on proposed State regulatory programs and program amendments submitted by the States must be based solely on a determination of whether the submittal is consistent with SMCRA and its implementing Federal regulations and whether the other requirements of 30 CFR Parts 730, 731, and 732 have been met.

##### 3. National Environmental Policy Act

No environmental impact statement is required for this rule since section 702(d) of SMCRA (30 U.S.C. 1292(d)) provides that agency decisions on proposed State regulatory program provisions do not constitute major Federal actions within the meaning of section 102(2)(C) of the National Environmental Policy Act of 1969 (42 U.S.C. 4332(2)(C)).

##### 4. Paperwork Reduction Act

This rule does not contain information collection requirements that

require approval by OMB under the Paperwork Reduction Act (44 U.S.C. 3507 *et seq.*).

#### 5. Regulatory Flexibility Act

The Department of the Interior has determined that this rule will not have a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*). The State submittal which is the subject of this rule is based upon counterpart Federal regulations for which an economic analysis was prepared and certification made that such regulations would not have a significant economic effect upon a substantial number of small entities. Accordingly, this rule will ensure that existing requirements previously promulgated by OSM will be implemented by the State. In making the determination as to whether this rule would have a significant economic impact, the Department relied upon the data and assumptions for the counterpart Federal regulations.

#### List of Subjects in 30 CFR Part 943

Intergovernmental relations, Surface mining, Underground mining.

Dated: October 21, 1994.

Charles E. Sandberg,

Acting Assistant Director, Western Support Center.

[FR Doc. 94-26603 Filed 10-26-94; 8:45 am]

BILLING CODE 4310-05-M

## DEPARTMENT OF EDUCATION

### 34 CFR Part 682

RIN 1840-AC09

#### Federal Family Education Loan Program

AGENCY: Department of Education.

ACTION: Notice of proposed rulemaking; correction.

**SUMMARY:** On October 13, 1994, the Department of Education published in the *Federal Register* a notice of proposed rulemaking (NPRM) for the Federal Family Education Loan (FFEL) Program (59 FR 52038). The proposed rules stated that there were no paperwork requirements contained in the regulations. This document corrects the "Paperwork Reduction Act of 1980" section for those regulations.

**ADDRESSES:** All comments concerning these proposed regulations should be addressed to Ms. Patricia Newcombe, Chief, Federal Family Education Loan Program Section, Loans Branch, U.S. Department of Education, 600

Independence Avenue, Room 4310, Regional Office Building 3, Washington, DC 20202-5343. Comments may also be sent through the internet to "FFEL—OBRA@ed.gov."

**FOR FURTHER INFORMATION CONTACT:** Mr. Douglas D. Laine, Program Specialist, Federal Family Education Loan Program Section, Loans Branch, U.S. Department of Education, 600 Independence Avenue, SW., Room 4310, Regional Office Building 3, Washington, DC 20202-5343, telephone: (202) 708-8242. Individuals who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1-800-877-8339 between 8 a.m. and 8 p.m., Eastern time, Monday through Friday.

Dated: October 21, 1994.

David A. Longanecker,

Assistant Secretary for Postsecondary Education.

1. The following correction is made in the FR Doc. 94-25363, published in the *Federal Register* on October 13, 1994 (59 FR 52038).

On page 52041, the "Paperwork Reduction Act of 1980" section is corrected to read as follows:

#### Paperwork Reduction Act of 1980

"Sections 682.305, 682.401, and 682.404 contain information collection requirements. As required by the Paperwork Reduction Act of 1980, the Department of Education will submit a copy of these proposed regulations to the Office of Management and Budget for its review. (44 U.S.C. 3504(h))

The proposed regulations affect schools, lenders, and guaranty agencies that participate in the FFEL Program as well as States in which schools with high cohort default rates are located. These proposed regulations do not increase annual public reporting burden.

Organizations and individuals desiring to submit comments on the information collection requirements should direct them to the Office of Information and Regulatory Affairs, Office of Management and Budget, Room 10235, New Executive Office Building, Washington, DC 20503; Attention: Daniel J. Chenok."

[FR Doc. 94-26581 Filed 10-26-94; 8:45 am]

BILLING CODE 4000-01-P

## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 228

[FRL-5098-1]

#### Ocean Dumping; Proposed Site Designation

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

**SUMMARY:** EPA today proposes to designate an Ocean Dredged Material Disposal Site (ODMDS) in the Atlantic Ocean offshore Miami, Florida, as an EPA-approved ocean dumping site for the disposal of suitable dredged material. This proposed action is necessary to provide an acceptable ocean disposal site for consideration as an option for dredged material disposal projects in the greater Miami, Florida vicinity. This proposed site designation is for an indefinite period of time, but the site is subject to continuing monitoring to insure that unacceptable adverse environmental impacts do not occur.

**DATES:** Comments must be received on or before December 12, 1994.

**ADDRESSES:** Send comments to: Wesley B. Crum, Chief, Coastal Programs Section, Water Management Division, U.S. Environmental Protection Agency, Region IV, 345 Courtland Street NE., Atlanta, Georgia 30365.

The file supporting this proposed designation is available for public inspection at the following locations: EPA Public Information Reference Unit (PIRU), Room 2904 (rear), 401 M Street SW., Washington, D.C. 20460. EPA/Region IV, 345 Courtland Street NE., Atlanta, Georgia 30365.

Department of the Army, Jacksonville District Corps of Engineers, 400 West Bay Street, P.O. Box 4970, Jacksonville, FL 32232-0019.

**FOR FURTHER INFORMATION CONTACT:** Christopher J. McArthur, 404/347-3555 ext. 2056.

#### SUPPLEMENTARY INFORMATION:

##### A. Background

Section 102(c) of the Marine Protection, Research, and Sanctuaries Act (MPRSA) of 1972, as amended, 33 U.S.C. 1401 *et seq.*, gives the Administrator of EPA the authority to designate sites where ocean disposal may be permitted. On October 1, 1986, the Administrator delegated the authority to designate ocean disposal sites to the Regional Administrator of the Region in which the sites are located. This proposed designation of a

site offshore Miami, Florida, which is within Region IV, is being made pursuant to that authority.

The EPA Ocean Dumping Regulations promulgated under MPRSA (40 CFR Chapter I, Subchapter H, Section 228.4) state that ocean dumping sites will be designated by promulgation in this Part 228. A list of "Approved Interim and Final Ocean Dumping Sites" was published on January 11, 1977 (42 FR 2461 [January 11, 1977]). The list established the existing Miami ("Miami Beach") site as an interim site. The site is now listed in 40 CFR 228.12(a)(3). Interested persons may participate in this proposed rulemaking by submitting written comments within 45 days of the date of this publication to the address given above.

### B. EIS Development

Section 102(2)(C) of the National Environmental Policy Act (NEPA) of 1969, as amended, 42 U.S.C. 4321 *et seq.*, requires that federal agencies prepare an Environmental Impact Statement (EIS) on proposals for legislation and other major federal actions significantly affecting the quality of the human environment. The object of NEPA is to build into the Agency decision making process careful consideration of all environmental aspects of proposed actions. While NEPA does not apply to EPA activities of this type, EPA has voluntarily committed to prepare EISs in connection with ocean disposal site designations such as this (see 39 FR 16186 [May 7, 1974]).

EPA, in cooperation with the Jacksonville District of the U.S. Army Corps of Engineers (COE), has prepared a Draft EIS (DEIS) entitled "Draft Environmental Impact Statement for Designation of An Ocean Dredged Material Disposal Site Located Offshore Miami, Florida." On September 7, 1990, the Notice of Availability (NOA) of the DEIS for public review and comment was published in the *Federal Register* (55 FR 36891 [September 7, 1990]). Anyone desiring a copy of the EIS may obtain one from the addresses given above. The public comment period on the draft EIS was to have closed on October 22, 1990. However, the closing date was changed to December 7, 1990 due to a request by the State of Florida.

EPA received 12 comment letters on the Draft EIS. There were three main concerns expressed in those letters: (1) Placement of beach quality sand in the ODMDS; (2) potential for movement of silt and clay sized particles out of the disposal area and onto environmentally sensitive hardbottoms and coral reefs to the west during the occurrence of Gulf

Stream frontal eddies; and (3) disposal of contaminated sediments from locations such as the Miami River. Concerns raised by the State of Florida, regarding use of suitable material for beach nourishment, will be addressed in the FEIS. EPA concurs with the State of Florida regarding the use of suitable material for beach nourishment, in circumstances where this use is practical. A real-time monitoring system will be instituted by the Army Corps of Engineers to identify the occurrence of Gulf Stream frontal eddies. During the occurrence of such eddies, disposal at the ODMDS will discontinue. Details of the monitoring plan and protocol will be included in the Site Management and Monitoring Plan as part of the FEIS. Before any material can be placed within an ODMDS, it must be evaluated and shown to be acceptable for ocean disposal in accordance with ocean dumping regulations (40 CFR 227.13). Certain portions of the sediments proposed to be dredged from the Miami River have been found to be unacceptable for ocean disposal.

The EIS will serve as a Biological Assessment for purposes of Section 7 of the Endangered Species Act coordination. By itself, site designation of the Miami ODMDS will not adversely impact any threatened or endangered species under the purview of the National Marine Fisheries Service (NMFS) and the U.S. Fish and Wildlife Service (FWS). Use of the ODMDS is not expected to adversely impact any threatened or endangered species. Pursuant to Section 7 of the Endangered Species Act, the National Marine Fisheries Service (NMFS) has been asked by EPA to concur with EPA's conclusion that this site designation will not affect the endangered species under their jurisdictions.

EPA has evaluated the proposed site designation for consistency with the State of Florida's (the State) approved coastal management program. EPA has determined that the designation of the proposed site is consistent to the maximum extent practicable with the State coastal management program, and has submitted this determination to the State for review in accordance with EPA policy.

In a letter dated September 13, 1990, the Florida Department of State agreed that the proposed designation will have no effect on any archaeological or historic sites or properties listed, or eligible for listing, in the *National Register of Historic Places* in accordance with the National Preservation Act of 1966 (Public Law 89-6654), as amended.

The proposed action discussed in the DEIS is the permanent designation for continuing use of the existing interim ocean disposal site near Miami, Florida. The purpose of the proposed action is to provide an environmentally acceptable option for the ocean disposal of dredged material. The need for the permanent designation of the Miami ODMDS is based on a demonstrated COE need for ocean disposal of maintenance dredged material from the Federal navigation projects in the greater Miami area. However, every disposal activity by the COE is evaluated on a case-by-case basis to determine the need for ocean disposal for that particular case. The need for ocean disposal for other projects, and the suitability of the material for ocean disposal, will be determined on a case-by-case basis as part of the COE's process of issuing permits for ocean disposal for private/federal actions and a public review process for their own actions.

For the Miami ODMDS, the COE and EPA would evaluate all federal dredged material disposal projects pursuant to the EPA criteria given in the Ocean Dumping Regulations (40 CFR Parts 220-229) and the COE regulations (33 CFR 209.120 and Parts 335-338). The COE also issues Marine Protection, Research, and Sanctuaries Act (MPRSA) permits to private applicants for the transport of dredged material intended for disposal after compliance with regulations is determined. EPA has the right to disapprove any ocean disposal project if, in its judgment, all provisions of MPRSA and the associated implementing regulations have not been met.

The DEIS discusses the need for this site designation and examines ocean disposal site alternatives to the proposed action. Non-ocean disposal options have been examined in the previously published Feasibility Report and EIS for the Miami Harbor Channel Project. Alternatives to ocean disposal may include upland disposal within the port area, disposal in Biscayne Bay, and beach disposal. Upland disposal in the intensively developed Port of Miami-Biscayne Bay area has not been found feasible. The Port of Miami itself is built partially on fill in Biscayne Bay. Undeveloped areas within cost-effective haul distances are environmentally valuable in their own right.

Almost all inshore waters of the Biscayne Bay area are part of the Biscayne Bay Aquatic Preserve. The waters of the southern portion of Biscayne Bay, now included in the Aquatic Preserve, are to be incorporated, along with some offshore waters, into

the Biscayne National Park in the near future. The Florida Department of Environmental Regulation (DER) has afforded the waters of these areas special protection as Outstanding Florida Waters. This effectively removes virtually all of the Biscayne Bay area from consideration for disposal of dredged material.

Dredged sand might be placed on beaches in the Miami Beach area. Suitable rock might be placed in nearshore waters. These options are feasible only where a substantial quantity of the desired type of material is separable from silt or other undesirable material.

The COE has been authorized to deepen Miami Harbor. For that project, environmental and economic analyses were performed and an EIS was prepared. The COE examined and documented the feasibility of each of the above-described disposal options and found none to be feasible.

The following ocean disposal alternatives were evaluated in the Draft EIS:

#### 1. Alternative Sites on the Continental Shelf

In the Miami nearshore area, hardgrounds supporting coral and algal communities are concentrated on the continental shelf. Disposal operations on the shelf could adversely impact this reef habitat. Because the shelf is narrow, about 3.3 nmi (6 km) off Government Cut, the transport of dredged materials for disposal beyond the shelf is both practical and economically feasible. Therefore, alternative sites on the continental shelf are not desirable.

#### 2. Designated Interim Site (Candidate Site)

The preferred alternative considered in this document is the final designation of an ODMDS. This site is an area of approximately one square nautical mile with the following corner coordinates: 25°45'30" N, 80°03'54" W; 25°45'30" N, 80°02'50" W; 25°44'30" N, 80°02'50" W; 25°44'30" N, 80°03'54" W. The site is centered at: 25°45'00" N and 80°03'22" W. This site is considered suitable in terms of practicality and economic feasibility. Sections 228.5 and 228.6 of EPA's Ocean Dumping Regulations and Criteria 40 CFR establish criteria for the evaluation of ocean disposal sites.

#### 3. Alternative Sites Beyond the Continental Shelf

The western edge of the Gulf Stream meanders about one mile east of the candidate site. Dumping in the Gulf Stream was considered, but the enormous task and expense of

monitoring disposal under such conditions caused sufficient concern to eliminate that option.

#### 4. No Action

Under the "no action" alternative, the interim site would not receive final designation. The Water Resources Act of 1992, Title V, Section 506(a) prohibits the continued use of ocean dump sites which have not been designated by EPA as Section 102 dump sites after January 1, 1997. If EPA fails to designate the Miami ODMDS by that date, the continued foreseeable need to have an appropriate site for disposal of suitable sediments from dredging projects in the Miami area would place pressure on the Corps and EPA to approve on a project-by-project basis the use of temporary ocean dumping locations pursuant to either Clean Water Act Section 404 or MPRSA Section 103.

The DEIS presents the information needed to evaluate the suitability of ocean disposal areas for final designation use and is based on one of a series of disposal site environmental studies. The environmental studies and final designation are being conducted in accordance with the requirements of MPRSA, the Ocean Dumping Regulations, and other applicable federal environmental legislation.

Comments received on the DEIS will be addressed in the FEIS. This Proposed Rule is being published between the DEIS and the Final EIS (FEIS). EPA will accept comments on the Proposed Rule during the 45-day NEPA review period. Comments on the Proposed Rule will be addressed in the Final Rule, which will be published following the completion of the 30-day NEPA review period of the FEIS. Responses in the Final Rule may refer to earlier published responses, as appropriate.

#### C. Proposed Site Designation

The proposed site is located east of Miami, Florida, the western boundary being 3.6 nautical miles (nmi) offshore. The proposed ODMDS occupies an area of about 1 square nautical mile (nmi<sup>2</sup>), in the configuration of an approximate 1 nmi by 1 nmi square. Water depths within the area range from 427 to 785 feet. The coordinates of the Miami site proposed for final designation are as follows:

25°45'30" N	80°03'54" W;
25°45'30" N	80°02'50" W;
25°44'30" N	80°03'54" W; and
25°44'30" N	80°02'50" W.

Center coordinates are 25°45'00" N and 80°03'22" W.

#### D. Regulatory Requirements

Pursuant to the Ocean Dumping Regulations, 40 CFR Part 228.5, five general criteria are used in the selection and approval for continuing use of ocean disposal sites. Sites are selected so as to minimize interference with other marine activities, to prevent any temporary perturbations associated with the disposal from causing impacts outside the disposal site, and to permit effective monitoring to detect any adverse impacts at an early stage. Where feasible, locations off the Continental Shelf and other sites that have been historically used are to be chosen. If, at any time, disposal operations at a site cause unacceptable adverse impacts, further use of the site can be restricted or terminated by EPA. The proposed site conforms to the five general criteria.

In addition to these general criteria in Section 228.5, Section 228.6 lists the 11 specific criteria used in evaluating a proposed disposal site to assure that the general criteria are met. Application of these 11 criteria constitutes an environmental assessment of the impact of disposal at the site. The characteristics of the proposed site are reviewed below in terms of these 11 criteria (the EIS may be consulted for additional information).

#### 1. Geographical Position, Depth of Water, Bottom Topography, and Distance [from Coast 228.6(a)(1)] 40 CFR

The boundary and center coordinates of the proposed site are given above. The western boundary of the proposed site is located about 3.6 nmi offshore of Miami, Florida. The site is an approximate 1 nmi by 1 nmi square configuration. Water depth in the area ranges from 427 to 785 feet.

#### 2. Location in Relation to Breeding, Spawning, Nursery, Feeding, or Passage Areas of Living Resources in Adult or Juvenile Phases [40 CFR 228.6(a)(2)]

Many of the area's species spend their adult lives in the offshore region, but are estuary-dependent because their juvenile stages use a low salinity estuarine nursery region. Specific migration routes are not known in the Miami area. The site is not known to include any major breeding or spawning area, except for sea turtles which use the entire beach area of eastern Florida as nesting habitat. Due to the motility of finfish, it is unlikely that disposal activities will have any significant impact on any of the species found in the area.

*3. Location in Relation to Beaches and Other Amenity Areas [40 CFR 228.6(a)(3)]*

The candidate site is located at least 3.6 nautical miles from the coast. Shore-related amenities include Virginia Key, the Biscayne Bay Aquatic Preserve, Biscayne National Park, and the Bill Baggs Cape Florida State Recreational Area. Currents in the vicinity trend alongshore in a general north-south orientation. It is therefore unlikely that detectable quantities of dredged material will be transported onto beaches. Considering the distance that the proposed disposal site is offshore of beach areas, dredged material disposal at the site is not expected to have an effect on the recreational uses of these beaches. Modelling performed by the COE indicates that disposed material will not impact these areas.

*4. Types and Quantities of Wastes Proposed To Be Disposed of, and Proposed Methods of Release, Including Methods of Packing the Waste, If Any [40 CFR 228.6(a)(4)]*

It is anticipated that the candidate site will be used primarily for disposal of maintenance material from the Port of Miami. Maintenance dredging has only occurred four times since 1957. Another foreseen use of the site would be the Miami Harbor Deepening Project. Estimated volume for this project is expected to be 6 million cubic yards. For each future dredging project, each disposal plan must be evaluated on a case-by-case basis to ensure that ocean disposal is the best alternative and that the material meets the Ocean Dumping Criteria in 40 CFR Part 227.

*5. Feasibility of Surveillance and Monitoring [40 CFR 228.6(a)(5)]*

Due to the proximity of the site to shore, surveillance will not be difficult. Survey vessels, dredges or aircraft overflights are feasible surveillance methods. However, the depths at this site make conventional ODMDS monitoring techniques difficult to utilize. The Site Management and Monitoring Plan (SMMP) for the Miami ODMDS has been developed and was included as an appendix in the DEIS. This SMMP establishes a sequence of monitoring surveys to be undertaken to determine any impacts resulting from disposal activities. The SMMP may be modified for cause by the responsible agency.

*6. Dispersal, Horizontal Transport and Vertical Mixing Characteristics of the Area Including Prevailing Current Direction and Velocity, If Any [40 CFR 228.6(a)(6)]*

Prevailing currents parallel the coast and are generally oriented along a north-south axis. Northerly flow predominates. Mean surface currents range from 62 to 95 cm/sec with maximum velocities of about 150 cm/sec. Current speeds are lower and current reversals more common in near-bottom waters. Mean velocities of 3.5 cm/sec and maximum velocities of 27 cm/sec have been reported for near-bottom waters in the area. A pycnocline occurs in site waters throughout the year at reported depths ranging from about 60 feet in the summer to 325 feet in the winter. A dredged material dispersion study conducted by the COE for both the short- and long-term fate of material disposed at the proposed site indicates little possibility of disposed material affecting near-shore reefs. Measures as discussed in the Management and Monitoring Plan will be instituted during disposal operations to minimize the possibility of material being transported to the near-shore reefs.

*7. Existence and Effects of Current and Previous Discharges and Dumping in the Area (Including Cumulative Effects) [40 CFR 228.6(a)(7)]*

The proposed ODMDS was used for the first time in April 1990. Only 225,000 cubic yards of maintenance material was disposed in the proposed ODMDS. In conjunction with this use of the site, the Corps of Engineers in cooperation with the National Oceanic and Atmospheric Administration (NOAA) monitored the physical processes and the dispersive characteristics of the dredged material plume. Monitoring results indicated that the material discharged, except for a low concentration residual remaining within the water column, reached bottom within the designated site boundaries. During the monitoring, the resulting plumes were observed to be transported in a north to northeast direction. The full monitoring report will be included as part of the Final EIS. Due to the limited quantity of material disposed at the site, an effects study has not been initiated. Effects monitoring is discussed in the Site Management and Monitoring Plan as part of the EIS.

No other discharges or dumping occurs in the site. The Miami-Dade Central publicly owned treatment plant outfall discharges approximately 1.2 miles west of the site. The effects from

this discharge are local and predominantly in a north-south direction due to prevailing currents and should not have any effect within the site.

*8. Interference With Shipping, Fishing, Recreation, Mineral Extraction, Desalination, Fish and Shellfish Culture, Areas of Special Scientific Importance and Other Legitimate Uses of the Ocean [40 CFR 228.6(a)(8)]*

While shipping is heavy at the Port of Miami, the infrequent use of this site should not significantly disrupt either commercial shipping or recreational boating. Commercial and recreational fishing activities are concentrated in inshore and nearshore waters. No mineral extraction, desalination, or mariculture activities occur in the immediate area. Scientific resources present throughout this area are not geographically limited to the proposed Miami ODMDS or nearby waters.

*9. The Existing Water Quality and Ecology of the Site as Determined By Available Data or By Trend Assessment or Baseline Surveys [40 CFR 228.6(a)(9)]*

Water quality at the proposed ODMDS is variable and is influenced by discharges from inshore systems, frequent oceanic intrusions, and periodic upwelling. The proposed disposal site lies on the continental slope in an area traversed by the western edge of the Florida Current. The location of the western edge of the current determines to a large extent whether waters at the site are predominantly coastal or oceanic. Frequent intrusions or eddies of the Florida Current transport oceanic waters over the continental shelf in the proposed ODMDS vicinity. Periodic upwelling/downwelling events associated with wind stress also influence waters in the area.

No critical habitat or unique ecological communities have been identified at the candidate site. Buffer zone protection has been applied to any existing fish havens, artificial reef communities, turtle nesting areas, and onshore amenities in the general region of the site.

*10. Potentiality for the Development or Recruitment of Nuisance Species in the Disposal Site [40 CFR 228.6(a)(10)]*

The disposal of dredged materials should not attract or promote the development of nuisance species. No nuisance species have been reported to occur at previously utilized disposal sites in the vicinity.

**11. Existence at or in Close Proximity to the Site of Any Significant Natural or Cultural Features of Historical Importance [40 CFR 228.6(a)(11)]**

No known natural or cultural features of historical importance occur at or in close proximity to the site. No such features were noted in a video survey of the proposed disposal area.

**E. Site Management**

Site management of the Miami ODMDS is the responsibility of EPA as well as the COE. The COE issues permits to private applicants for ocean disposal; however, EPA/Region IV assumes overall responsibility for site management.

The Site Management and Monitoring Plan (SMMP) for the proposed Miami ODMDS was developed as a part of the process of completing the EIS. This plan provides procedures for both site management and for the monitoring of effects of disposal activities. This SMMP is intended to be flexible and may be modified by the responsible agency for cause.

**F. Proposed Action**

The EIS concludes that the proposed site may appropriately be designated for use. The proposed site is compatible with the 11 specific and 5 general criteria used for site evaluation.

The designation of the Miami site as an EPA-approved ODMDS is being published as Proposed Rulemaking. Overall management of this site is the responsibility of the Regional Administrator of EPA/Region IV.

It should be emphasized that, if an ODMDS is designated, such a site designation does not constitute EPA's approval of actual disposal of material at sea. Before ocean disposal of dredged material at the site may commence, the COE must evaluate a permit application according to EPA's Ocean Dumping Criteria. EPA has the right to disapprove the actual disposal if it determines that environmental concerns under MPRSA have not been met.

The Miami ODMDS is not restricted to disposal use by federal projects; private applicants may also dispose suitable dredged material at the ODMDS once relevant regulations have been satisfied. This site is restricted, however, to suitable dredged material from the greater Miami, Florida vicinity.

**G. Regulatory Assessments**

Under the Regulatory Flexibility Act, EPA is required to perform a Regulatory Flexibility Analysis for all rules that may have a significant impact on a substantial number of small entities. EPA has determined that this proposed

action will not have a significant impact on small entities since the designation will only have the effect of providing a disposal option for dredged material. Consequently, this Rule does not necessitate preparation of a Regulatory Flexibility Analysis.

Under Executive Order 12866, EPA must judge whether a regulation is "significant" and therefore subject to the requirement of a Regulatory Impact Analysis. This action will not result in an annual effect on the economy of \$100 million or more or cause any of the other effects which would result in its being classified by the Executive Order as a "significant" rule. Consequently, this Rule does not necessitate preparation of a Regulatory Impact Analysis.

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

**List of Subjects in 40 CFR Part 228**

Environmental protection, Water pollution control.

Dated: September 23, 1994.

**John H. Hankinson, Jr.,**  
Regional Administrator.

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

**PART 228—[AMENDED]**

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

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

2. Section 228.12(a)(3) is amended by removing the complete entry for the Miami Beach approved interim dredged material dumping site and adding § 228.12(b)(95) to read as follows:

**§ 228.12 Delegation of management authority for ocean dumping sites.**

\* \* \* \* \*

(b) \* \* \*

(95) Miami, Florida; Ocean Dredged Material Disposal Site—Region IV.

**Location:**

25°45'30" N	80°03'54" W;
25°45'30" N	80°02'50" W;
25°44'30" N	80°03'54" W;
25°44'30" N	80°02'50" W.

Center coordinates are 25°45'00" N and 80°03'22" W.

Size: Approximately 1 square nautical mile.

Depth: Ranges from 427 to 785 feet.

Primary use: Dredged material.

Period of use: Continuing use.

Restriction: Disposal shall be limited to suitable dredged material from the greater

Miami, Florida vicinity. Disposal shall comply with conditions set forth in the most recent approved Site Management and Monitoring Plan.

[FR Doc. 94-26662 Filed 10-26-94; 8:45 am]

BILLING CODE 6560-50-P

**40 CFR Part 281**

[FRL-5095-5]

**Utah; Final Approval of State Underground Storage Tank Program**

**AGENCY:** Environmental Protection Agency.

**ACTION:** Notice of Tentative Determination on Application of State of Utah for Final Approval, Public Hearing and Public Comment Period.

**SUMMARY:** The State of Utah has applied for final approval of its underground storage tank program under Subtitle I of the Resource Conservation and Recovery Act (RCRA). The Environmental Protection Agency (EPA) has reviewed the Utah application and has made the tentative decision that Utah's underground storage tank (UST) program satisfies all of the requirements necessary to qualify for final approval. Notably, the State of Utah's statute authorizes the issuance of regulations that are broader in scope than the Federal regulations. EPA intends to grant final approval to the State to operate its program in lieu of the Federal program. The State of Utah's application for final approval is available for public review and comment.

**DATES:** All comments on Utah's final approval application must be received by the close of business on November 28, 1994. The public hearing is tentatively scheduled for December 16, 1994.

**ADDRESSES:** Written comments should be sent to U.S. EPA, Attn: Leslie Zawacki, mail code (8HWM-WM), Region 8, 999 18th Street, Suite 500, Denver, Colorado 80202.

If a public hearing is held it will be at the Department of Environmental Quality, 168 North 1950 West, Salt Lake City, Utah 84116, at 1 p.m.

Copies of Utah's final approval application are available during normal working days at the following addresses for inspection and copying: from 8 a.m.—5 p.m. at the Utah Department of Environmental Quality, Division of Environmental Response and Remediation, 168 North 1950 West, 1st Floor, Salt Lake City, Utah 84116, phone: (801) 536-4100; and from 12 p.m.—4 p.m. at the U.S. EPA Region 8,

Library, Suite 144, 999 18th Street, Denver, Colorado 80202, phone: (303) 294-7616.

**FOR FURTHER INFORMATION CONTACT:** Leslie Zawacki, Underground Storage Tank Program Section, U.S. EPA, Region 8, 8HWM-WM, 999 18th Street, Denver, Colorado 80202, phone: (303) 293-1665.

**SUPPLEMENTARY INFORMATION:** EPA has tentatively scheduled a public hearing on this determination. If a sufficient number of people express interest in participating in a hearing by writing to EPA or calling the contact within 30 days of the date of publication of this notice, EPA will hold a hearing on the date given below in the **DATES** section. EPA will notify all persons who submit comments on this notice if it decides to hold the hearing. In addition, anyone who wishes to learn whether the hearing will be held may call the person listed in the **FOR FURTHER INFORMATION CONTACT** section.

#### A. Background

Section 9004 of the Resource Conservation and Recovery Act (RCRA) enables EPA to approve state underground storage tank programs to operate in the State in lieu of the Federal underground storage tank (UST) program. Program approval is granted by EPA if the Agency finds that the State program: (1) is "no less stringent" than the Federal program in all seven elements, and includes notification requirements of section 9004(a)(8), 42 U.S.C. 6991c(a)(8); and (2) provides for adequate enforcement of compliance with UST standards (Section 9004(a), 42 U.S.C. 6991c(a)).

#### B. State of Utah

In February 1986, the State of Utah established authority through the Utah Solid and Hazardous Waste Act to implement an underground storage tank program, the State further developed its authority in the UST Act in February 1989. The State adopted the federal rules and developed some additional rules in February 1989. The State submitted a draft application for state program approval in September 1992. EPA reviewed and commented on the draft application and requested additional information to be included in the final application.

On September 20, 1993, Utah submitted an official application for final approval. Prior to its submission, Utah provided an opportunity for public notice and comment in the development of its underground storage tank program as required under § 281.50(b). EPA has reviewed Utah's application, and has tentatively determined that the State's

program meets all of the requirements necessary to qualify for final approval. Consequently, EPA intends to grant final approval to Utah to operate its program in lieu of the Federal program.

This tentative determination to approve the Utah UST program applies to all activities in Utah outside of Indian Country, as defined in 18 U.S.C. 1151. The Environmental Protection Agency retains all underground storage tank authority under RCRA which applies to Indian Country in Utah.

Before EPA would be able to approve the State of Utah UST program for any portion of "Indian Country," the State would have to provide an appropriate analysis of the State's jurisdiction to enforce in these areas. In order for a state to satisfy this requirement, it must demonstrate to the EPA's satisfaction that it has authority pursuant to applicable principles of Federal Indian Law to enforce its laws against existing and potential pollution sources within any geographical area for which it seeks program approval. EPA is not satisfied that Utah has, at this time, made the requisite showing of its authority with respect to such lands.

In withholding program approval for these areas, EPA is not making a determination that the State either has adequate jurisdiction or lacks such jurisdiction. Should the State of Utah choose to submit analysis with regard to its jurisdiction over all or part of "Indian Country" in the State, it may do so without prejudice.

EPA's future evaluation of whether to approve the Utah program for "Indian Country," to include Indian reservation lands, will be governed by EPA's judgment as to whether the State has demonstrated adequate authority to justify such approval, based upon its understanding of the relevant principles of Federal Indian law and sound administrative practice. The State may wish to consider EPA's discussion of the related issue of tribal jurisdiction found in the preamble to the Indian Water Quality Standards Regulation (see 56 FR 64876, December 12, 1991).

In accordance with section 9004 of RCRA 42 U.S.C. 6991c and 40 CFR 281.50(e), the Agency will accept written comments on EPA's tentative determination until November 28, 1994. Copies of Utah's application are available for inspection and copying at the locations indicated in the "Addresses" section of this notice.

EPA will consider all public comments on its tentative determination received during the public comment period. Issues raised by those comments may be the basis for a decision to deny final approval to Utah. EPA expects to

make a final decision on whether or not to approve Utah's program by January 25, 1995 and will give notice of it in the **Federal Register**. The notice will include a summary of the reasons for the final determination and a response to all major comments.

The Office of Management and Budget has exempted this rule from the requirements of section 6 of Executive Order 12866.

Pursuant to the provisions of 5 U.S.C. 605(b), I hereby certify that this approval will not have a significant economic impact on a substantial number of small entities. The approval effectively suspends the applicability of certain Federal regulations in favor of Utah's program, thereby eliminating duplicative requirements for owners and operators of underground storage tanks in the State. It does not impose any new burdens on small entities. This rule, therefore, does not require a regulatory flexibility analysis.

#### List of Subjects in 40 CFR Part 281

Environmental protection, Administrative practice and procedure, Hazardous materials, State program approval, Underground storage tanks.

**Authority:** This notice is issued under the authority of Section 9004 of the Solid Waste Disposal Act as amended 42 U.S.C. 6991c.

Dated: October 5, 1994.

**William P. Yellowtail,**  
Regional Administrator.

[FR Doc. 94-26248 Filed 10-26-94; 8:45 am]  
BILLING CODE 6560-50-P

## DEPARTMENT OF THE INTERIOR

### Fish and Wildlife Service

#### 50 CFR Part 18

#### Development of Permit Regulations for Polar Bear Trophy Importation Under the 1994 Amendments to the Marine Mammal Protection Act

**AGENCY:** Fish and Wildlife Service, Interior.

**ACTION:** Notice of intent.

**SUMMARY:** On April 30, 1994, the Marine Mammal Protection Act (Act) was amended to allow the issuance of permits to import sport-hunted trophies of polar bears (*Ursus maritimus*) (excluding internal organs) legally taken by the applicant while hunting in Canada, provided certain findings have been made by the U.S. Fish and Wildlife Service (Service). These permits may also authorize the importation of polar bears taken, but not imported, prior to enactment of the Amendments,

provided certain conditions are met. The Service has received a number of inquiries concerning the importation of polar bear trophies. This notice provides information on the steps the Service is taking to implement this new provision of the Act and the anticipated timeframes. The Service is working concurrently on developing permit regulations and gathering data to make the legal and scientific findings required under section 104(c)(5)(A) of the Act. Applications for the import of sport-hunted polar bear trophies will not be accepted until the completion of the permit rulemaking process early in 1995. The Service will be able to act on applications once it has resolved several outstanding questions and is able to make the required scientific findings, in consultation with the Marine Mammal Commission (MMC), and after notice and opportunity for public comment. In the meantime, a list of interested parties has been established to receive all relevant information as the process proceeds.

**DATES:** The Service anticipates publishing a proposed rule of permit requirements and procedures to import polar bear trophies by November 1994 for public review and comment. A decision on the proposal is expected to be published in early 1995. A notice of proposed rulemaking on the scientific findings will be published soon thereafter.

**ADDRESSES:** To receive copies of the Federal Register notices associated with this issue, send your name and address to the U. S. Fish and Wildlife Service, Chief, Office of Management Authority, 4401 N. Fairfax Drive, room 420(c), Arlington, VA 22203. This information will be maintained on a mailing list.

**FOR FURTHER INFORMATION CONTACT:** Marshall Jones, Chief, Office of Management Authority, (703/358-2093) or Margaret Tieger, Acting Chief, Branch of Permits, (703/358-2104, extension 5507) at the above address.

**SUPPLEMENTARY INFORMATION:** Prior to enactment of amendments to the Act in 1994, those seeking authority to import polar bear trophies from Canada were required to obtain a waiver of the Act's moratorium on taking and importing

marine mammals. The 1994 Amendments included a streamlined procedure for authorizing such imports by permit. Section 104(c)(5) of the Act sets out a permitting process, as well as the specific findings that must be made before permits can be issued to import these trophies into the United States. The Service is developing proposed regulations that will outline the permit application requirements, procedures, issuance criteria, and fee. The law requires the Service to establish and charge a reasonable fee for issuing polar bear trophy import permits. As specified in the Amendments, all fees would be used for polar bear conservation programs being conducted in Alaska and Russia. The Service anticipates publishing a proposed rule promptly so, after a review of all available data and public comments, a decision can be published as early as possible in calendar year 1995.

The Service is unable to accept applications for the import of sport-hunted polar bear trophies until the permit rulemaking process is complete in early 1995. Once the Service has received comments on the application requirements under the proposed rule, an application form will be developed and submitted to the Office of Management and Budget for approval under the Paperwork Reduction Act.

At the same time that the permit rulemaking process is occurring, the Service is working with the Canadian wildlife authorities to obtain information necessary to make the findings required by section 104(c)(5)(A) of the Act. Prior to issuing a permit, the Service must find that (1) the applicant has provided the necessary documentation to show that the polar bear was legally harvested in Canada by the applicant; (2) Canada has a monitored and enforced sport-hunting program consistent with the purposes of the 1971 International Agreement on the Conservation of Polar Bears; (3) Canada's sport-hunting program is based on scientifically sound quotas ensuring the maintenance of the affected population stock at a sustainable level; (4) the export and subsequent import are consistent with the provisions of the Convention on International Trade in

Endangered Species (CITES) and other international agreements and conventions; and (5) the export and subsequent import are not likely to contribute to illegal trade in bear parts.

The Service is to make these findings after notice and opportunity for public comment and in consultation with the MMC, an independent Federal agency with statutory authority to make recommendations pursuant to Title II of the Act. Several questions have come to the attention of the Service. A contract report prepared for the MMC in 1993 has questioned whether Canada's sport-hunting program is fully consistent with Article III of the Agreement. In addition, the Amendments require the Service to make the determination of sustainability of hunting quotas at the population level, but Canada manages polar bears at the subpopulation level. The Service is currently pursuing the resolution of these and related questions concerning its ability to make the required findings. Once these questions have been resolved and the Service is able to make the findings outlined above, it will be able to act on applications. The Service seeks information regarding each of these five findings.

While conducting these activities, the Service will need to evaluate its actions under the National Environmental Policy Act (NEPA), as appropriate.

By April 30, 1996, the Service is to undertake a scientific review of the impact of permits issued on the Canadian polar bear population stocks. An opportunity for public comment will be part of this review, with the responses included in the final report. Permit issuance can continue after September 30, 1996, only if the Service determines, based on scientific review, that the issuance of permits is not having a significant adverse impact on the polar bear populations stocks in Canada.

**Authority:** 16 U.S.C. 1361 *et seq.*

Dated: October 21, 1994.

**George T. Frampton, Jr.,**  
Assistant Secretary, Fish and Wildlife and Parks.

[FR Doc. 94-26587 Filed 10-26-94; 8:45 am]

BILLING CODE 4310-55-P

# Notices

Federal Register

Vol. 59, No. 207

Thursday, October 27, 1994

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.

## AGENCY FOR INTERNATIONAL DEVELOPMENT

### Loan Guarantees to Israel; Notice of Investment Opportunity

The Government of Israel (the "GOI") wishes to select managing underwriters for the structuring and sale of U.S. Agency for International Development ("USAID")-guaranteed loans. The USAID-guaranteed loans have been authorized by Public Law 102-391, and are being provided in connection with Israel's extraordinary humanitarian effort to resettle and absorb immigrants into Israel from the republics of the former Soviet Union, Ethiopia and other countries.

The legislation authorizes the guaranty by USAID of up to \$10 billion principal amount of loans over the next five years, with a maximum of \$2 billion in loans, offered in one or more tranches, to be guaranteed in each of the five fiscal years. This Notice is in connection with the GOI's selection of managing underwriters for one or more offerings contemplated to be made under the authorization for the current fiscal year.

The GOI would like to receive proposals from interested underwriters on an expedited basis. A Request for Proposals ("RFP") will be available from the GOI on or about October 26, 1994. Proposals must be submitted, in accordance with the RFP, by 4:00 p.m. on October 31, 1994. For information regarding the submission of proposals, please contact Mr. Eliahu Ziv-Zitoun, Chief Fiscal Officer, Ministry of Finance of the Government of Israel, 350 Fifth Avenue, New York, New York 10118 (fax: 212/736-2759).

To accomplish the GOI's objectives, the GOI's lead manager must at a minimum:

1. Perform and discuss with the GOI and its financial advisor a complete quantitative analysis of the cash flows

generated by the proposed structures and proposed pricing of securities;

2. Complete the underwriting of all securities offered for sale;

3. Establish and maintain a post-sale trading market for the securities; and

4. Coordinate all activities relating to the proposed financing plan with the GOI and its financial advisor.

Selection of underwriters and the terms of the loans are initially subject to the individual discretion of the GOI and thereafter subject to approval by USAID. In order to be eligible for selection as a managing underwriter, an institution must be a member of the National Association of Securities Dealers, and otherwise meet the legal requirements for serving in such role.

The full repayment of the loans will be guaranteed by USAID. To be eligible for an USAID guaranty, the loans must be repayable in full no later than the thirtieth anniversary of the disbursement of the principal amount thereof. The USAID guaranty will be backed by the full faith and credit of the United States of America and will be issued pursuant to authority in Section 226 of the Foreign Assistance Act of 1961, as amended. Disbursements under the loans will be subject to certain conditions required of the GOI by USAID as set forth in agreements between USAID and the GOI.

Additional information regarding USAID's responsibilities in this guaranty program can be obtained from the undersigned: Room 225, 515 22nd Street NW., Washington, DC 20523-0235, telephone: 202/663-2771.

Dated: October 25, 1994.

**Michael G. Kitay,**

*Assistant General Counsel, U.S. Agency for International Development.*

[FR Doc. 94-26758 Filed 10-26-94; 8:45 am]

BILLING CODE 6116-01-M

### Privacy Act; System of Records

**AGENCY:** Agency for International Development, USAID.

**ACTION:** Notice of an amendment of a Privacy Act System of Records.

**SUMMARY:** USAID is amending system of records A.I.D.-15 "Employees Payroll Records" to change paragraph a. in the system location.

**FOR FURTHER INFORMATION CONTACT:** Jan Miller, 202-647-6380.

**SUPPLEMENTARY INFORMATION:** In System A.I.D.-15, in System location, paragraph a. is revised as follows:

*System location:* a. Office of Information Resource Management, Agency for International Development, 1100 Wilson Boulevard, Rosslyn, Virginia 22209.

\* \* \* \* \*  
Dated October 18, 1994.

**Willette L. Smith,**

*Public Affairs Specialist.*

[FR Doc. 94-26636 Filed 10-26-94; 8:45 am]

BILLING CODE 6116-01-M

### Privacy Act; System of Records

**AGENCY:** Agency for International Development, USAID.

**ACTION:** Notice of amendment of a Privacy Act System of Records.

**SUMMARY:** USAID is amending the system of records entitled A.I.D.-3 "Employees Automated Records" to include new categories of USAID employees and new data elements that have been generated by the Mission Staffing Pattern System.

**FOR FURTHER INFORMATION CONTACT:** Jan Miller, 202-647-6380.

**SUPPLEMENTARY INFORMATION:** System A.I.D.-3 is amended as follows:

1. Categories of individuals covered by the system is revised to read as follows:

- a. A.I.D. employees including: Direct-hire employees assigned positions in the United States; United States citizen direct-hire employees assigned to positions overseas; and employees of Federal, state, or local government agencies detailed or assigned to A.I.D.;

- b. Applicants for employment; and
- c. Non-direct hires such as Personal Services Contractors.

2. In "Categories of records in the system", the introductory text is revised and paragraph k. is added to read as follows: This automated system consists of eleven files of computerized records maintained on magnetic discs and magnetic tapes. These files are described below. The first seven (a through g) and the tenth (j) pertain to the category of individuals defined in a. above; the eighth (h) pertains only to the category of individuals defined in b. above; the ninth file (i) is maintained separately from the other eight files; the

eleventh (k) pertains to category of individuals defined in a. and b. above.

\* \* \* \* \*

k. New Data File—Automated Mission Staffing Pattern System that will include a record on each USAID employee (both direct and non-direct hire) and consists of the following information: data elements previously identified in the Master Data File and additional data elements such as only that designates local, U.S. or third country hire, Contract Start and End Dates, to be used for personal contractors only, Total Cost Existing Contract, to be used for personal contractors only, and All Other Annual Costs. This data file is the only file that contains information on non-direct hires.

3. In Policies and practices for storing, retrieving, accessing, retaining, and disposing of records in the system, in "Retrievability" the introductory text is revised and paragraph k. is added to read as follows.

*Retrievability:* The eleven files described above are indexed in the following manner and may be retrieved as indicated; however, personal data in all files are readily retrieved through the Index File.

\* \* \* \* \*

(k) Automated Mission Staffing Pattern System: by Organization

4. The first paragraph in "System Manager(s) and address" is revised to read as follows:

*System manager(s) and address:* Chief, Office of Information Resources Management, Agency for International Development, 1100 Wilson Boulevard, Rosslyn, Virginia 22209.

\* \* \* \* \*

Dated: October 18, 1994.

Willette L. Smith,

Public Affairs Specialist.

[FR Doc. 94-26635 Filed 10-26-94; 8:45 am]

BILLING CODE 6116-01-M

## DEPARTMENT OF AGRICULTURE

### Animal and Plant Health Inspection Service

[Docket No. 94-095-1]

#### Availability of Environmental Assessment and Finding of No Significant Impact

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Notice.

**SUMMARY:** We are advising the public that an environmental assessment and finding of no significant impact have been prepared by the Animal and Plant Health Inspection Service relative to the renewal of a permit to allow the field testing of genetically engineered organisms. The environmental assessment provides a basis for our conclusion that the field testing of the genetically engineered organisms will not present a risk of introducing or disseminating a plant pest and will not have a significant impact on the quality of the human environment. Based on its finding of no significant impact, the Animal and Plant Health Inspection Service has determined that an environmental impact statement need not be prepared.

**ADDRESSES:** Copies of the environmental assessment and finding of no significant impact are available for public inspection 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. Persons wishing to inspect those documents are requested to call ahead on (202) 690-2817 to facilitate entry into the reading room.

**FOR FURTHER INFORMATION CONTACT:** Dr. Arnold Foudin, Deputy Director, Biotechnology Permits, BBEP, APHIS, USDA, room 850, Federal Building, 6505 Belcrest Road, Hyattsville, MD 20782, (301) 436-7612. For copies of the environmental assessment and finding of no significant impact, write to Mr. Clayton Givens at the same address.

Please refer to the permit number listed below when ordering the document.

**SUPPLEMENTARY INFORMATION:** The regulations in 7 CFR part 340 (referred to below as the regulations) regulate the introduction (importation, interstate movement, and release into the environment) of genetically engineered organisms and products that are plant pests or that there is reason to believe are plant pests (regulated articles). A permit must be obtained before a regulated article may be introduced into the United States. The regulations set forth the procedures for obtaining a limited permit for the importation or interstate movement of a regulated article and for obtaining a permit for the release into the environment of a regulated article. The Animal and Plant Health Inspection Service (APHIS) has stated that it would prepare an environmental assessment and, when necessary, an environmental impact statement before issuing a permit for the release into the environment of a regulated article (see 52 FR 22906).

In the course of reviewing each permit application, APHIS assessed the impact on the environment that releasing the organisms under the conditions described in the permit application would have. APHIS has issued a permit for the field testing of the organisms listed below after concluding that the organisms will not present a risk of plant pest introduction or dissemination and will not have a significant impact on the quality of the human environment. The environmental assessment and finding of no significant impact, which are based on data submitted by the applicants and on a review of other relevant literature, provide the public with documentation of APHIS' review and analysis of the environmental impacts associated with conducting the field tests.

The environmental assessment and finding of no significant impact have been prepared by APHIS relative to the issuance of a permit to allow the field testing of the following genetically engineered organisms:

Permit No.	Permittee	Date issued	Organisms	Field test location
94-196-01, renewal of permit 92-156-01, issued on 9-23-92.	Calgene, Incorporated ..	8-18-94	Canola plants genetically engineered to express oil modification genes.	Georgia.

The environmental assessment and finding of no significant impact have been prepared in accordance with: (1) The National Environmental Policy Act of 1969 (NEPA) (42 U.S.C. 4321 *et seq.*), (2) Regulations of the Council on

Environmental Quality for Implementing the Procedural Provisions of NEPA (40 CFR parts 1500-1508), (3) USDA Regulations Implementing NEPA (7 CFR part 1b), and (4) APHIS Guidelines Implementing NEPA (44 FR

50381-50384, August 28, 1979, and 44 FR 51272-51274, August 31, 1979).

Done in Washington, DC, this 21st day of October 1994.

Terry L. Medley,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 94-26637 Filed 10-26-94; 8:45 am]

BILLING CODE 3410-34-P

## ARMS CONTROL AND DISARMAMENT AGENCY

### Performance Review Board; Membership

AGENCY: Arms Control and Disarmament Agency.

ACTION: Notice of membership of Performance Review Board.

SUMMARY: In accordance with 5 U.S.C. 4314(c)(4), the U.S. Arms Control and Disarmament Agency announces the appointment of Performance Review Board members.

EFFECTIVE DATE: January 1, 1995.

FOR FURTHER INFORMATION CONTACT: Nancy Aderholdt, Director of Personnel, U.S. Arms Control and Disarmament Agency, Washington, D.C. 20451 (202) 647-2034.

The following are the names and present titles of the individuals appointed to the register from which Performance Review Boards will be established by the U.S. Arms Control and Disarmament Agency during the period beginning on the effective date of this notice and ending when a new register is published and becomes effective in approximately one year. Specific Performance Review Boards will be established as needed from this register.

These appointments supersede those in the announcement published at 58 FR 60177 on November 15, 1993.

Name	Title
Ralph Earle, II ...	Deputy Director.
Lisa Farrell .....	Chief of staff.
Victor Alessi .....	Executive Assistant.
Donald Gross ....	Senior Policy Analyst.
Thomas Graham, Jr..	Special Representative-NPT.
James Sweeney	Special Representative-CSA.
Robert Sherman	Executive Director, SPAC.
Amy Sands .....	Assistant Director, Intelligence, Verification and Information Support Bureau.
O. James Sheaks.	Deputy Assistant Director, Intelligence, Verification and Information Support Bureau.

Name	Title
Alfred Lieberman.	Chief, Operations Analysis and Information Management Office, Intelligence, Verification and Information Support Bureau.
Lawrence Scheinman.	Assistant Director, Nonproliferation and Regional Arms Control Bureau.
Norman Wulf .....	Deputy Assistant Director, Nonproliferation and Regional Arms Control Bureau.
Robert Rochlin ..	Chief Scientist, Nonproliferation and Regional Arms Control Bureau.
Michael Rosenthal.	Chief, International Nuclear Affairs Division, Nonproliferation and Regional Arms Control Bureau.
Lori Esposito Murray.	Assistant Director, Multilateral Affairs Bureau.
Donald Mahley ..	Deputy Assistant Director, Multilateral Affairs Bureau.
Michael Guhin ...	Associate Assistant Director, Multilateral Affairs Bureau.
William Staples	Chief, Scientific & Technological Policy Division, Multilateral Affairs Bureau.
Nacht, Michael ..	Assistant Director, Strategic and Eurasian Affairs Bureau.
R. Lucas Fischer	Deputy Assistant Director, Strategic and Eurasian Affairs Bureau.
Stanley Riveles ..	Chief, Strategic Negotiations & Implementation Division, Strategic and Eurasian Affairs Bureau.
Karin Look .....	Chief, Strategic Transition Division, Strategic and Eurasian Affairs Bureau.
David Wollan ....	Chief, Theater and Strategic Defenses Division, Strategic and Eurasian Affairs Bureau.
Robert Summers	Chief, Defense Conversion Division, Strategic and Eurasian Affairs Bureau.
Cathleen Lawrence.	Director of Administration, Office of Administration.
Mary Elizabeth Hoinkes.	General Counsel.
Joerg Menzel ....	Principal Deputy of the On-Site Inspection Agency.

Cathleen Lawrence,

Director of Administration.

[FR Doc. 94-26674 Filed 10-26-94; 8:45 am]

BILLING CODE 6820-32-M

## BIPARTISAN COMMISSION ON ENTITLEMENT AND TAX REFORM

### Meeting

Notice is hereby given, pursuant to Public Law 92-463, that the Bipartisan Commission on Entitlement and Tax Reform will hold a meeting on November 21, 1994, at 1:00 p.m. in the Cannon House Office Building, Room 210, Washington, DC 20510.

The meeting of the Commission shall be open to the public. The proposed agenda includes discussion of issues relating to the Commission's charter, including but not limited to, options for controlling the spiraling growth on entitlement expenditures and the need to examine the structure of the current federal income tax system.

Records shall be kept of all Commission proceedings and shall be available for public inspection in Room 825 of the Hart Senate Office Building, 120 Constitution Avenue, NE., Washington, DC 20510.

J. Robert Kerrey,

Chairman.

John C. Danforth,

Vice Chairman.

[FR Doc. 94-26584 Filed 10-26-94; 8:45 am]

BILLING CODE 4151-04-M

### Meeting

Notice is hereby given, pursuant to Public Law 92-463, that the Bipartisan Commission on Entitlement and Tax Reform will hold a meeting on November 30, 1994, at 1:00 p.m. in the Cannon House Office Building, Room 210, Washington, D.C. 20510.

The meeting of the Commission shall be open to the public. The proposed agenda includes discussion and possible adoption of policy recommendations relating to the Commission's charter, including but not limited to, options for controlling the spiraling growth on entitlement expenditures and the need to examine the structure of the current federal income tax system.

Records shall be kept of all Commission proceedings and shall be available for public inspection in Room 825 of the Hart Senate Office Building, 120 Constitution Avenue, N.E., Washington, D.C. 20510.

J. Robert Kerrey,

Chairman.

John C. Danforth,

Vice Chairman.

[FR Doc. 94-26585 Filed 10-26-94; 8:45 am]

BILLING CODE 4151-04-M

## DEPARTMENT OF COMMERCE

## National Institute of Standards and Technology

[Docket Number 940980-4280]

## Announcement of Available Funding for Competitions-Advanced Technology Program (ATP)

AGENCY: National Institute of Standards and Technology, Technology Administration, Commerce.

ACTION: Notice.

**SUMMARY:** The Technology Administration's National Institute of Standards and Technology (NIST) announces available funding for various competitions under the Advanced Technology Program (ATP). During 1995, the ATP will hold the following competitions:

(1) General Competition 95-01 in which proposals in all areas of technology meeting the ATP criteria are solicited, and;

(2) Several Program Competitions focused on specific technology or technology application areas.

This notice provides general information for all the competitions planned for 1995. Proposal due dates, program competition topics, and other competition-specific instructions for the General Competition and each of the Program Competitions will be published in the Commerce Business Daily (CBD) at a later date.

Those interested in applying for ATP funding must contact the ATP at the address shown later in this notice to obtain application materials. The Proposal Preparation Kit available upon request from the ATP contains the application forms, background material, and instructions referenced in this notice. The new ATP Proposal Preparation Kit may be used either for General Competitions or Program Competitions. The Advanced Technology Program is Program Number 11.612 in the Catalog of Federal Domestic Assistance.

Due dates for the general and program competition will be published in the CBD at the time each competition is announced. Should there ever be an extension of the due date for any ATP competition, that information will be provided via a notice published in the CBD as well as a recorded message on the ATP toll-free "Hotline" number (1-800-ATP-FUND). For this reason, we recommend that applicants check this recorded message prior to the closing date.

The specific date and location will be announced in the CBD regarding a

public meeting for parties considering applying for funding in the ATP General Competition 95-01. Attendance at this public meeting is not required of potential proposers. The purpose of the meeting is to provide general information regarding the ATP procedures, selection process, and proposal preparation to potential applicants unfamiliar with the ATP. No discussion of specific proposals will occur at this meeting. Dates and times of analogous public meetings for the program competitions will be announced in the CBD, transmitted to those on the ATP mailing list, and described on the ATP toll-free Hotline.

**FOR FURTHER INFORMATION CONTACT:** To request a copy of the ATP Proposal Preparation Kit and to have your name added to the ATP mailing list for future mailings use whichever of these four options is the most convenient for you:

(1) Call the ATP toll-free number, 1-800-ATP-FUND. You will have the option of hearing recorded messages regarding the status of the ATP or speaking to one of our customer representatives who will take your name and address. If our representatives are all busy when you call, leave a message after the tone. To ensure that the information is entered correctly, please speak distinctly and slowly and spell the words that might cause confusion. Leave your phone number as well as your name and address.

(2) Contact ATP via fax at (301) 926-9524. A backup fax number is (301) 869-1150.

(3) Contact ATP via electronic mail at [atp@micf.nist.gov](mailto:atp@micf.nist.gov). Include your name, full mailing address and phone number.

(4) Write to the ATP at the address shown below:

Advanced Technology Program,  
Administration Building (101), Room  
A430, National Institute of Standards  
and Technology, Quince Orchard at  
Clopper Road, Gaithersburg, MD 20899-  
0001.

Note that the ATP is mailing new Proposal Preparation Kits to all those individuals whose names are currently in the ATP computer data base. Such individuals need not contact the ATP to request a kit. The anticipated mailing date is sometime this winter. The ATP toll-free Hotline message stated above will report when this mailing is made.

**SUPPLEMENTARY INFORMATION:****Background**

The ATP is managed by the National Institute of Standards and Technology, an element of the Technology Administration (TA) of the Department of Commerce. ATP was established by

section 5131 of the Omnibus Trade and Competitiveness Act of 1988 (Pub. L. 100-418, 15 U.S.C. 278n), as modified by Public Law 102-245.

The ATP works with U.S. industry to advance the nation's competitiveness—and economy—by helping to fund the development of high-risk but powerful new technologies that underlie a broad spectrum of potential new applications, commercial products, and services. Through cooperative agreements with individual companies or groups of companies, large and small, the ATP invests in industrial projects to develop technologies with high-payoff potential for the nation. The ATP accelerates technologies that—because they are risky—are unlikely to be developed in time to compete in rapidly changing world markets without such a partnership of industry and government. By sharing the cost of such projects, the ATP catalyzes industry to pursue promising technologies. The Proposal Preparation Kit expands on the goals of the ATP and describes in detail what constitutes a good ATP proposal.

The ATP operates under program procedures published at part 295, title 15, of the Code of Federal Regulations. These procedures were updated (59 FR, page 663, January 6, 1994). A copy of the updated version of these procedures is provided in the ATP Proposal Preparation Kit.

Cooperative research agreements rather than grants are the funding instruments used for ATP awards. A cooperative research agreement differs from a grant with respect to the amount of interaction between the Federal Government and the recipient, and is used to provide financial assistance when substantial involvement is anticipated between the government and the recipient.

**Invitation for Proposals**

The ATP CBD notices to be published later will invite applications for funding from:

(1) Individual United States businesses in amounts not to exceed \$2 million (federal share) over three years. Single applicants must fund all indirect costs associated with the project.

(2) Industry-led joint research and development ventures, where ATP support will serve as a catalyst for the proposed joint venture project, and provided, however, that the ATP share is a minority share of the cost of the venture for up to five years.

Applicant eligibility is discussed in detail in the ATP Proposal Preparation Kit.

All awards are subject to the availability of appropriations. Future or

continued funding for multi-year projects will be at the discretion of NIST and will be contingent on such factors as satisfactory performance and the availability of funds.

#### Abbreviated Proposals

ATP reserves the right to use abbreviated proposal for any general or program competition. Information regarding the use of abbreviated proposals will be included in the CBD announcement of that specific competition. The purpose of abbreviated proposals is to provide applicants with limited resources early feedback regarding whether the proposed project falls within the scope of the ATP and whether the project proposed appears sufficiently promising relative to the selection criteria to warrant preparation of a full proposal. In competitions where abbreviated proposals are accepted, applicants who submit such proposals will be notified in writing whether or not ATP recommends submission of a full proposal.

ATP may provide feedback to proposers in one of the following three ways:

- (1) (Used for abbreviated proposals only); A written transmittal giving a yes/no recommendation regarding preparation of a full proposal;
- (2) A checklist noting concerns regarding the proposal or abbreviated proposal. This transmittal may be accompanied by a statement summarizing common shortcomings noted in the proposals submitted to that competition;
- (3) An oral debriefing by telephone summarizing the strengths and weaknesses of the proposal.

Which of these feedback mechanisms is used will depend on the competition and may depend on the number of proposals received.

Proprietary information is abbreviated and full proposals will be protected. If your proposal contains proprietary information, mark it accordingly; however, the title page must not include proprietary information. We recommend including the following legend on the title page: "Proposal contains proprietary information. Title page nonproprietary."

Full proposals must be prepared in accordance with the instructions in the ATP Proposal Preparation Kit. In competitions involving abbreviated proposals, heed the general advice provided in the ATP Proposal Preparation Kit, but follow the specific instructions announced in the specific CBD announcements.

#### Funds Available for Cooperative Research Agreements

An estimated \$20 to \$25 million in first-year funding will be available for General Competition 95-01. The number of awards will depend on the quality of the proposals received and the amount of funding requested by the proposals under consideration for awards. Based on ATP's experience the number of awards is unlikely to exceed 30. An estimated \$100 to \$125 million in first-year funding will be available for the several program competition to be announced. For every ATP competition, NIST reserves the right to fund proposals totalling more or less than the amount of funding tentatively allocated to that competition if the number of high quality proposals received is judged to be greater or fewer respectively than anticipated.

#### Preparation of Full Proposal and Reporting Requirements

The ATP Proposal Preparation Kit, available from the ATP, contains background material on the ATP, detailed contents and formatting guidelines for the preparation of full proposals, and the required forms. Also included is information of reporting and audit requirements for recipients. To be accepted for review, full proposals must meet all of the requirements outlined in the Kit. Full proposals that fail to meet one or more of those requirements will be considered non-responsive to the solicitation.

#### Award Criteria and Proposal Review Process

The criteria used to evaluate proposals submitted to the ATP and the proposal review process are documented in the Proposal Preparation Kit.

#### Negotiation of Cooperative Agreements

NIST reserves the right to negotiate project scope and funding levels with ATP cooperative research agreement recipients.

#### Submission of Revised Proposals

An applicant may submit a full proposal that is a revised version of a full proposal submitted to a previous ATP competition. NIST will examine such proposals to determine whether substantial revisions have been made. Where the revisions are determined not to be substantial, NIST reserves the right to score and rank, or where appropriate, to reject, such proposals based on reviews of the previously-submitted proposal.

#### Transfer of Proposals

NIST reserves the right to transfer a full proposal received in response to a General Competition invitation to a Program Competition underway in the same general timeframe if the subject matter of the proposal clearly falls within the scope of the Program Competition. NIST will not transfer proposals from Program Competitions to General Competitions. Applicants will be notified if and when a proposal is transferred from a General Competition to a Program Competition.

#### Other Requirements, Requests, and Provisions

No award of Federal funds shall be made to an applicant or recipient who has an outstanding delinquent Federal debt until either the delinquent account is paid in full, a negotiated repayment schedule is established and at least one payment is received, or other arrangements satisfactory to the Department are made.

All for-profit and nonprofit applicants are subject to a name check review process. Name checks are intended to reveal if any key individuals associated with the applicant have been convicted of or are presently facing criminal charges such as fraud, theft, perjury, or other matters which significantly reflect on the applicant's management honesty or financial integrity.

Unsatisfactory performance under prior Federal awards may result in an application not being considered for funding.

If applicants incur any costs prior to an award being made, they do so solely at their own risk of not being reimbursed by the Government. Notwithstanding any verbal or written assurance that may have been received, there is no obligation on the part of the Department of Commerce to cover pre-award costs.

#### Primary Applicant Certification

All primary applicants must submit a completed form CD-511, "Certifications Regarding Debarment, Suspension, and Other Responsibility Matters; Drug-Free Workplace Requirements and Lobbying," and the following explanation is hereby provided:

a. Nonprocurement Debarment and Suspension—Prospective participants, as defined at 15 CFR part 26, section 105 are subject to 15 CFR part 26, "Nonprocurement Debarment and Suspension" and the related section of the certification form prescribed above applies;

b. Drug-Free Workplace—Grantees (as defined at 15 CFR part 605) are subject

to 15 CFR 26, subpart F, "Governmentwide Requirements for Drug-Free Workplace (Grants)" and the related section of the certification form prescribed above applies;

c. **Anti-Lobbying**—Persons (as defined at 15 CFR part 28, section 105) are subject to the lobbying provisions of 31 USC 1352, "Limitations on use of appropriated funds to influence certain Federal contracting and financial transactions," and the lobbying section of the certification form prescribed above applies to applications/bids for grants, cooperative agreements, and contracts for more than \$100,000, and loans and loan guarantees for more than \$150,000, or the single family maximum mortgage limit for affected programs, whichever is greater; and,

d. **Anti-Lobbying Disclosures**—Any applicant that has paid or will pay for lobbying using any funds must submit an SF-LLL, "Disclosure of Lobbying Activities," as required under 15 CFR part 28, Appendix B.

**Lower Tier Certification**—Recipients shall require applicants/bidders for subgrants, contracts, subcontracts, or other lower tier covered transactions at any tier under the award to submit, if applicable, a completed Form CD-512, "Certifications Regarding Debarment, Suspension, Ineligibility and Voluntary Exclusion—Lower Tier Covered Transactions and Lobbying" and Form SF-LLL, "Disclosure of Lobbying Activities." Although the CD-512 is intended for the use of primary recipients and should not be transmitted to NIST, the SF-LLL submitted by any tier recipient or subrecipient should be forwarded in accordance with the instructions contained in the award document.

A false statement on any application for funding under ATP may be grounds for denial or termination of funds and grounds for possible punishment by a fine or imprisonment as provided in 18 U.S.C. 1001. The ATP does not involve the mandatory payment of any matching funds from state or local government and does not affect directly any state or local government. Accordingly, the Department of Commerce has determined that Executive Order 12372, "Intergovernmental Review of Federal Programs" is not applicable to this program. Recipients and subrecipients are subject to all Federal laws and Federal and Department of Commerce policies, regulations and procedures applicable to financial assistance awards.

Applicants are hereby notified that any equipment or products authorized to be purchased with funding provided under this program must be American-

made to the maximum extent feasible in accordance with Public Law 103-317, section 607 (a) and (b). Adequate justification will be required for any proposed purchase of equipment or products that are not American-made.

Dated: October 21, 1994.

**Arati Prabhakar,**

*Director, NIST.*

[FR Doc. 94-26658 Filed 10-26-94; 8:45 am]

BILLING CODE 3510-13-M

## COMMISSION OF FINE ARTS

### Notice of Meeting

The Commission of Fine Arts' next meeting is scheduled for 17 November 1994 at 10:00 a.m. in the Commission's offices in the Pension Building, Suite 312, Judiciary Square, 441 F Street, NW., Washington, DC 20001 to discuss various projects affecting the appearance of Washington, DC, including buildings, memorials, parks, etc.; also matters of design referred by other agencies of the government.

Inquiries regarding the agenda and requests to submit written or oral statements should be addressed to Charles H. Atherton, Secretary, Commission of Fine Arts, at the above address or call 202-504-2200.

Dated in Washington, DC, October 21, 1994.

**Charles H. Atherton,**

*Secretary.*

[FR Doc. 94-26631 Filed 10-26-94; 8:45 am]

BILLING CODE 6330-01-M

## CORPORATION FOR NATIONAL SERVICE

**AmeriCorps State and Direct Grant Program, Learn and Serve America K-12 Grant Program, and Learn and Serve America Higher Ed Grant Program 1995 Policies and Priorities**

**ACTION:** Notice.

**SUMMARY:** The Corporation for National and Community Service (the Corporation) is proposing changes and inviting comments with regard to three of its main programs: AmeriCorps\*USA, Learn & Serve America K-12, and Learn & Serve America Higher Education. This notice is divided into three parts corresponding to these programs. The proposed changes—which would apply to the FY 1995 grant cycle—were developed in response to lessons learned with the completion of the Corporation's first grant cycle and are non-regulatory in nature. A broad range of areas is covered, including the

following: a revised timeline; revised applications; proposed criteria for the renewal of grants; revised priorities within the main issue areas of education, public safety, human needs and the environment; guidelines for the continued improvement of programs; revisions to the selection criteria for programs; and additional priorities that will be given in the selection processes. The Corporation invites all interested parties to comment on the issues discussed in this notice. Any comments received will be given careful consideration in the development of final FY 1995 policies and grant applications.

**DATES:** Comments on the Corporation's AmeriCorps State and Direct Grant Program, and Learn and Serve America Higher Ed Grant Program 1995 policies and priorities must be received no later than November 28, 1994. Due to application deadlines, comments on the Learn and Serve America K-12 Grant Program 1995 policies and priorities must be received no later than November 14, 1994.

**ADDRESSES:** Responses to this notice may be mailed to the Office of AmeriCorps Programs, The Corporation for National Service, 1110 Vermont Avenue, NW., Washington, DC 20525, between 9 a.m. and 5 p.m.

**FOR FURTHER INFORMATION CONTACT:** Rusty Greiff, General Counsel's office, at (202) 606-5000 x. 256 between the hours of 9 a.m. and 6 p.m. Eastern Standard Time. For individuals with disabilities, information will be made available in alternative formats, upon request.

### SUPPLEMENTARY INFORMATION:

#### Applications

The Corporation invites comments on the following FY 1994 applications. Interested parties who do not have copies of these applications should obtain one through their State Commissions:

*AmeriCorps*

National Direct Application  
State Application

*Learn and Serve America—K-12*

School-Based Programs—State  
Educational Agencies  
School-Based Programs—Grantmaking  
Entities

School-Based Programs—Indian Tribes  
and U.S. Territories

School-Based Programs—Chief  
Executive Officer's Fund for the  
Advancement of Service Learning

School-Based Programs—Local  
Educational Agencies

Community-Based Programs—State  
Commissions and Grantmaking  
EntitiesLearn and Serve America—Higher  
Education1995 GRANT TIMELINE  
(Revised 10/18/94, 4 pm)

	Distribute appli- cations	Application due dates	Notification	Program startup
AmeriCorps State: Renewals .....	Dec. 5 .....	March 31 .....	June 15 .....	Sept. 1, 1995.
New Applications .....	Dec. 5 .....	March 31 .....	June 15 .....	Sept. 1, 1995.
AmeriCorps Direct: Renewals/Expansions .....	Dec. 5 .....	March 1 .....	May 10 .....	Sept. 1, 1995.
New Applications (Includes Planning Grants) .....	Dec. 5 .....	March 15 .....	May 10 .....	Sept. 1, 1995.
Learn & Serve—HE: Renewals .....	Dec. 5 .....	Feb. 28 (Progress Re- port)- March 21 .....	May 15 .....	Sept. 1, 1995.
New Applications .....	Dec. 5 .....	March 21 .....	May 15 .....	Sept. 1, 1995.
Learn & Serve—K-12: Renewals .....	Nov. 15 .....	Jan. 20 .....	April 10 .....	Sept. 1, 1995.
New Applications .....	Nov. 15 .....	Jan. 20 .....	April 10 .....	Sept. 1, 1995.
Subtitle H Innovative and Demonstration Programs .....	Jan. 15 .....	April 13 .....	July 1 .....	Sept. 1, 1995.

Copies of these applications are available through the individual State Commissions and the Corporation for those who wish to review them and provide feedback to the Corporation.

**AmeriCorps State and National Direct  
Federal Grant Programs****I. Policies and Guidelines for Renewals  
of Existing Grantees****A. Renewals**

The Corporation in general anticipates renewing grants for existing programs that meet quality standards. However, renewals are not automatic, and will be evaluated on the following renewal criteria:

**1. Year One Progress to Date (80%)**

The degree to which grantees have made reasonable progress towards objectives and can articulate problems or issues that occurred in the first year. These include objectives related to members, the community and the program itself, including:

a. Development of well-organized service activities which have direct and demonstrable results.

b. Degree of community support and involvement and evidence of impact on the community

c. Quality of financial management and extent to which the match has been raised or exceeded.

d. Quality of program management and the extent to which high-quality program staff have been selected, trained and placed.

e. The degree to which recruitment goals have been met and the AmeriCorps members have been retained in the program.

f. National Identity—The extent to which the program is recognizable as AmeriCorps in the community and by the members.

g. State commissions, national non-profits and federal agencies serving as grantors will also be evaluated on:

i. Their success in following the timeline and workplan for getting grant awards to programs, monitoring their progress and providing technical assistance.

ii. The extent to which issues and problems have been promptly and effectively addressed.

iii. The extent to which they have implemented plans to evaluate programs.

**2. Year Two Plans (20%).**

a. Clear articulation of problems encountered in Year One and how they will be addressed in Year Two.

b. A sound plan for sensible growth and improvement.

c. If expansion is planned, clear and compelling programmatic reasons for doing so and the organization's capacity to expand.

d. If expansion is planned, the extent to which the organization's Year One activities warrant expansion.

e. Clear and well-thought-out program objectives for Year Two that are consistent with Year One.

f. State commissions, national non-profits and federal agencies serving as grantors will also be evaluated on:

i. the quality of their plans for expansion;

ii. the quality of the plan for technical assistance and program monitoring;

iii. the degree to which they understand problems they encountered

in Year One and how they will address them in Year Two;

4. If, for State Commission grantors only, the state plan has been revised, the degree to which it reflects the state's experience with AmeriCorps and Learn and Serve programs; and

5. The quality of the state's framework, for State Commission grantors only, within which comprehensive program monitoring and evaluations can be made.

**B. Conversion of Planning Grants to  
Operating Grants for Formula-Funding**

The Corporation is recommending that State Commissions give priority to converting Formula-funded planning grants to operational programs over new applications, if the proposals meet quality standards.

**C. Members, Site, Program, Budget  
Expansion Criteria**

The Corporation will give priority to expanding the number of members in existing program sites, and to expanding the number of sites themselves, if the program has a solid track record and sound needs and plans for expansion and meets the other criteria for renewal. If the expansion request exceeds 25% of the Year One budget or the planned expansion is to base the program in two different cities, then the program expansion will be considered a new application and will not receive priority.

**D. Issue Area Priorities**

The Corporation has not changed the priority area emphases for renewals. This decision reflects the Corporation's belief that the extension of these

priorities during the renewal process will contribute to building successful programs and stronger relationships with the field. The priority areas for renewals are:

#### 1. Public Safety

a. Crime Control and Response—Improving criminal justice services, law enforcement, and victim services.

b. Crime Prevention—Reducing the incidence of violence.

#### 2. Education

a. School Readiness—Further early childhood development.

b. School Success—Improve the educational achievement of school-age youth and adults who lack basic academic skills by utilizing comprehensive strategies with potential for long-term impact.

#### 3. Human Needs

a. Health—Provide comprehensive health prevention, wellness, and community-based health care.

b. Home—Reduce the number of homeless Americans, open housing markets to minorities, empower and revitalize rural, suburban and urban communities.

#### 4. Environment

a. Neighborhood Environment—Promote sustainable communities by reducing environmental risks, especially in low income neighborhoods, and by incorporating environmental design and technologies to conserve natural and cultural resources.

b. Natural Environment—Conserve, restore and sustain natural habitats.

### II. Policies and Preferences for New State Competitive and National Direct Applicants

In addition to those preferences and objectives described by the Corporation's statute and regulations, the Corporation's recommendations reflect our objectives of encouraging new applicants to focus on our new priorities. The Corporation's recommendations reflect our objective to encourage the tailoring of our FY 1994 priorities for new applicants. The Corporation will solicit proposals for new programs which supplement the existing range of AmeriCorps programs, including new models in priority areas not covered by existing programs.

#### A. Issue Areas To Be Targeted

Outlined below are staff recommendations on the issue areas to be targeted for new state competitive and national direct program applications:

1. Community Policing—Supporting community policing efforts through building partnerships with neighborhood residents, identifying community problems, and working with police officers to solve these problems.

2. Victim Assistance—Working on programs in public agencies or community-based organizations to provide a wide range of support services to victims of crime and to help link victims to other providers of information and services within the justice system and community.

3. Neighborhood Environment—Initiate innovative grass-roots programs in low income neighborhoods that promote sustainable communities by reducing environmental risks, and conserving natural resources.

4. Early childhood development—Improve the health and school readiness of young children through child care, Head Start, and other pre-school programs; programs to improve parenting skills and community-based efforts to provide comprehensive services to families with young children (including pregnant women).

5. School Success—Broaden or coordinate the range of services available through schools such as tutoring, after-school enrichment programs, service-learning, health and child care service and efforts to involve parents in their children's education as part of a comprehensive strategy to improve school achievement and student retention.

#### B. Programmatic Preferences

The Corporation will give preferences to new applicants who integrate the following into their proposals:

##### 1. Concentration

The Corporation is encouraging programs to concentrate the efforts of AmeriCorps Members. In general, preference will be given to programs that propose service activities at fewer sites rather than more sites, that focus activities in the priority areas, and that involve groups of Corps Members in contrast to individually-placed Corps Members. Similarly, programs that regularly bring Corps Members together for training, identity, and service will be preferred over those that propose more diffused organizations.

##### 2. Specialization

Programs that propose to develop priority area specializations are accorded preference over programs with a more generalist focus. Specifically not encouraged are programs that propose to engage Corps Members in many activities addressing many priorities.

##### 3. Diversity

Programs that show a specific strategy for attracting members with diverse backgrounds will be given a preference. The Corporation encourages programs to treat diversity broadly, searching beyond their ordinary participant base to include, for example, individuals from other ethnic groups and people with disabilities. Programs are encouraged, if appropriate, to include intergenerational components.

##### 4. Education Awards Only

Because the Corporation has more funds available for education awards than for program costs, we continue to urge applicants that have adequate resources to cover program costs to request education awards only.

#### C. Localities for Concentration

Empowerment Zones, Enterprise Communities and areas affected by military downsizing. The Corporation will accord special consideration to applicants who propose to sponsor AmeriCorps service activities in officially-designated empowerment zones or enterprise communities, and areas impacted by military downsizing.

#### D. Selection Criteria

Selection criteria for new applicants remain those established in 1994, based on the quality of the proposal and the proposed program's ability to:

1. Get things done in communities.
2. Strengthen communities.
3. Expand opportunities for members.
4. Encourage responsibility.
5. Be innovative.
6. Be replicated in other areas.
7. Be sustained beyond Corporation support.

#### Learn and Serve America K-12 Grant Program

All Learn and Serve America: School- and Community-Based Programs address needs within at least one of the four priority areas of the Corporation: Environment, Education, Human Needs and Public Safety. Because the objectives of Learn and Serve America focus more on education reform and participant development, however, it is critical for us to focus primarily on program improvement and quality priorities, rather than issue areas. Therefore the policies and priorities for renewals of existing grantees and new applicants are the same.

#### I. Renewals

In general, the Corporation anticipates renewing grants for existing programs that meet quality standards. However, renewals are not automatic. Renewal

applications for Learn and Serve America K-12 grants to State Educational Agencies will be evaluated based on the following criteria.

#### A. Quality of the Year Two Plan (60%)

##### 1. Goals and Objectives

The goals and objectives of the plan are:

- Clearly stated.
- Measurable.
- Achievable.
- Time-phased.
- Appropriate & effective vehicles for promoting service-learning.

##### 2. Design and Activities

The design and activities set forth in the plan:

- Are clearly related to achieving stated goals and objectives.
- Meet community needs and involves individuals from diverse backgrounds (including economically disadvantaged youth and individuals with physical or cognitive disabilities) who will serve together to explore the underlying causes of community problems.
- Involve youth in the planning, implementation, and evaluation of the plan.
- Provide for productive and meaningful educational experiences which incorporate service-learning methods.

##### 3. Learn and Serve America Priorities

The quality and extent to which the goals and objectives and program design address the following programmatic priorities:

- Infrastructure and capacity-building.
- Partnerships with other education reform efforts.
- Qualitative/quantitative research and evaluation.
- Coordinated streams of service.

##### 4. Organizational Capacity

The plan describes sound processes for:

- Training.
- Technical assistance.
- Supervision.
- Quality control.
- Evaluation.
- Administration.
- Equitable distribution of funds to local grantees.
- Ensuring quality and evaluating the efforts of the grantee and local subgrantees.
- The principal leaders who will implement the plan are well qualified for their responsibilities.

##### 5. Evaluation

The plan includes an adequate process for evaluating:

- Overall performance (of the grantee and subgrantees).
- Program activities.
- Youth development/educational outcomes.
- Community impact.

##### 6. Sustainability

The extent to which the applicant:

- Demonstrates the ability and willingness to collaborate with the State Commission, Alternative Administrative Entity, or Transitional Entity.
- Fosters collaborative efforts among local educational agencies, local government agencies, community-based agencies, businesses, and State agencies.
- Has strong, broad-based partnerships and community support.
- Presents evidence that financial resources will be available to continue the Learn and Serve America effort after the expiration of the grant.

- Has strong, broad-based partnerships and community support.
- Presents evidence that financial resources will be available to continue the Learn and Serve America effort after the expiration of the grant.

##### 7. Innovation and Replicability

The extent to which the plan:

- Advances knowledge about how to do effective and innovative community service and service-learning.
- Enhances the effort within the broader K-12 field.
- Will assist others in learning from experience and replicating the program concept.

##### 8. Cost-Effectiveness

The extent to which the budget:

- Correlates with the program narrative.
- Details costs by providing justification and appropriate calculations for each line item.
- Sufficiently supports project activities.
- Represents reasonable costs, given current rates.

##### B. Performance to Date (40%)

The Corporation recommends that consideration of past performance be based on whether the grantee has:

- Made reasonable progress toward accomplishing project goals and objectives.
- Adequately addressed issues or problems that occurred or has developed sufficient plans to address them in year two.
- Met reporting requirements in a timely manner.
- Conducted adequate planning, capacity-building and training activities.
- Implemented, operated, and expanded service-learning programs through grants to local partnerships, as stated in the original proposal.

6. Implemented, operated, and expanded school-based programs involving adult volunteers, if applicable.

#### II. Priority Areas for New Grants and Renewals

In addition to those objectives and priorities described by the Corporation statute and regulations, the Corporation is recommending that new and existing grantees be requested to address the following priorities in their Learn and Serve America plans.

##### A. State Infrastructure/Capacity Building

An effective service-learning state infrastructure includes a statewide network of service-learning practitioners, policy makers and members who advocate the advancement of service-learning methodology. This infrastructure also includes state financial and human resources committed to service-learning efforts, as well as state level support for service-learning. Infrastructure is key to realizing the full potential of service-learning to reform education and rebuild communities. There is a need to build both legislative and financial support at the state level, especially as future federal funding may not be available. Priority will be given to state plans that institutionalize service-learning, as well as those that leverage dollars at the state and local levels.

##### B. Partnerships With Other Education Reform Efforts

To help build the infrastructure needed to support service-learning as a methodology for education reform, the Corporation will encourage linkages with other education reform efforts, such as Goals 2000, School-to-Work transition and middle grades restructuring. States will be encouraged to promote such linkages through advocating for the inclusion of service-learning language in state education reform legislation and school board policies.

Connections to state and federal education reform efforts help promote institutionalization and sustainability. As states consider school restructuring or the new methodology of education reformers, the Corporation should encourage them to include service-learning in their plans. Priority will be given to programs that utilize dollars from other federal education legislation or promote linkage with state level reform efforts.

### C. Qualitative/Quantitative Research and Evaluation

Up to this point, the service-learning research focus has been mainly on personal development with data collection being mostly anecdotal. To further expand and sustain service-learning as a legitimate pedagogy, the field needs a solid base of research to support it. Once academic improvement is solidly documented, more members of the education community will support service-learning as a legitimate tool for education reform. Priority will be granted to proposals which plan to document service-learning outcomes, especially those focusing on measurement of improved academic achievement and attendance, and reductions in disciplinary actions. This type of solid research will be useful during the reauthorization process.

### D. Coordinated Streams of Service

When all CNCS grantees in a given state work together, it is possible to "get things done" more effectively and efficiently. AmeriCorps Members can strengthen Learn and Serve programs by serving as service-learning coordinators at the school district or individual school level. Senior Corps members can offer valuable skills and experience to Learn and Serve members through pre-service training and post-service reflection activities. Priority will be granted to proposing linking the various streams of service in the state.

### III. Renewal Period

The Corporation recommends renewing grants for one year only. This will allow Learn and Serve America staff to ensure greater quality in plans and to promote program improvement.

### IV. Program Components To Be Addressed

The Corporation recommends that the following program components be addressed in FY 1995. These components were identified by staff and outside peer reviewers as overall weaknesses in the proposals submitted under Learn and Serve America in 1994.

#### A. Academic Components

Connections to the curriculum/education reform Proposals submitted this year demonstrate the need for the Corporation to work with grantees at three levels of the service-learning integration continuum: awareness/basic introduction to service-learning methodology; making clear connections to the academic curriculum; and articulating clear academic outcomes and ways to measure those outcomes. If the Corporation is to fund service-

learning programs, then we need to work with grantees to enhance the academic components of their plans.

#### B. Evaluation

The Corporation recommends that grantees be encouraged to consider evaluation at three levels: information to be collected for the national evaluation; evaluation of the work at the primary grantee level, such as State Education Agency, State Commission, or national non-profit; and the evaluation of local program (subgrantee) activities. Grantees will be encouraged to define clear, measurable goals and objectives, as well as to develop or select adequate measurement tools.

#### C. Innovation/Replicability

The Corporation recommends grantees to seek viable approaches in achieving program replicability and innovation. The Corporation encourages programs to work closely with the Learn and Serve America K-12 staff to establish a framework to assist in the development of new ideas and the expansion of or building upon proven model programs.

#### D. Sustainability

The Corporation encourages grantees to design a clearly defined and detailed plan for program sustainability. Grantees should articulate a comprehensive long-term plan that not only cites specific monetary and in-kind resources, but incorporates state infrastructure and capacity building.

#### E. Coordination With Other Service Streams in the State

Programs are encouraged to coordinate their service efforts with the state's service network, including youth, educators, State Commission members, policy makers, parents, representatives from community organizations and national nonprofits. Improving collaboration strengthens state service-learning efforts, presents a stronger, more unified voice for service-learning at the state policy level, promotes sustainability and helps states achieve goals with fewer dollars through resource sharing.

#### F. Indian Tribes and U.S. Territories

The Corporation anticipates that its technical assistance and outreach efforts to Indian Tribes and Territories will improve in Year Two. The Corporation encourages Indian Tribes and Territories to identify specific areas of need so the Corporation may better assess less developed program areas and strengthen the overall quality of Indian Tribe proposals for Year Two.

### V. Guidelines for 1994 Renewals

#### A. Amount of Funding Requested by Applicants for Renewal

The Corporation recommends the following guidelines concerning the amount of funding that may be requested by year two grantees.

##### 1. State Educational Agencies

The FY 1995 appropriation for SEA allotment grants will increase approximately 25%. The SEAs will be informed of exactly what their formula allotments will be in FY 1995 when renewal materials are sent to them.

##### 2. State Commissions, Grantmaking Entities (School- and Community-Based), and Fund for the Advancement of Service-Learning Grantees

Approximate second year funding levels were determined during the year one application process. All applicants in these categories were asked to submit three year plans.

##### 3. Indian Tribes/Territories

Most grants are expected to upgrade from planning to operational programs. We plan to limit these requests to an additional 60-75% increase over the amount of the FY 1994 planning grant.

#### B. Information Required in Addition to the Quarterly Report

The Corporation is requesting that renewal applicants submit the following for consideration:

1. Updated statement of goals and objectives.
2. Workplan for the second program year.
  - a. Program activities as they relate to goals and objectives:
    - i. description of subgranting (number of continuation subgrants v. number of new subgrants);
    - ii. state level infrastructure development;
    - iii. plan for addressing Corporation priorities.
  - b. Training and technical assistance plans for year two.
  - c. Evaluation update.
  - d. Program sustainability
  - e. Efforts to replicate
  - f. Innovative program elements
3. Updated personnel information (if applicable).
4. Second year budget narrative and form (Cost effectiveness).

### Learn and Serve America: Higher Education FY 1995 Policies and Priorities

#### I. Policies and Guidelines for Renewals of Existing Grantees

In general, the Corporation anticipates renewing grants for existing programs

that meet quality standards. Renewal funding will not be automatic. Decisions will be based on two factors: progress to date (80%) and future plans (20%).

A. Information on progress to date will be collected primarily through the semi-annual progress report (quarterly report for demonstration programs) and secondarily through other methods, that include informal monitoring, contact with program personnel and site visits. Progress reports will include the following information, which translate into criteria for renewal decisions:

1. Number of participants:
  - a. The degree to which recruitment goals have been met. The amount of attrition observed.
2. Service and learning activities:
  - a. The quality of service placements. The degree to which activities are well-supervised, well-suited to participants' skill and training, and designed to achieve demonstrable impacts on community needs. The quality of reflection activities. The clarity of learning objectives associated with these activities.

3. Implementation:
  - a. The extent to which high-quality program staff have been recruited, selected, trained, and placed. The degree to which the program is following its timeline and implementation plan. The reasonableness of explanations for deviations from or adjustments to the timeline.

4. Progress toward objectives:
  - a. The degree to which there is quantitative or other evidence of progress toward approved objectives related to community, participants, and institutional impacts. The degree to which the program has developed a system to collect data and demonstrate outcomes.

5. Progress toward sustainability:
  - a. The degree to which the program has explored alternative sources of funding and built stronger institutional and community support.

6. Important findings from internal evaluation and monitoring:
  - a. The reliability of mechanisms for feedback and continuous improvement. The degree to which participants, service beneficiaries, and partners are satisfied with the program. The extent to which the program has identified problems, areas for improvement, or lessons learned, and taken appropriate action.

7. Financial management and match:
  - a. The extent to which the match has been raised. The extent to which a fundraising plan has been developed. The extent to which quarterly financial reports and up-to-date records of line-

item expenditures show balanced and appropriate spending across program areas. The reasonableness of explanations for unusually low or high expenditures in particular budget lines.

b. In addition, in making renewal decisions, the Corporation will take into account grantees' responsiveness to inquiries and requests from program staff and their timeliness in notifying program staff of major problems in implementation.

B. Information on *future plans* will be collected through a brief application for renewal funding. Proposals should build on progress in the previous year, reflecting lessons learned and actions that correct weaknesses. The information will include:

1. Clear outcome objectives for the next year, consistent with objectives for the current year.
2. Next year's activities.
3. Implementation plan and timeline, reflecting lessons learned from the current year.
4. An update on expenditures and obligations under the current grant.
5. Next year's budget with detailed narrative.

In general, first-year programs (non-demonstration) may apply for 90 percent of their current grant amounts. Second-year programs may apply for 80 percent of their current grant amounts.

Current demonstration programs with AmeriCorps Members may maintain or expand the number of Members (up to 25 percent, in general). In the second year application, programs proposing expansion will be required to justify the expansion in terms of need, organizational capacity, success in first-year implementation, and adequacy of plans for managing expansion. Part-time programs with AmeriCorps Members whose terms of service are longer than one year may propose a new class of AmeriCorps Members in the second year. Such a proposal constitutes an expansion.

## II. Policies and Guidelines for New Applicants

A. The Corporation intends to streamline FY 1995 applicants into one of three categories that reflect major distinctions in program design and activities:

- (1) Individual institution of higher education or partnership,
- (2) Consortium, or
- (3) Demonstration program with AmeriCorps Members. Some proposal narrative guidelines and selection criteria will apply to all three categories. Other guidelines and criteria will apply specifically to one but not the others. Instead of listing specific criteria for

public comment, the Corporation has decided to invite direct input on what criteria should apply to each category. In particular, the Corporation welcomes input on the development of criteria appropriate for consortium applicants.

B. Overall, the selection criteria will build on those established in the FY 1994 application. The FY 1995 guidelines will reflect the following key points:

1. The Corporation will reaffirm the Learn and Serve America program's emphasis on building capacity and strengthening infrastructure, in particular by setting clear narrative guidelines and selection criteria specifically for consortium applicants.

2. The Corporation will place added emphasis on the applicant's ability to articulate clear objectives with demonstrable outcomes and means of assessment.

3. The Corporation will encourage programs to focus on a single issue area or community need, instead of scattering activities among several areas.

C. The Corporation will give priority to applicants according to the following guidelines:

1. The issue areas to be targeted under AmeriCorps\*USA also will apply to Learn and Serve America: Higher Education. These are community policing, victim assistance, neighborhood environment, early childhood development, and school success.

2. In order to fund an array of institutions that reflects the diversity of American higher education, the Corporation will give priority to programs involving community colleges, HBCUs, Hispanic-serving institutions, and tribally controlled colleges.

3. The Corporation may give priority to certain applicants in order to achieve geographic diversity among funded programs.

D. The Corporation will continue to fund demonstration programs that involve AmeriCorps Members.

1. New demonstration programs must have both a strong focus on a national priority and an emphasis on building service-learning capacity.

2. The Corporation will give preference to programs that involve at least 20 AmeriCorps Members overall, that place Members in teams of two or more at each project site, that propose service activities at fewer rather than more sites, and that focus activities in a single issue area.

3. The Corporation will structure grants to new demonstration programs so that the length of the grant parallels the Members' terms of service. For

example, if a program engages part-time Members in a two-year term, then the FY 1995 grant will include funds for two years, with release of funds in the second year contingent upon performance in the first year and availability of appropriations. Part-time terms spanning three years will be discouraged.

Dated: October 21, 1994.

Catherine Milton,

Vice President, Corporation for National Service.

[FR Doc. 94-26588 Filed 10-26-94; 8:45 am]

BILLING CODE 8050-28-P-M

## DEPARTMENT OF DEFENSE

### Department of the Army

#### Army Science Board; Closed Meeting

In accordance with Section 10(a)(2) of the Federal Advisory Committee Act (P.L. 92-463), announcement is made for the following Committee Meeting:

Name of Committee: Army Science Board (ASB).

Date of Meeting: 14-15 November 1994.

Time of Meeting: 1000-1730.

Place: U.S. Army Natick RD&E Center, Natick, MA.

Agenda: The Army Science Board's Independent Assessment of "The Army's Soldier System Technology Program and Investment Strategy." This meeting will be closed to the public in accordance with Section 552b(c) of Title 5, U.S.C., specifically subparagraph (1) thereof, and Title 5, U.S.C., Appendix 2, subsection 10(d). The classified and unclassified matters to be discussed are so inextricably intertwined as to preclude opening all portions of the meeting. The ABS Administrative Officer, Sally Warner, may be contacted for further information at (703) 695-0781.

Sally A. Warner,

Administrative Officer, Army Science Board.

[FR Doc. 94-26568 Filed 10-26-94; 8:45 am]

BILLING CODE 3710-08-M

## DEPARTMENT OF EDUCATION

### Notice of Proposed Information Collection Requests

AGENCY: Department of Education.

ACTION: Notice of Proposed Information Collection Requests.

SUMMARY: The Acting Director, Information Resources Management Service, invites comments on the proposed information collection

requests as required by the Paperwork Reduction Act of 1980.

DATES: Interested persons are invited to submit comments on or before November 28, 1994.

ADDRESSES: Written comments should be addressed to the Office of Information and Regulatory Affairs, Attention: Dan Chenok: Desk Officer, Department of Education, Office of Management and Budget, 725 17th Street NW., Room 3208, New Executive Office Building, Washington, DC 20503. Requests for copies of the proposed information collection requests should be addressed to Patrick J. Sherrill, Department of Education, 400 Maryland Avenue, SW., Room 5624, Regional Office Building 3, Washington, DC 20202-4651.

#### FOR FURTHER INFORMATION CONTACT:

Patrick J. Sherrill (202) 708-9915. Individuals who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1-800-877-8339 between 8 a.m. and 8 p.m., Eastern time, Monday through Friday.

SUPPLEMENTARY INFORMATION: Section 3517 of the Paperwork Reduction Act of 1980 (44 U.S.C. Chapter 35) requires that the Office of Management and Budget (OMB) provide interested Federal agencies and the public an early opportunity to comment on information collection requests. OMB may amend or waive the requirement for public consultation to the extent that public participation in the approval process would defeat the purpose of the information collection, violate State or Federal law, or substantially interfere with any agency's ability to perform its statutory obligations. The Acting Director of the Information Resources Management Service, publishes this notice containing proposed information collection requests prior to submission of these requests to OMB. Each proposed information collection, grouped by office, contains the following: (1) Type of review requested, e.g., new, revision, extension, existing or reinstatement; (2) Title; (3) Frequency of collection; (4) The affected public; (5) Reporting burden; and/or (6) Recordkeeping burden; and (7) Abstract. OMB invites public comment at the address specified above. Copies of the requests are available from Patrick J. Sherrill at the address specified above.

Dated: October 21, 1994.

Ingrid Kolb,

Acting Director, Information Resources, Management Service.

### Office of Elementary and Secondary Education

Type of Review: Extension.

Title: New and Continuing Applications for Grants Under the Migrant Education Even Start (MEES) Operated by State Educational Agencies (SEAs).

Frequency: Annually.

Affected Public: State or local governments.

#### Reporting Burden

Responses: 51.

Burden Hours: 838.

#### Recordkeeping Burden

Recordkeepers: 14.

Burden Hours: 56.

Abstract: "Migrant and Seasonal Worker Program, Children and Adult Education, Special Projects, State Educational Agencies (SEAs)" or consortia of SEAs are required to submit an application to the Secretary for Federal funds to design and operate special projects to improve the education of migrant preschool children and their parents.

[FR Doc. 94-26580 Filed 10-26-94; 8:45 am]

BILLING CODE 4000-01-M

## DEPARTMENT OF ENERGY

### Preparation of an Environmental Impact Statement (EIS) To Clean Out and Deactivate the Hanford, Washington Plutonium Finishing Plant (PFP) Complex (Except for Storage Areas), To Stabilize PFP Plutonium-Bearing Materials and To Store the Stabilized Material

AGENCY: Department of Energy (DOE).

ACTION: Notice of Intent (NOI).

SUMMARY: DOE announces its intent to prepare an EIS pursuant to the National Environmental Policy Act of 1969 (NEPA) (42 U.S.C. 4321 *et seq.*) in accordance with the Council on Environmental Quality (CEQ) regulations for implementing the Procedural Provisions of NEPA (40 CFR parts 1500-1508) and the DOE implementing procedures (10 CFR part 1021). DOE invites public comment and will conduct a series of public scoping meetings to provide an opportunity for the public and interested agencies to comment on the alternatives and the scope of issues to be addressed in the EIS.

The proposed action would clean out inactive PFP complex facilities (except for storage areas), stabilize reactive residual plutonium-bearing materials to a form suitable for long term storage, and store the stabilized material until DOE makes final storage and disposition decisions. The proposed action would minimize safety concerns, reduce the exposure of site workers to radiation, and reduce the risk to the public. Upon completion of the action, the PFP-complex would be deactivated to a state ready for potential decontamination and dismantlement (D&D) and/or potential future uses. Additional NEPA documentation will be prepared by DOE before any decision is made to D&D the PFP and/or to use it for other purposes. At this time, no future missions beyond continued vault storage have been

identified for the PFP-complex. Future production of plutonium for defense purposes is not being proposed and is not part of Hanford's current mission. Existing vault storage of nuclear materials would continue pending future NEPA documentation and a DOE decision on the ultimate storage or disposition of the materials; on June 21, 1994, DOE issued a NOI to prepare a programmatic EIS on the storage and disposition of weapons-usable fissile materials.

**DATES:** DOE invites all interested parties, including affected Federal, State and local agencies, Indian Nations, and the general public to submit comments or suggestions concerning the scope of the issues to be addressed, alternatives to be analyzed, and the environmental

impacts to be assessed in the Plutonium Finishing Plant Cleanout EIS by December 12, 1994. To ensure that all relevant environmental issues are considered, the public, agencies, and organizations are also invited to attend public scoping workshops in which oral and written comments will be welcomed on the proposed PFP EIS. Oral and written comments will be given equal weight in the scoping process. Written comments must be postmarked by December 12, 1994 to ensure their consideration. Comments postmarked after that date will be considered to the extent practicable.

Public scoping workshops to provide information and discuss and receive comments on the scope of the EIS will be held on the dates and at the locations given below:

Hood River, Oregon .....	Date: Thursday, November 10, 1994 .....	Hood River Inn, Best Western, 1108 E. Marina Way, Hood River, OR 97031, (503) 386-2200.
Portland, Oregon .....	Date: Friday, November 11, 1994 .....	Red Lion/Lloyd's Center, 1000 Multnomah, Portland, OR 97204, (503) 281-6111.
Richland, Washington ..	Date: Tuesday, November 15, 1994 .....	O'Callahan's at the Shilo, 50 Comstock, Richland, WA 99352, (509) 946-4661.
Seattle, Washington .....	Date: Thursday, November 17, 1994 .....	Bellevue Hilton Hotel, 100 112th Avenue, Bellevue, WA 98004, (206) 455-3330.
Spokane, Washington ...	Date: Monday, November 28, 1994 .....	Cavanaugh's Inn at the Park, W. 303 North River Drive, Spokane, WA 99352, (509) 326-8000.

Each public scoping workshop will begin with a welcome and brief overview of the proposed EIS and will include sub-workshops on specific items of interest in which the public can ask questions and provide comments to DOE officials. Notes will be taken in the sub-workshops to record public concerns for the official workshop record. Each workshop will conclude with a session that will be recorded by a public stenographer and will become part of the official workshop record. This portion of the workshop will be chaired by a presiding officer, but will not be conducted as an evidentiary hearing; speakers will not be cross-examined although the presiding officer and DOE representatives may ask clarifying questions. Individuals requesting to speak on behalf of an organization must identify the organization. In the interest of ensuring that all who wish to speak have an opportunity to do so, each individual speaker will be given a 5-minute limit except that a speaker representing an organization (one per organization) will be given a 10-minute limit.

The agenda will be repeated twice a day at each location, in afternoon and evening sessions. The hours for the sessions will be: 12:30 PM-1:30 PM (workshop session), 1:30 PM-4:30 PM (formal scoping meeting), 5:30 PM-6:30

PM (workshop session), and 6:30 PM-9:30 PM (formal scoping meeting).

Requests to speak at these workshops may be made by calling the toll-free telephone number, 1-800-516-3740 by 3:00 PM the day before the meeting or by writing to the DOE (see **ADDRESSES** below).

Persons who have not submitted a request to speak in advance may register to do so at the workshops and will be called on to speak on a first-come, first-served basis as time permits. Written comments will also be accepted at the meetings, and speakers are encouraged to provide written versions of their oral comments for the record.

DOE will review scoping comments to determine their applicability to the proposed PFP cleanout EIS. An Implementation Plan (IP) for the PFP EIS will provide guidance for preparation of the PFP EIS and establish its scope and content (10 CFR 1021.312). The IP will briefly summarize the scoping comments received and their disposition. The IP will be issued prior to the release of the draft EIS and copies will be made available for inspection.

Written comments on the scope of the PFP EIS, questions or comments concerning the PFP cleanout program, requests for speaking times at the public scoping meetings, and requests for

copies of the IP and/or the Draft EIS (DEIS) should be directed to the designated Richland contacts below.

**ADDRESSES:**

**FOR FURTHER INFORMATION CONTACT:**

Mr. Jim Mecca, U.S. Department of Energy, P.O. Box 550 (MSIN B1-42), Richland, WA 99352, Attention: NL Peters, Telephone: (509) 946-3683

Mr. Ben Burton, U.S. Department of Energy, P.O. Box 550 (MSIN B1-42), Richland, WA 99352, Telephone: (509) 946-3683

For information on the DOE NEPA process, contact: Carol M. Borgstrom, Director, Office of NEPA Oversight (EH-25), U.S. Department of Energy, 1000 Independence Avenue SW., Washington, D.C. 20585, Telephone: 202-586-4600 or leave a message at 1-800-472-2756.

EIS technical reports, background data, materials incorporated by reference, and other related documents are available either through the contacts listed above or at:

DOE Freedom of Information Reading Room, Forrestal Building, 1000 Independence Ave. S.W., Washington, D.C.

DOE Public Reading Room, Washington State University, Tri-Cities Branch, 100 Sprout Road, Richland, WA 99352.

and at the following DOE information repositories:

University of Washington, Suzzallo Library, Government Publication, Seattle, WA 98195  
 Gonzaga University, Foley Center, E. 502 Boone, Spokane, WA 99258  
 Portland State University, Branford Price Millar Library, SW Harrison and Park, Portland, OR 97207.

#### SUPPLEMENTARY INFORMATION:

##### Background

The Federal government began operating the Hanford Site, near Richland, Washington, in 1943 as part of the Manhattan Project to produce plutonium for national defense purposes. Metallic uranium fuel was irradiated in nuclear reactors at the Hanford Site to create plutonium, which was converted to plutonium nitrate and purified through chemical processing for use in nuclear weapons.

Initial production of plutonium metal at the PFP complex began in July, 1949. The complex is located on Hanford's 200 West Area Plateau approximately 32 miles northwest of Richland, Washington. The complex includes production areas, reclamation processes, laboratories and plutonium storage vaults. Several defense missions were carried out within the PFP complex. As the need arose, processes were installed in the PFP to recover as much plutonium as possible and metal production capabilities were updated. Some of the process areas have been deactivated over the last 20 years; however, plutonium recovery activities continued until the production mission ended in 1989. Secure materials storage vaults have been in operation since the early 1960s.

Today, operable areas of the complex include the Plutonium Reclamation Facility (PRF), the Remote Mechanical "C" (RMC) line plus process support and research laboratories, the secure storage vaults and support areas. About 240 employees work at the PFP.

The DOE believes the continued presence of relatively large quantities of chemically reactive materials in their present form and location within the PFP poses an unacceptable long-term risk to the workers and the environment. Consequently, in 1993, DOE announced its proposal to operate certain processes in the PFP to stabilize those materials and to prepare an Environmental Assessment (EA) pursuant to NEPA.

As part of the NEPA process for the proposed EA, DOE conducted public meetings in the summer and fall of 1993 in Richland, WA; Seattle, WA; Portland,

OR; Hood River, OR; and Spokane, WA to discuss the proposal to stabilize the chemically reactive materials. As a result of the public comments received, DOE decided that an EIS would be the appropriate level of NEPA review. DOE also decided to expand the scope of review to include cleanout of the PFP (except for storage vaults) to a state where the facility would be ready for D&D and/or future uses.

To alleviate immediate safety concerns, interim actions have been taken or are underway to minimize the amount of reactive residual materials left in process areas when the plutonium production mission ended in 1989. The range of interim actions includes transferring solutions into vented metal containers for safe storage, repackaging of certain solutions from plastic bottles to safer containers, cleanup of surface radioactive contamination to reduce worker exposure, and removal of portions of ventilation ductwork and piping which contain residual plutonium. The thermal stabilization of sludges is a proposed interim action being addressed by an EA currently in progress. Other interim actions could be proposed during the EIS preparation period to address other specific safety concerns. All interim actions are or will be covered by appropriate NEPA documentation.

The proposed action would place the PFP complex in a state ready for potential D&D and/or a future mission while maintaining its current material storage capability.

##### Purpose and Need for Agency Action

The DOE needs to take action to minimize safety concerns, reduce the exposure of Hanford Site workers to radiation, and reduce the risk to the public. The proposed action would clean out inactive PFP complex facilities (except storage areas), stabilize reactive residual material for long-term storage, and store the stabilized material pending a DOE decision on ultimate storage or disposition of fissile materials. Upon completion of the proposed action, the PFP complex would be in a state ready for D&D and/or future uses.

##### Preliminary Description of Cleanout Alternatives

The following cleanout alternatives are currently being considered for detailed analysis in the EIS:

###### 1. Wet Cleaning

Contaminated equipment or facility surfaces would be sprayed with or soaked or immersed in nitric acid and

rinsed with dilute acid. The rinse solutions would be collected in tankage and stabilized in a manner similar to other acid solutions. Acid washing could be enhanced for greater cleaning by using additives such as cerium or silver persulfate.

###### 2. Mechanical Cleaning

Methods for mechanical cleaning include abrasive blasting, wiping, scraping and brushing. Blasting would produce a fine powder containing plutonium which would be collected and stabilized in a manner similar to other solids, then stored in PFP vaults. Wiping or scraping would produce a similar powder, plus waste in the form of wiping materials (rags, paper, etc.) These methods require workers to be close to contaminated surfaces.

##### Preliminary Description of Stabilization Alternatives

The PFP contains a variety of reactive plutonium-bearing materials that need to be stabilized for long-term storage pending DOE decisions on ultimate storage or disposition. Stabilized material has minimal chemical reactivity and generally would be in solid form with a low water or organic content to minimize radiolysis. Most of the reactive materials are in process areas and equipment. (A portion of the materials stored in PFP vaults must also continue to be repackaged and stabilized as necessary for long-term storage).

For purposes of analysis, the reactive materials have been divided into groups. The materials in each group are expected to be amenable to the same stabilization process. The groups are as follows:

- Nitrate solutions
- Chloride solutions
- Other solutions including organic solutions
- Inorganic solids
- Oxides
- Metals and alloys
- Combustibles (used rags, used filters, plastic forms)
- Miscellaneous compounds

Each of these groups contains materials which are chemically dissimilar to materials in other groups and may require separate stabilization processing. Therefore, the preferred stabilization alternative is likely to consist of more than a single process.

The following stabilization alternatives are currently being considered for detailed analysis in the EIS.

### 1. Stabilization via Plutonium Reclamation Facility

This alternative would involve the restart and operation of the Plutonium Reclamation Facility (PRF), portions of the Remote Mechanical C (RMC) line and two small glovebox processes that would convert and stabilize chemically reactive plutonium-bearing scrap for long-term storage.

The PRF processes would be operated to convert certain plutonium-bearing materials to an aqueous solution. These materials include the plutonium oxide powder, incinerator ash, and scrap solutions. These materials would be dissolved with various acids and other chemicals to produce an impure plutonium nitrate solution. The process would use a heavy organic solution to extract plutonium from other impurities.

The plutonium nitrate solutions would be converted to solid plutonium oxide, which is suitable for long-term storage. The equipment for this conversion process would be remotely operated from a shielded control room. The process would involve mixing the nitrate feed with oxalic acid to form a plutonium oxalate precipitate. The precipitate would be filtered out of the liquid and thermally oxidized to plutonium oxide.

### 2. Direct Denitration

This alternative would involve the operation of small scale equipment which could be installed within two to four existing gloveboxes in the RMC processing area.

The denitration process would be operated to stabilize materials which can be dissolved in nitric acid to form a nitrate solution. Materials would first be dissolved to form the impure nitrate solution, then small amounts of solution would be heated slowly to evaporate the water. The temperature would be increased to form a calcined plutonium oxide powder with other impurities.

### 3. Alkaline Precipitation

As in the case of the direct denitration alternative, this alternative would involve the operation of small scale equipment which could be installed in two to four existing gloveboxes in the RMC processing area.

The alkaline precipitation process would use alkaline hydroxides or oxalate compounds to precipitate plutonium from solution. The precipitate would then be filtered and thermally oxidized to plutonium oxide.

### 4. Molten Salt Calcination

This alternative would involve the operation of small- to medium-scale

equipment which could be installed in two existing gloveboxes plus a new glovebox in the RMC process area or in another suitable area of the PFP.

The molten salt calcination process would use a gas-agitated pool of molten sodium carbonate to convert plutonium-bearing materials to plutonium oxide. The process could stabilize many types of materials including solutions (nitrates, chlorides, organics) and solids such as inorganic solids and combustibles. Some feeds would have to be pretreated prior to processing via size reduction or dissolution in various solutions.

### No Action Alternative

Under this alternative, residues would remain in certain process equipment, gloveboxes, process canyon areas and ductwork. Cleanout of the facility would not take place and the residual material would not be stabilized or stored. Vault storage would continue as an ongoing action under this alternative; the materials in the vaults would continue to be inventoried, repackaged, and stabilized as necessary. Interim actions would be completed, along with basic safety upgrades. Surveillance and maintenance would continue at present required levels.

DOE does not intend to analyze in detail the potential alternative of cleaning out the PFP but not stabilizing the residual material (i.e., storing the material without stabilization). Such an alternative would present safety concerns, would not meet the purpose and need for the proposed action, and is therefore unreasonable.

### Preliminary Identification of Environmental Issues

The issues listed below have been tentatively identified for analysis in the PFP EIS. This list is presented to facilitate public comment on the scope of the EIS. It is not intended to be all-inclusive or to predetermine the potential impacts of any of the alternatives.

(1) Potential effects on the public and on-site workers from releases of radioactive and other hazardous materials during operations and from reasonably postulated accidents;

(2) Potential waste from the proposal, including pollution prevention and waste minimization;

(3) Potential effects on air and water quality and other environmental consequences of operations and potential accidents;

(4) Potential cumulative effects of operations at the Hanford Site, including relevant impacts from other

past, present, and reasonably foreseeable activities at the site;

(5) Potential effects on endangered species, floodplain/wetlands, and archaeological/historical sites;

(6) Radiation exposure to workers;

(7) Potential socioeconomic impacts, including environmental justice issues on surrounding communities;

(8) Unavoidable adverse environmental effects;

(9) Short-term uses of the environment versus long-term productivity; and

(10) Potential irretrievable and irreversible commitments of resources.

### Regulatory Framework

Federal and State laws that are of major importance to environmental management activities at Hanford include the Atomic Energy Act of 1954 as amended; the Resource Conservation and Recovery Act (RCRA); the Washington State Hazardous Waste Management Act, Chapter 70.105 RCW; the Federal Facility Compliance Act of 1992; and the Clean Air Act. The Atomic Energy Act requires the management, processing and use of radioactive materials in a manner that protects workers, public health, and the environment. RCRA and the Washington State Hazardous Waste Management Act establish requirements for management of hazardous and mixed waste, including generation, treatment, storage, and disposal.

DOE has submitted an air operating permit application to EPA and the permit is expected to be issued in the November 1995 timeframe; the requirements of the existing air quality permits for PFP are expected to encompass all the anticipated requirements of any new permit.

### Related NEPA Documentation

NEPA documents that have been or are being prepared for activities at Hanford or are related to the proposed action include, but are not limited to, the following:

(1) *(Draft) Environmental Assessment for Sludge Stabilization at the Plutonium Finishing Plant, Hanford Site, Richland, Washington, DOE/EA-0978, draft dated September 1994.* This draft environmental assessment evaluates a proposed interim action at the PFP to heat-stabilize, and then store, chemically-reactive, plutonium-bearing sludge from certain unshielded gloveboxes, to allay immediate safety concerns. A draft Environmental Assessment was sent to the affected States and Indian Nations for review on September 20, 1994.

(2) *Final Environmental Impact Statement for Disposal of Hanford Defense High-Level Transuranic and Tank Wastes*, Hanford Site, Richland, Washington, DOE/EIS-0113, December 1987. U.S. Department of Energy, Washington, D.C. This EIS analyzed the impacts of disposal of Hanford defense wastes.

(3) *Final Environmental Statement for Waste Management Operations, Hanford Reservation*, Richland, Washington, ERDA-1538, 1975. U.S. Energy Research and Development Administration, Washington, D.C. This EIS analyzed the environmental impacts of Hanford Site waste management operations.

(4) *Hanford Remedial Action-Environmental Impact Statement (HRA-EIS)*. The HRA-EIS will assess the potential environmental consequences of alternatives for conducting a remedial action program at the Hanford Site for inactive hazardous, low-level radioactive, transuranic, and mixed-waste sites. DOE published a NOI to prepare the HRA-EIS on August 21, 1992 (47 FR 37959-37964).

(5) *Programmatic Environmental Impact Statement for Environmental Restoration and Waste Management (EM-PEIS)*. The EM-PEIS will address waste management alternatives for existing and proposed actions and DOE complex-wide issues associated with long-term waste management policies and practices. In this Programmatic EIS, the Department is evaluating the Hanford Site as an alternative site for managing DOE wastes. An Implementation Plan for this Programmatic EIS was issued in January 1994. The final Programmatic EIS is scheduled to be issued in October 1995.

(6) *DOE Nuclear Weapons Complex Reconfiguration Programmatic Environmental Impact Statement*. On July 23, 1993, the Department published a revised Notice of Intent (56 FR 39528) to prepare a Programmatic EIS for reconfiguration of its nuclear weapons complex due to nuclear weapons stockpile reductions. The Department currently is considering how the scope of this Programmatic EIS should be revised further to reflect more recent budget and stockpile reduction decisions.

(7) *Tank Waste Remediation System Environmental Impact Statement (TWRS-EIS) and Safe Interim Storage (SIS) Environmental Impact Statement*. The NOI for these two EISs was published on January 27, 1994. Scoping meetings for the EISs were held simultaneously in five public meetings. The SIS Draft EIS was issued in July

1994. The TWRS-EIS is in early stages of preparation.

(8) *Programmatic Environmental Impact Statement for Long Term Storage and Disposition of Weapons-Usable Fissile Material*. The NOI for this PEIS was published on June 21, 1994. This PEIS will evaluate alternatives for long-term storage of all weapons-usable fissile materials and the disposition of surplus weapons-usable fissile materials declared surplus to national defense needs by the President. Public scoping workshops were held during August, September and October 1994.

Issued in Washington, D.C., on this 21st day of October, 1994.

Peter N. Brush,

Principal Deputy Assistant Secretary,  
Environment, Safety and Health.

[FR Doc. 94-26668 Filed 10-26-94; 8:45 am]

BILLING CODE 6450-01-P

### Federal Energy Regulatory Commission

[Docket Nos. CP92-595-002 and CP92-606-003]

#### Great Lakes Gas Transmission Limited Partnership; Proposed Changes in FERC Gas Tariff

October 21, 1994.

Take notice that on September 29, 1994, Great Lakes Gas Transmission Limited Partnership (Great Lakes) tendered for filing First Revised Sheet No. 4, Original Sheet No. 4A, and Second Revised Sheet No. 6 to its FERC Gas Tariff, Second Revised Volume No. 1. Great Lakes states these proposed tariff sheets were filed to reflect Great Lakes' compliance with the Commission's January 26, 1994, orders in Docket Nos. CP92-595-000 and CP92-606-000.

Great Lakes states that the Commission's orders authorized Great Lakes to construct facilities to provide Part 284 blanket transportation service to Rochester Gas and Electronic Company and Sithe/Independence Power Partners, L.P. Great Lakes explains that the Commission recognized that there would be an additional 12,000 Mcf of capacity available per day. Great Lakes relates that it conducted an open season which resulted in Mercury Exploration Company becoming the shipper for that capacity. Great Lakes asserts that the sheets reflect the separately stated incremental rates set forth in the Commission orders for such services.

Great Lakes requests that the tariff sheets become effective November 1, 1994. Great Lakes relates that

construction was completed earlier than expected, and the facilities authorized in Docket No. CP92-606-000 will be able to be placed into service on November 1, 1994, rather than the originally estimated date of January 1, 1995. Great Lakes states that this filing has been served on all of its customers and the Public Service Commissions of the states of Minnesota, Wisconsin, and Michigan.

Any party 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 Section 385.211 of the Commission's regulations. All such protests should be filed on or before October 28, 1994. 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. 94-26595 Filed 10-26-94; 8:45 am]

BILLING CODE 6717-01-M

[Docket No. RP93-36-000]

#### Natural Gas Pipeline Company of America; Notice of Informal Settlement Conference

October 21, 1994.

Take notice that an informal settlement conference will be convened in this proceeding on Friday, October 28, 1994, at 10:00 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 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 wishing 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, please contact David R. Cain (202) 208-0917 or John P. Roddy (202) 208-1176.

Lois D. Cashell,

Secretary.

[FR Doc. 94-26589 Filed 10-26-94; 8:45 am]

BILLING CODE 6717-01-M

[Docket No. MG92-3-001]

**Pacific Gas Transmission Co.; Notice of Filing**

October 21, 1994.

Take notice that on September 30, 1994, Pacific Gas Transmission Company (PGT) submitted revised standards of conduct under Order Nos. 497 *et seq.*<sup>1</sup> and Order No. 566.<sup>2</sup> PGT states that it is revising its standards of conduct to incorporate the changes required by Order No. 566.

PGT states that all parties of record in the above-referenced docket have been served with copies of this filing.

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, N.E., Washington, D.C., 20426, in accordance with Rules 211 or 214 of the Commission's Rules of Practice and Procedure (18 CFR § 385.211 or § 385.214 (1994)). All such motions to intervene or protest should be filed on or before November 7, 1994. 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. 94-26592 Filed 10-26-94; 8:45 am]

BILLING CODE 6717-01-M

<sup>1</sup> Order No. 497, 53 FR 22139 (June 14, 1988), III FERC Stats. & Regs. ¶ 30,820 (1988); Order No. 497-A, order on rehearing, 54 FR 52781 (December 22, 1989), III FERC Stats. & Regs. 30,868 (1989); Order No. 497-B, order extending sunset date, 55 FR 53291 (December 28, 1990), III FERC Stats. & Regs. ¶ 30,908 (1990); Order No. 497-C, order extending sunset date, 57 FR 9 (January 2, 1992), III FERC Stats. & Regs. ¶ 30,934 (1991), rehearing denied, 57 FR 5815 (February 18, 1992), 58 FERC ¶ 61,139 (1992); *Tenneco Gas v. FERC* (affirmed in part and remanded in part), 969 F. 2d 1187 (D.C. Cir. 1992); Order No. 497-D, order on remand and extending sunset date, III FERC Stats. & Regs. ¶ 30,958 (December 4, 1992), 57 FR 58978 (December 14, 1992); Order No. 497-E, order on rehearing and extending sunset date, 59 FR 243 (January 4, 1994), 65 FERC ¶ 61,381 (December 23, 1993); Order No. 497-F, order denying rehearing and granting clarification, 59 FR 15336 (April 1, 1994), 66 FERC ¶ 61,347 (March 24, 1994); and Order No. 497-G, order extending sunset date, 59 FR 32864 (June 27, 1994), III FERC Stats. & Regs. ¶ 30,996 (June 17, 1994).

<sup>2</sup> Standards of Conduct and Reporting Requirements for Transportation and Affiliate Transactions, Order No. 566, 59 FR 32885 (June 27, 1994), III FERC Stats. & Regs. ¶ 30,997 (June 17, 1994), order on rehearing, Order No. 566-A, 59 FR 52896 (October 20, 1994), 69 FERC ¶ 61,044 (October 14, 1994).

[Docket No. RP94-183-003]

**Southern Natural Gas Co., South Georgia Natural Gas Co.; Notice of Filing of Revised Tariff Sheets**

October 21, 1994.

Take notice that on October 19, 1994, Southern Natural Gas Company (Southern) tendered for filing as part its FERC Gas Tariff, First Revised Volume No. 2A, the tariff sheets listed on Exhibit A hereto, to be effective August 1, 1994. Also, South Georgia Natural Gas Company (South Georgia) tendered for filing as part of its FERC Gas Tariff, First Revised Volume No. 2, the tariff sheets listed on Exhibit B hereto, to be effective August 1, 1994.

Southern and South Georgia state that the purpose of this filing is to revise the tariff sheets as required by the Commission's "Order Accepting Tariff Sheets Subject to Conditions and Amending Certificates" dated September 23, 1994, in the above-captioned dockets. Such tariff sheets were filed by Southern and South Georgia on July 5, 1994, to effectuate changes to the Rate Schedules applicable to the offsystem storage service Southern and South Georgia provide through use of storage facilities and services rendered by ANR Pipeline Company and ANR Storage Company. Said September 23 order conditionally approved the terms of the tariff sheets filed on July 5, 1994.

Specifically, the Commission's September 23 Order required Southern and South Georgia to refile the tariff sheets with an effective date of August 1, 1994. Also, the Commission ordered Southern to correct the Tariff Volume designation on the tariff sheets to First Revised Volume No. 2A. Southern and South Georgia did not make any changes to the text of the revised tariff sheets from the sheets that were filed on July 5, 1994, except that South Georgia corrected one typographical error on Sheet No. 106.

Southern and South Georgia state that copies of the filing will be served upon their customers, interested state commissions and all parties to this proceeding.

Any person desiring to protest said filing should file a protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, N.E., Washington, DC 20426, in accordance with Rule 211 of the Commission's Rules of Practice and Procedure. All such protests should be filed on or before October 28, 1994.

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.

**Exhibit A—Southern Natural Gas Company**

October 18, 1994.

First Substitute First Revised Sheet No. 18  
 First Substitute First Revised Sheet No. 28  
 First Substitute First Revised Sheet No. 29  
 First Substitute First Revised Sheet No. 30  
 First Substitute First Revised Sheet No. 50  
 First Substitute First Revised Sheet No. 60  
 First Substitute First Revised Sheet No. 61  
 First Substitute First Revised Sheet No. 62  
 First Substitute First Revised Sheet No. 85  
 First Substitute Second Revised Sheet No. 86  
 First Substitute Second Revised Sheet No. 87  
 First Substitute Second Revised Sheet No. 88  
 First Substitute Second Revised Sheet No. 89  
 First Substitute Second Revised Sheet No. 90  
 First Substitute First Revised Sheet No. 91  
 First Substitute First Revised Sheet No. 92  
 First Substitute Original Sheet No. 92a  
 First Substitute First Revised Sheet No. 93  
 First Substitute Original Sheet No. 93a  
 First Substitute Nineteenth Revised Sheet No. 94  
 First Substitute Original Sheet No. 94a  
 First Substitute Original Sheet No. 94b  
 First Substitute Second Revised Sheet No. 96  
 First Substitute First Revised Sheet No. 98  
 First Substitute First Revised Sheet No. 99  
 First Substitute First Revised Sheet No. 100  
 First Substitute First Revised Sheet No. 104  
 First Substitute Original Sheet No. 104a

**Exhibit B—South Georgia Natural Gas Company**

October 18, 1994.

First Substitute First Revised Sheet No. 20  
 First Substitute First Revised Sheet No. 21

First Substitute First Revised Sheet No. 49  
 First Substitute First Revised Sheet No. 50  
 First Substitute Second Revised Sheet No. 69  
 First Substitute Second Revised Sheet No. 70  
 First Substitute First Revised Sheet No. 71  
 First Substitute Second Revised Sheet No. 72  
 First Substitute Second Revised Sheet No. 74  
 First Substitute Second Revised Sheet No. 75  
 First Substitute Nineteenth Revised Sheet No. 76  
 First Substitute Original Sheet No. 76a  
 First Substitute Second Revised Sheet No. 78  
 First Substitute First Revised Sheet No. 81  
 First Substitute First Revised Sheet No. 82  
 First Substitute First Revised Sheet No. 83  
 First Substitute Second Revised Sheet No. 99  
 First Substitute Second Revised Sheet No. 100  
 First Substitute First Revised Sheet No. 101  
 First Substitute Second Revised Sheet No. 102  
 First Substitute Second Revised Sheet No. 104  
 First Substitute Second Revised Sheet No. 105  
 Twentieth Revised Sheet No. 106  
 First Substitute Original Sheet No. 106a  
 First Substitute Second Revised Sheet No. 108  
 First Substitute First Revised Sheet No. 110  
 First Substitute First Revised Sheet No. 112

[FR Doc. 94-26591 Filed 10-26-94; 8:45 am]  
 BILLING CODE 6717-01-M

[Docket No. RP95-15-000]

### Texas Eastern Transmission Corp.; Notice of Proposed Changes in FERC Gas Tariff

October 21, 1994.

Take notice that on October 18, 1994, Texas Eastern Transmission Corporation (Texas Eastern) submitted as part of its FERC Gas Tariff, Sixth Revised Volume No. 1, the following tariff sheets, with a proposed effective date of December 1, 1994:

First Revised Sheet No. 503  
 First Revised Sheet No. 504  
 Sheet Nos. 505-513

Texas Eastern states that the proposed operational flow order (OFO), as set

forth as Section 4.3(L) of the General Terms and Conditions, permits Texas Eastern to issue an OFO if total storage withdrawal capability is projected to decline to less than the total daily contracted firm storage withdrawal rights.

Texas Eastern states that it has served this filing on all firm storage 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 October 28, 1994. 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. 94-26590 Filed 10-26-94; 8:45 am]

BILLING CODE 6717-01-M

[Docket No. MG88-54-004]

### Trunkline Gas Co.; Filing

October 21, 1994.

Take notice that on September 26, 1994, Trunkline Gas Company (Trunkline) filed its revised standards of conduct under Order Nos. 497 *et seq.*<sup>1</sup> and Order No. 566.<sup>2</sup> Trunkline states

<sup>1</sup> Order No. 497, 53 FR 22139 (June 14, 1988), III FERC Stats. & Regs. ¶ 30,820 (1988); Order No. 497-A, *order on rehearing*, 54 FR 52781 (December 22, 1989), III FERC Stats. & Regs. ¶ 30,868 (1989); Order No. 497-B, *order extending sunset date*, 55 FR 53291 (December 28, 1990), III FERC Stats. & Regs. ¶ 30,908 (1990); Order No. 497-C, *order extending sunset date*, 57 FR 9 (January 2, 1992), III FERC Stats. & Regs. ¶ 30,934 (1991), rehearing denied, 57 FR 5815 (February 18, 1992), 58 FERC ¶ 61,139 (1992); *Tenneco Gas v. FERC* (affirmed in part and remanded in part), 969 F.2d 1187 (D.C. Cir. 1992); Order No. 497-D, *order on remand and extending sunset date*, III FERC Stats. & Regs. ¶ 30,958 (December 4, 1992), 57 FR 58978 (December 14, 1992); Order No. 497-E, *order on rehearing and extending sunset date*, 59 FR 243 (January 4, 1994), 65 FERC ¶ 61,381 (December 23, 1993); Order No. 497-F, *order denying rehearing and granting clarification*, 59 FR 15336 (April 1, 1994), 66 FERC ¶ 61,347 (March 24, 1994); and Order No. 497-G, *order extending sunset date*, 59 FR 32884 (June 27, 1994), III FERC Stats. & Regs. ¶ 30,996 (June 17, 1994).

<sup>2</sup> Standards of Conduct and Reporting Requirements for Transportation and Affiliate Transactions, Order No. 566, 59 FR 32885 (June 27,

that it is revising its standards of conduct to incorporate the changes required by Order No. 566.

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 or 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 or 385.214). All such motions to intervene or protest should be filed on or before November 7, 1994. 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. 94-26594 Filed 10-26-94; 8:45 am]

BILLING CODE 6717-01-M

[Docket No. MG90-03-003]

### Trunkline LNG Co.; Filing

October 21, 1994.

Take notice that on September 26, 1994, Trunkline LNG Company (Trunkline LNG) filed its revised standards of conduct under Order Nos. 497 *et seq.*<sup>1</sup> and Order No. 566.<sup>2</sup>

1994), III FERC Stats. & Regs. ¶ 30,997 (June 17, 1994); Order No. 566-A, *order on rehearing*, 69 FERC ¶ 61,044 (October 14, 1994) 59 FR 52896 (October 20, 1994) III FERC Stats. & Regs. ¶ 61, (October 1994).

<sup>1</sup> Order No. 497, 53 FR 22139 (June 14, 1988), III FERC Stats. & Regs. ¶ 30,820 (1988); Order No. 497-A, *order on rehearing*, 54 FR 52781 (December 22, 1989), III FERC Stats. & Regs. ¶ 30,868 (1989); Order No. 497-B, *order extending sunset date*, 55 FR 53291 (December 28, 1990), III FERC Stats. & Regs. ¶ 30,908 (1990); Order No. 497-C, *order extending sunset date*, 57 FR 9 (January 2, 1992), III FERC Stats. & Regs. ¶ 30,934 (1991), rehearing denied, 57 FR 5815 (February 18, 1992), 58 FERC ¶ 61,139 (1992); *Tenneco Gas v. FERC* (affirmed in part and remanded in part), 969 F.2d 1187 (D.C. Cir. 1992); Order No. 497-D, *order on remand and extending sunset date*, III FERC Stats. & Regs. ¶ 30,958 (December 4, 1992), 57 FR 58978 (December 14, 1992); Order No. 497-E, *order on rehearing and extending sunset date*, 59 FR 243 (January 4, 1994), 65 FERC ¶ 61,381 (December 23, 1993); Order No. 497-F, *order denying rehearing and granting clarification*, 59 FR 15336 (April 1, 1994), 66 FERC ¶ 61,347 (March 24, 1994); and Order No. 497-G, *order extending sunset date*, 59 FR 32884 (June 27, 1994), III FERC Stats. & Regs. ¶ 30,996 (June 17, 1994).

<sup>2</sup> Standards of Conduct and Reporting Requirements for Transportation and Affiliate Transactions, Order No. 566, 59 FR 32885 (June 27, 1994), III FERC Stats. & Regs. ¶ 30,997 (June 17, 1994); Order No. 566-A, *order on rehearing*, 69 FERC ¶ 61,044 (October 14, 1994) 59 FR 52896,

Continued

Trunkline LNG states that it is revising its standards of conduct to incorporate the changes required by Order No. 566.

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 or 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 or 385.214). All such motions to intervene or protest should be filed on or before November 7, 1994. 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. 94-26593 Filed 10-26-94; 8:45 am]

BILLING CODE 6717-01-M

#### Western Area Power Administration

##### Energy Planning and Management Program

AGENCY: Western Area Power Administration, DOE.

ACTION: Notice to extend consultation and comment period.

**SUMMARY:** The Western Area Power Administration (Western) is announcing an extension of the consultation and comment period for the Energy Planning and Management Program (Program). The consultation and comment period was to end on October 11, 1994. By this notice, Western extends the comment period for an additional 30 days.

**EFFECTIVE DATES:** The consultation and comment period for the Program will end on November 10, 1994. Written comments should be received by the end of the consultation and comment period to be assured of consideration.

**FOR FURTHER INFORMATION CONTACT:** To submit written comments, or for additional information, please contact:

Robert C. Fullerton, Western Area Power Administration, P.O. Box 3402, A6100, Golden, CO 80401-0098, (303) 275-1610

James D. Davies, Billings Area Office, Western Area Power Administration, P.O. Box 35800, Billings, MT 59107-5800, (406) 657-6532

(October 27, 1994) III FERC Stats. and Regs. ¶61, (October 27, 1994).

Stephen A. Fausett, Loveland Area Office, Western Area Power Administration, P.O. Box 3700, Loveland, CO 80539-3003, (303) 490-7201

J. Tyler Carlson, Phoenix Area Office, Western Area Power Administration, P.O. Box 6457, Phoenix, AZ 85005-6457, (602) 352-2453

James C. Feider, Sacramento Area Office, Western Area Power Administration, 1825 Bell Street, Suite 105, Sacramento, CA 95825-1097, (916) 649-4418

Kenneth G. Maxey, Salt Lake City Area Office, Western Area Power Administration, P.O. Box 11606, Salt Lake City, UT 84147-0606, (801) 524-6372.

**SUPPLEMENTARY INFORMATION:** The Program was proposed in the **Federal Register** on August 9, 1994 (59 FR 40543). The Program proposed integrated resource planning for Western's long-term firm customers, and the marketing of power in support of customer planning efforts.

Issued in Golden, Colorado, September 30, 1994.

William H. Clagett,  
Administrator.

[FR Doc. 94-26670 Filed 10-26-94; 8:45 am]

BILLING CODE 6450-01-M

#### ENVIRONMENTAL PROTECTION AGENCY

[FRL-5097-6]

##### Access to Confidential Business Information by DESA, Inc.

AGENCY: Environmental Protection Agency (EPA).

ACTION: Informational notice.

**SUMMARY:** EPA Region IV awarded Enforcement Support Services (ESS) Contract 68-S4-4001 to prime contractor, DESA, Inc. (DESA). EPA has authorized DESA access to information in Region IV Superfund files which has been submitted to EPA under the environmental statutes administered by the Agency. Some of this information may be claimed or determined to be confidential business information (CBI).

**DATES:** To be considered, comments concerning CBI access must be received by November 1, 1994.

**ADDRESSES:** Send comments to Fran Harrell, Contracting Officer, U.S. Environmental Protection Agency, 345 Courtland Street, NE, Atlanta, GA 30365.

**FOR FURTHER INFORMATION CONTACT:** Fran Harrell, (404) 347-2374 ext. 6821.

**SUPPLEMENTARY INFORMATION:** Under contract No. 68-S4-4001, DESA provides agency-wide information management support services to the Environmental Protection Agency for the operation of dockets, records management support programs, record centers, and file rooms in certain Headquarters, Regional, Laboratory, and other offices. In performing these tasks, DESA employees have access to Agency documents for purposes of document processing, filing, abstracting, analyzing, inventorying, retrieving, tracking, etc. The documents to which DESA has access potentially include all documents submitted under the Resource Conservation and Recovery Act, Clean Air Act, Clean Water Act, and Comprehensive Environmental Response, Compensation, and Liability Act. Some of these documents may contain information claimed as CBI.

Pursuant to EPA regulations at 40 CFR Part 2, Subpart B, EPA has determined that DESA requires access to CBI to perform the work required under the contract. These regulations provide for five days notice before contractors are given CBI.

DESA is required by contract to protect confidential information. When DESA's need for the documents is completed, DESA will return them to EPA.

Dated: October 18, 1994.

John H. Hankinson, Jr.,  
Regional Administrator.

[FR Doc. 94-26663 Filed 10-26-94; 8:45 am]

BILLING CODE 6560-50-P

[FRL-5098-2]

##### National Advisory Council for Environmental Policy and Technology; Ecosystems Information and Assessments Committee; Public Meeting

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of public meeting.

**SUMMARY:** Under the Federal Advisory Committee Act, PL 92463, EPA gives notice of a two-day meeting of the Ecosystems Information and Assessments Committee of the National Advisory Council for Environmental Policy and Technology (NACEPT). NACEPT provides advice and recommendations to the Administrator of EPA on a broad range of environmental policy issues, and this meeting is being held to discuss the Ecosystems Information and Assessments Committee agenda for the coming year. The Administrator has

asked NACEPT to concentrate on ecosystem management and how long-term ecological, economic, and social needs can be integrated to achieve a place-driven approach to environmental management.

The Ecosystems Information and Assessments Committee will concentrate on specific information and assessment issues required to support a successful place-based approach to ecosystem management. These issues will include discussion of the role of EPA in information access and dissemination to support place-based ecosystems management; discussion of information technologies available to support place-based ecosystems management; and discussion of assessments in support of place-based ecosystems management.

The Ecosystems Information and Assessments Committee, as does NACEPT, comprises a representative cross-section of EPA's partners and constituents. However, in order to gain additional insights and perspectives from all interested parties as this committee begins its work, time has been allotted during the meeting for oral comments from the public. Any member of the public wishing to present oral comments on any of these issues can schedule an appointment by contacting Joe Sierra at the address and telephone numbers below. Due to time constraints, oral presentations will be strictly held to five minutes, and slots are limited.

Available time slots will be allocated on a first-come, first-served basis to those scheduling a presentation in advance. Written comments will be accepted at any time prior to, or at, the meeting.

**DATES:** The two-day public meeting will be held on Tuesday, December 6, 1994, from 9 a.m. to 5 p.m. and on Wednesday, December 7, 1994 from 8:30 a.m. to 1:00 p.m. On both days the meeting will be held at the Quality Hotel Capitol Hill, 415 New Jersey Ave. N.W., Washington, D.C. 20001.

**ADDRESSES:** Written comments should be sent to: Joseph A. Sierra, DFO, Ecosystems Information & Assessments Committee/NACEPT, Office of Cooperative Environmental Management, U.S. EPA (1601F), 401 M Street SW., Washington, D.C. 20460.  
**FOR FURTHER INFORMATION CONTACT:** Joseph A. Sierra, Designated Federal Official, Direct line (202) 260-6839, Secretary's line (202) 260-6891.

Dated: October 18, 1994.

Joseph A. Sierra,  
Designated Federal Official.

[FR Doc. 94-26667 Filed 10-26-94; 8:45 am]  
BILLING CODE 6560-50-M

[FRL-5097-8]

### Brewer Gold Mine Site; Notice of Proposed Settlement

**AGENCY:** Environmental Protection Agency.

**ACTION:** Notice of Proposed Settlement.

**SUMMARY:** Under Section 122(h) of the Comprehensive Environmental Protection Agency (EPA) has offered to potentially responsible party a Cost Recovery Agreement to settle claims for past and future removal actions at the Brewer Gold Mine Site, Jefferson, South Carolina. EPA will consider public comments on the proposed settlement for thirty (30) days. EPA may withdraw from or modify the proposed settlement should such comments disclose facts or considerations which indicate the proposed settlement is inappropriate, improper, or inadequate. Copies of the proposed settlement are available from: Ms. Carolyn McCall, Waste Management Division, U.S. EPA, Region IV, 345 Courtland Street, NE., Atlanta, Georgia 30365, 404/347-5059.

Written comments may be submitted to Ms. McCall within 30 days of the date of publication.

Dated: October 14, 1994.

Richard D. Green,  
Deputy Director.

[FR Doc. 94-26665 Filed 10-26-94; 8:45 am]  
BILLING CODE 6560-50-M

[FRL-5097-7]

### Norcross Mercury Spill Site; Notice of Proposed Settlement

**AGENCY:** Environmental Protection Agency.

**ACTION:** Notice of proposed settlement.

**SUMMARY:** Under Section 122(h) of the Comprehensive Environmental Protection Agency (EPA) has offered to potentially responsible party a Cost Recovery Agreement to settle claims for past and future removal actions at the Norcross Mercury Spill Site, Norcross, Georgia. EPA will consider public comments on the proposed settlement for thirty (30) days. EPA may withdraw from or modify the proposed settlement should such comments disclose facts or considerations which indicate the proposed settlement is inappropriate, improper, or inadequate. Copies of the proposed settlement are available from: Ms. Carolyn McCall, Waste Management Division, U.S. EPA, Region IV, 345 Courtland Street NE., Atlanta, Georgia 30365, 404/347-5059.

Written comments may be submitted to Ms. McCall within 30 days of the date of publication.

Dated: October 14, 1994.

Richard D. Green,  
Deputy Director.

[FR Doc. 94-26664 Filed 10-26-94; 8:45 am]  
BILLING CODE 6560-50-M

### FEDERAL COMMUNICATIONS COMMISSION

[Report No. 2036]

#### Petition for Reconsideration and Clarification of Actions in Rulemaking Proceedings

October 24, 1994.

Petition for reconsideration and clarification have been filed in the Commission rulemaking proceedings listed in this Public Notice and published pursuant to 47 CFR 1.429(e). The full text of these documents are available for viewing and copying in Room 239, 1919 M Street, N.W., Washington, D.C. or may be purchased from the Commission's copy contractor ITS, Inc. (202) 857-3800. Opposition to these petitions must be filed by November 14, 1994. See § 1.4(b) (1) of the Commission's rules (47 CFR 1.4(b) (1)). Replies to an opposition must be filed within 10 days after the time for filing oppositions has expired.

**Subject:** Amendment of Part 63 of the Commission's Rules to Provide for Notification by Common Carriers of Service Disruptions (CC Docket No. 91-273).

Number of Petitions Filed: 2.

**Subject:** Amendment of § 73.202(b), Table of Allotments, FM Broadcast Stations. (Tawas City, Michigan) (MM Docket No. 93-228, RM-8295).

Number of Petition Filed: 1.

Federal Communications Commission.

William F. Caton,  
Acting Secretary.

[FR Doc. 94-26615 Filed 10-26-94; 8:45 am]  
BILLING CODE 6712-01-M

### FEDERAL ELECTION COMMISSION

[Notice 1994-16]

#### Privacy Act; Proposed Notice of New and/or Revised Systems of Records

Pursuant to the provisions of the Privacy Act of 1974, Public Law 93-579, 5 U.S.C. 552(e)(11), the Federal Election Commission is publishing for comment new and revised systems of records that are maintained by the Commission.

A new systems report was filed with the Chairman of the Senate Committee

on Governmental Affairs, the Chairman of the House Committee on Government Operations and the Office of Management and Budget on October 21, 1994.

These systems have been revised or proposed as a result of a re-evaluation of the manner in which records are maintained by the Commission.

The new system of records which has been added is the Inspector General Investigative Files (FEC 12). The authority under which this system is maintained is 5 U.S.C. 552a(j)(2) and 5 U.S.C. 552a(k)(2). See 11 CFR part 1.14. All other systems have been revised to incorporate administrative changes which have taken place since the last publication of FEC systems of records in 1984 and 1988.

These new and revised systems should provide improved protection for the privacy and property rights of Commission employees, applicants for employment and those who deal with the Commission.

The Commission is proposing to exempt new records system FEC 12 from certain provisions of the Privacy Act. A Notice of Proposed Rulemaking for this purpose is found elsewhere in today's **Federal Register**.

Comments must be received on or before November 28, 1994. Comments must be in writing and addressed to: Tina VanBrakle, Privacy Act Officer, 999 E Street, NW., Washington, DC 20463.

Dated: October 24, 1994.

**Trevor Potter,**  
Chairman.

#### Table of Contents

FEC 1	Requests for advisory opinions.
FEC 2	Audits and investigations.
FEC 3	Compliance actions.
FEC 4	Mailings lists.
FEC 5	Personnel records.
FEC 6	Candidate reports and designations.
FEC 7	Certification for primary matching funds and general elections campaign funds.
FEC 8	Payroll records.
FEC 9	Litigation actions.
FEC 10	Letter file. Public communications.
FEC 11	Contributor name index system.
FEC 12	Inspector general investigative files.

#### FEC 1

##### SYSTEM NAME:

Requests for advisory opinions.

##### SYSTEM LOCATION:

Federal Election Commission,  
Washington, DC 20463.

##### CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Individuals who have submitted a letter to the FEC that qualifies as an

advisory opinion request under FEC regulations.

##### CATEGORIES OF RECORDS IN THE SYSTEM:

Letters requesting advisory opinions and responses thereto from the FEC.

##### AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

2 U.S.C. 437d(a)(7) and 437f.

##### ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

Documents maintained for historical purposes and for use as precedent in subsequent requests for advisory opinions. Commissioners and staff use this system to respond to requests for opinions. These documents are available to the public for information and so that interested parties may submit comments to the Commission.

##### *Routine use for disclosure to the Department of Justice for use in litigation:*

It shall be a routine use of the records in this system of records to disclose them to the Department of Justice when:

(a) The agency, or any component thereof; or

(b) Any employee of the agency in his or her official capacity; or

(c) Any employee of the agency in his or her individual capacity where the Department of Justice has agreed to represent the employee; or

(d) The United States, where the agency determines that litigation is likely to affect the agency or any of its components,

is a party to litigation or has an interest in such litigation, and the use of such reports by the Department of Justice is deemed by the Federal Election Commission to be relevant and necessary to the litigation provided, however, that in each case the agency determines that disclosure of the records to the Department of Justice is a use of the information contained in the records that is compatible with the purpose for which the records were collected.

##### ROUTINE USE OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

##### *Routine use for Agency disclosure in litigation:*

It shall be a routine use of records maintained by this agency to disclose them in a proceeding before a court or adjudicative body before which the agency is authorized to appear when:

(a) The agency, or any component thereof; or

(b) Any employee of the agency in his or her official capacity; or

(c) Any employee of the agency in his or her individual capacity where the agency has agreed to represent the employee; or

(d) The United States, where the agency determines that litigation is likely to affect the agency, or any of its components, is a party to litigation or has an interest in such litigation, and the Federal Election Commission determines that, on a case-by-case basis, use of such records is relevant and necessary to the litigation, provided, however, that the agency determines that disclosure of the records is compatible with the purpose for which the records were collected.

##### POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

##### STORAGE:

Paper records and/or microfilm, on-line disk storage, and electronic data processing system.

##### RETRIEVABILITY:

Indexed and retrievable by name of requestor, date of opinion, request number, and, as applicable, by microfilm roll and frame number.

##### SAFEGUARDS:

Originals are kept in locked filing cabinets in limited access areas under personal surveillance during working hours and in locked rooms at other times. Copies are freely available.

##### RETENTION AND DISPOSAL:

Retained for at least four years from date of receipt and subject to disposal thereafter. Current disposal process generally results in retention of records until seven years after receipt.

##### SYSTEM MANAGER(S) AND ADDRESS:

The General Counsel, Federal Election Commission, Washington, DC 20463, (202/219-3690).

##### NOTIFICATION PROCEDURES:

Refer to Commission access regulations at 11 CFR 1.1 et seq., 41 FR 43064 (1976).

##### RECORD ACCESS PROCEDURES:

Same as above.

##### CONTESTING RECORD PROCEDURES:

Same as above.

##### RECORD SOURCE CATEGORIES:

Individual requestor, persons submitting comments and the Federal Election Commission.

#### FEC 2

##### SYSTEM NAME:

Audits and investigations.

**SYSTEM LOCATION:**

Federal Election Commission,  
Washington, DC 20463.

**CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:**

Candidates required to file statements and reports under the Federal Election Campaign Act.

**CATEGORIES OF RECORDS IN THE SYSTEM:**

Audit and investigation data.

**AUTHORITY FOR MAINTENANCE OF THE SYSTEM:**

2 U.S.C. 437d(a)(10), 437g(a) (2), (5) and 438(a) (8), (9); 26 U.S.C. 9007, 9038.

**ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:**

The General Counsel, Assistant Staff Directors, Commissioners, and their staffs may use audit and investigation data for informal hearings, administrative compliance, civil litigation, voluntary compliance or to refer matters to appropriate law enforcement authorities.

*Routine use for disclosure to the Department of Justice for use in litigation:*

It shall be a routine use of the records in this system of records to disclose them to the Department of Justice when:

(a) The agency, or any component thereof; or

(b) Any employee of the agency in his or her official capacity; or

(c) Any employee of the agency in his or her individual capacity where the Department of Justice has agreed to represent the employee; or

(d) The United States, where the agency determines that litigation is likely to affect the agency or any of its components,

is a party to litigation or has an interest in such litigation, and the use of such reports by the Department of Justice is deemed by the Federal Election Commission to be relevant and necessary to the litigation provided, however, that in each case the agency determines that disclosure of the records to the Department of Justice is a use of the information contained in the records that is compatible with the purpose for which the records were collected.

*Routine use for Agency disclosure in litigation:*

It shall be a routine use of records maintained by this agency to disclose them in a proceeding before a court or adjudicative body before which the agency is authorized to appear when:

(a) The agency, or any component thereof; or

(b) Any employee of the agency in his or her official capacity; or

(c) Any employee of the agency in his or her individual capacity where the agency has agreed to represent the employee; or

(d) The United States, where the agency determines that litigation is likely to affect the agency, or any of its components,

is a party to litigation or has an interest in such litigation, and the Federal Election Commission determines that, on a case-by-case basis, use of such records is relevant and necessary to the litigation, provided, however, that the agency determines that disclosure of the records is compatible with the purpose for which the records were collected.

**POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:****STORAGE:**

Paper records.

**RETRIEVABILITY:**

Indexed by name.

**SAFEGUARDS:**

Locked safes in limited access locations. Access is limited to FEC staff on a restricted basis and to appropriate law enforcement agencies as directed by the Commission.

**RETENTION AND DISPOSAL:**

Indefinite.

**SYSTEM MANAGER(S) AND ADDRESS:**

Assistant Staff Director for Audit,  
Federal Election Commission,  
Washington, DC 20463 (202/219-3440).

**NOTIFICATION PROCEDURES:**

Refer to Commission access regulations at 11 CFR 1.1 et seq., 41 FR 43064 (1976).

**RECORD ACCESS PROCEDURES:**

Same as above.

**CONTESTING RECORD PROCEDURES:**

Same as above.

**RECORD SOURCE CATEGORIES:**

With respect to open audits, the foregoing system is exempt pursuant to the provisions of 5 U.S.C. 552a(k)(2). See 11 CFR 1.14.

**FEC 3****SYSTEM NAME:**

Compliance actions.

**SYSTEM LOCATION:**

Federal Election Commission,  
Washington, DC 20463.

**CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:**

Individuals who have filed complaints (complainants) and persons complained about (respondents), candidates filing late reports, or no reports, and cases internally generated through review and audit of reports and statements filed by candidates.

**CATEGORIES OF RECORDS IN THE SYSTEM:**

Complaints, referrals, and responses thereto; internal investigations of reports on file at the Commission, depositions, interrogatories and responses thereto.

**AUTHORITY FOR MAINTENANCE OF THE SYSTEM:**

2 U.S.C. 437g(a)(1), (2), (4) and (5); 438(a)(7) and 438(b); 26 U.S.C. 9006 and 9038.

**ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:**

While any case is active, these documents are maintained as the agency's working or investigative file. Based upon information contained in the file, recommendations are made to the Commission as to the disposition of a case, and the Commission acts upon those recommendations. Compliance actions are assigned by the Associate General Counsel to an attorney and/or to appropriate staff for investigation. Administrative action and civil litigation are handled by the General Counsel's office. Evidence of knowing and willful violations of the law may be referred to the Attorney General.

*Routine use for disclosure to the Department of Justice for use in litigation:*

It shall be a routine use of the records in this system of records to disclose them to the Department of Justice when:

(a) The agency, or any component thereof; or

(b) Any employee of the agency in his or her official capacity; or

(c) Any employee of the agency in his or her individual capacity where the Department of Justice has agreed to represent the employee; or

(d) The United States, where the agency determines that litigation is likely to affect the agency or any of its components,

is a party to litigation or has an interest in such litigation, and the use of such reports by the Department of Justice is deemed by the Federal Election Commission to be relevant and necessary to the litigation provided, however, that in each case the agency determines that disclosure of the records to the Department of Justice is

a use of the information contained in the records that is compatible with the purpose for which the records were collected.

*Routine use for Agency disclosure in litigation:*

It shall be a routine use of records maintained by this agency to disclose them in a proceeding before a court or adjudicative body before which the agency is authorized to appear when:

- (a) The agency, or any component thereof; or
- (b) Any employee of the agency in his or her official capacity; or
- (c) Any employee of the agency in his or her individual capacity where the agency has agreed to represent the employee; or
- (d) The United States, where the agency determines that litigation is likely to affect the agency, or any of its components,

is a party to litigation or has an interest in such litigation, and the Federal Election Commission determines that, on a case-by-case basis, use of such records is relevant and necessary to the litigation, provided, however, that the agency determines that disclosure of the records is compatible with the purpose for which the records were collected.

**POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:**

**STORAGE:**

Paper records. Closed compliance cases are duplicated, stored on microfilm and are available to the public, minus information deemed to be exempt under the Freedom of Information Act.

**RETRIEVABILITY:**

This system is indexed and retrievable by name of complainant or respondent by compliance action number or by microfilm roll and frame number, as appropriate.

**SAFEGUARDS:**

This system is kept in locked filing cabinets in limited access areas under personal surveillance during working hours, and in locked filing cabinets in locked rooms at other times.

**RETENTION AND DISPOSAL:**

Indefinite.

**SYSTEM MANAGER(S) AND ADDRESS:**

The General Counsel, Federal Election Commission, Washington, DC 20463, (202/219-3440).

**NOTIFICATION PROCEDURES:**

Refer to Commission access regulations at 11 CFR 1.1 et seq., 41 FR 43064 (1976).

**RECORD ACCESS PROCEDURES:**

Same as above.

**CONTESTING RECORD PROCEDURES:**

Same as above.

**RECORD SOURCE CATEGORIES:**

Complainants, respondents, third parties who have been requested, or subpoenaed, to produce relevant information, and the Federal Election Commission.

**SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:**

With respect to open investigations, the system is exempt pursuant to 5 U.S.C. 552a(k)(2). See 11 CFR 1.14.

**FEC 4**

**SYSTEM NAME:**

Mailing Lists.

**SYSTEM LOCATION:**

Federal Election Commission, Washington, DC 20463.

**CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:**

- (a) Individuals and institutions who have requested a subscription to the *Record*.
- (b) Individuals who have requested FEC publications.
- (c) State and local election officials interested in keeping informed of developments.
- (d) Reporters who request releases; media added by the Press Office.

**CATEGORIES OF RECORDS IN THE SYSTEM:**

- (a) Lists of names, addresses, principal areas of interest.
- (b) List of names, addresses and subjects of interest to the requester.
- (c) List of names, addresses, duties and jurisdictions.
- (d) Computer listings.

**AUTHORITY FOR MAINTENANCE OF THE SYSTEM:**

2 U.S.C. 438(a) for all categories.

**ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND PURPOSES OF SUCH USES:**

- (a) Distribution of monthly newsletter, the *Record*, to subscribers.
- (b) To forward new publications and other informational materials to persons who have expressed an interest in the subject matter.
- (c) To distribute publications and other materials of interest to those who administer the election law of the states.
- (d) To mail press releases.

*Routine use for disclosure to the Department of Justice for use in litigation:*

It shall be a routine use of the records in this system of records to disclose them to the Department of Justice when:

(a) The agency, or any component thereof; or

(b) Any employee of the agency in his or her official capacity; or

(c) Any employee of the agency in his or her individual capacity where the Department of Justice has agreed to represent the employee; or

(d) The United States, where the agency determines that litigation is likely to affect the agency or any of its components,

is a party to litigation or has an interest in such litigation, and the use of such reports by the Department of Justice is deemed by the Federal Election Commission to be relevant and necessary to the litigation provided, however, that in each case the agency determines that disclosure of the records to the Department of Justice is a use of the information contained in the records that is compatible with the purpose for which the records were collected.

*Routine use for Agency disclosure in litigation:*

It shall be a routine use of records maintained by this agency to disclose them in a proceeding before a court or adjudicative body before which the agency is authorized to appear when:

- (a) The agency, or any component thereof; or
- (b) Any employee of the agency in his or her official capacity; or
- (c) Any employee of the agency in his or her individual capacity where the agency has agreed to represent the employee; or
- (d) The United States, where the agency determines that litigation is likely to affect the agency, or any of its components,

is a party to litigation or has an interest in such litigation, and the Federal Election Commission determines that, on a case-by-case basis, use of such records is relevant and necessary to the litigation, provided, however, that the agency determines that disclosure of the records is compatible with the purpose for which the records were collected.

**POLITICS AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:**

**STORAGE:**

Computerized for all categories.

**RETRIEVABILITY:**

- (a) Name or identification numbers.
- (b) Name.
- (c) Name, title, jurisdiction or region of the country.
- (d) Name of individual or name of media.

**SAFEGUARDS:**

Access code with password for all categories.

**RETENTION AND DISPOSAL:**

- (a) Purged every two years or upon request of subscriber.
- (b) Purged every two years.
- (c) Indefinite.
- (d) Indefinite.

**SYSTEM MANAGER(S) AND ADDRESS:**

The Assistant Staff Director for Information, Federal Election Commission, Washington, DC 20463, (202/219-3440).

**NOTIFICATION PROCEDURES:**

Refer to Commission access regulations at 11 CFR 1.1 et seq., 41 FR 43064 (1976).

**RECORD ACCESS PROCEDURES:**

Same as above.

**CONTESTING RECORD PROCEDURES:**

Same as above.

**RECORD SOURCE CATEGORIES:**

- (a) Individuals and organizations who request a subscription to the *Record*.
- (b) Individuals to whom the Information Division has mailed publications.
- (c) Officials requiring up-to-date information on elections administration.
- (d) Oral and written requests to be placed on list; media directories.

**FEC 5****SYSTEM NAME:**

Personnel records.

**SYSTEM LOCATION:**

Federal Election Commission, Washington, DC 20463.

**CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:**

Applicants for employment, current employees (including unpaid interns), and former employees.

**CATEGORIES OF RECORDS IN THE SYSTEM:**

- (a) SF-171's/résumés.
- (b) SF-7 Record Cards (current and former employees).
- (c) Official Personnel Folder (OPF).
- (d) Employee Performance Folders (EPF).
- (e) Individual Employee Master Files.
- (f) Discipline/Adverse Action Files.
- (g) Outside Employment Files.
- (h) Employee Medical File.
- (i) Grievance Files.
- (j) Appeal Files.

**AUTHORITY FOR MAINTENANCE OF THE SYSTEM:**

2 U.S.C. 437c and 5 CFR part 293.

**ROUTINE USES OF RECORDS IN THE SYSTEMS, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:**

(a) SF-171's/Résumés—used by Personnel staff and all levels of management to evaluate qualifications and make personnel selections.

(b) SF-7 Record Cards—used by Personnel staff to verify salary, grade and service of current and former employees for use by prospective employers, credit bureaus, etc.

(c) OPF—used by Personnel staff to process and record personnel actions, and by Personnel staff and line managers to evaluate skills, ability and qualifications for selection, promotion, and other personnel actions.

(d) EPF—used by Personnel staff to record performance-related information such as performance appraisals, and by line managers as basis for personnel actions.

(e) Individual Employee Master File—computer-stored record of all personnel actions and other pertinent employee data; used by Personnel staff to process and record personnel actions and by the authorized Data Systems staff and Payroll and Accounting staff to update and revise files, programs and produce required statistical reports.

(f) Discipline and Adverse Actions—used by Personnel staff and line managers in considering decisions on such actions, and for appeals, grievances and hearings.

(g) Outside Employment Files—used by Personnel and legal staff to consider requests for outside employment and to verify approval/disapproval.

(h) Employee Medical Files—used by Personnel staff and line managers to record employee medical information pertinent to their performance/attendance/conduct, and in reviewing the impact of medical conditions on their employment.

(i) Grievance Files—used by Personnel staff to record the disposition of employee grievances.

(j) Appeal Files—used by Personnel staff to record the disposition of employee appeals.

In addition to the above, in the event that a system of records maintained by this agency to carry out its functions indicated a violation or potential violation of law, whether civil, criminal or regulatory in nature, and whether arising by general statute or particular program statute, or by regulation, rule or order issued pursuant thereto, the relevant records in the system of records may be referred, as a routine use, to the appropriate agency, whether Federal, State, local or foreign, charged with the responsibility of investigation or prosecuting such violation or charged

with enforcing or implementing the statute, or rule, regulation or order issued pursuant thereto.

A record from the system of records may be disclosed as "routine use" to a Federal, State or local agency maintaining civil, criminal or other relevant enforcement information, or other pertinent information, such as current licenses, if necessary to obtain information relevant to an agency decision concerning the hiring or retention of an employee, the issuance of a security clearance, the letting of a contract or the issuance of a license, grant or other benefit.

A record from this system of records may be disclosed to a Federal agency, in response to its request, in connection with the hiring or retention of an employee, the issuance of a security clearance, the reporting of an investigation of an employee, the letting of a contract or the issuance of a license, grant or other benefit by the requesting agency, to the extent that the information is relevant and necessary to the requesting agency's decision in the matter.

A record from this system of records may be disclosed to an authorized complaints examiner, equal employment opportunity investigator, administrative law judge, arbitrator or other duly authorized official engaged in investigation or settlement of a grievance, complaint or appeal filed by an employee. A record from this system of records may be disclosed to the U.S. Office of Personnel Management in accordance with the agency's responsibility for evaluation and oversight of Federal personnel management.

A record from this system of records may be disclosed to officers and employees of a Federal agency for purposes of audit.

***Routine use for disclosure to the Department of Justice for use in litigation:***

It shall be a routine use of the records in this system of records to disclose them to the Department of Justice when:

- (a) The agency, or any component thereof; or
- (b) Any employee of the agency in his or her official capacity; or
- (c) Any employee of the agency in his or her individual capacity where the Department of Justice has agreed to represent the employee; or
- (d) The United States, where the agency determines that litigation is likely to affect the agency or any of its components,

is a party to litigation or has an interest in such litigation, and the use of such

reports by the Department of Justice is deemed by the Federal Election Commission to be relevant and necessary to the litigation provided, however, that in each case the agency determines that disclosure of the records to the Department of Justice is a use of the information contained in the records that is compatible with the purpose for which the records were collected.

*Routine use for Agency disclosure in litigation*

It shall be a routine use of records maintained by this agency to disclose them in a proceeding before a court or adjudicative body before which the agency is authorized to appear when:

- (a) The agency, or any component thereof; or
- (b) Any employee of the agency in his or her official capacity; or
- (c) Any employee of the agency in his or her individual capacity where the agency has agreed to represent the employee; or
- (d) The United States, where the agency determines that litigation is likely to affect the agency, or any of its components,

is a party to litigation or has an interest in such litigation, and the Federal Election Commission determines that, on a case-by-case basis, use of such records is relevant and necessary to the litigation, provided, however, that the agency determines that disclosure of the records is compatible with the purpose for which the records were collected.

**POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:**

- (a) Hard copy record kept in Personnel Office.
- (b) Hard copy record kept in Personnel Office.
- (c) Hard copy record kept in Personnel Office.
- (d) Hard copy record kept in Personnel Office.
- (e) Computer disk packs within central processing unit.
- (f) Hard copy record kept in Personnel Office.
- (g) Hard copy record kept in Personnel Office.
- (h) Hard copy record kept in Personnel Office.
- (i) Hard copy record kept in Personnel Office.
- (j) Hard copy record kept in Personnel Office.

**RETRIEVABILITY:**

- (a) Retrieval by hand of alphabetical files.
- (b) Retrieval by hand of alphabetical files.

- (c) Retrieval by hand of alphabetical files.
- (d) Retrieval by hand of alphabetical files.
- (e) On line access using SSN.
- (f) Retrieval by hand of alphabetical files.
- (g) Retrieval by hand of alphabetical files.
- (h) Retrieval by hand of alphabetical files.
- (i) Retrieval by hand of alphabetical files.
- (j) Retrieval by hand of alphabetical files.

**SAFEGUARDS:**

- (a) Locked file cabinet in locked office.
- (b) Locked Office.
- (c) Locked file cabinet in locked office.
- (d) Locked file cabinet in locked office.
- (e) Overall password for group number; individual password for each program; knowledge of password limited to appropriate personnel.
- (f) Locked file cabinet in locked office.
- (g) Locked file cabinet in locked office.
- (h) Locked file cabinet in locked office.
- (i) Locked file cabinet in locked office.
- (j) Locked file cabinet in locked office.

**RETENTION AND DISPOSAL:**

- (a) 1 year; shredded.
- (b) Indefinite.
- (c) Indefinite; transferred with employee to succeeding agency or retired to Federal Records Center upon retirement or termination/resignation from Federal service or death.
- (d) Indefinite; shredded within 30 days of employee departure unless part of ongoing adjudicatory action.
- (e) Indefinite.
- (f) 2 years; shredded.
- (g) 2 years; shredded.
- (h) Indefinite; transferred with employee to succeeding agency or retired to Federal Records Center upon retirement or termination/resignation from Federal service or death.
- (i) Indefinite.
- (j) Indefinite.

**SYSTEM MANAGER(S) AND ADDRESS:**

The Director of Personnel, Federal Election Commission, Washington, DC 20463, (202/219-3440).

**NOTIFICATION PROCEDURES:**

Refer to Commission access regulations at 11 CFR 1.1 et seq., 41 43064 (1976).

**RECORD ACCESS PROCEDURES:**

Same as above.

**CONTESTING RECORD PROCEDURES:**

Same as above.

**RECORD SOURCE CATEGORIES:**

Personnel applications, résumés, employment forms, records of personnel action.

**FEC 6**

**SYSTEM NAME:**

Candidate reports and designations.

**SYSTEM LOCATION:**

Federal Election Commission, Washington, DC 20463.

**CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:**

Candidates for Federal office required to file reports of contributions and expenditures and designations of campaign depositories and authorized committees.

**CATEGORIES OF RECORDS IN THE SYSTEM:**

Reports and Statements of candidates; reports by delegates and other persons making contributions or independent expenditures and designations on behalf of a Federal candidate but not through a political committee, candidate, or authorized committee or agent of a candidate.

**AUTHORITY FOR MAINTENANCE OF THE SYSTEM:**

2 U.S.C. 432(e), 434, and 437b(a)(1).

**ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:**

This system may be used by any person for information purposes. However, any information copied from such reports shall not be sold or utilized by any person for the purposes of soliciting contributions or for any commercial purpose.

*Routine use for disclosure to the Department of Justice for use in litigation:*

It shall be a routine use of the records in this system of records to disclose them to the Department of Justice when:

- (a) The agency, or any component thereof; or
- (b) Any employee of the agency in his or her official capacity; or
- (c) Any employee of the agency in his or her individual capacity where the Department of Justice has agreed to represent the employee; or
- (d) The United States, where the agency determines that litigation is likely to affect the agency or any of its components,

is a party to litigation or has an interest in such litigation, and the use of such

reports by the Department of Justice is deemed by the Federal Election Commission to be relevant and necessary to the litigation provided, however, that in each case the agency determines that disclosure of the records to the Department of Justice is a use of the information contained in the records that is compatible with the purpose for which the records were collected.

*Routine use for Agency disclosure in litigation:*

It shall be a routine use of records maintained by this agency to disclose them in a proceeding before a court or adjudicative body before which the agency is authorized to appear when:

- (a) The agency, or any component thereof; or
  - (b) Any employee of the agency in his or her official capacity; or
  - (c) Any employee of the agency in his or her individual capacity where the agency has agreed to represent the employee; or
  - (d) The United States, where the agency determines that litigation is likely to affect the agency, or any of its components,
- is a party to litigation or has an interest in such litigation, and the Federal Election Commission determines that, on a case-by-case basis, use of such records is relevant and necessary to the litigation, provided, however, that the agency determines that disclosure of the records is compatible with the purpose for which the records were collected.

**POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING AND DISPOSING OF RECORDS IN THE SYSTEM:**

**STORAGE:**

Paper records and/or microfilm and on-line disk storage electronic data processing system.

**RETRIEVABILITY:**

Retrievable by candidate's name, or by State in which candidate seeks election; candidate identification number or last name for computer storage.

**SAFEGUARDS:**

Locked filing cabinets.

**RETENTION AND DISPOSAL:**

Reports are preserved for a 10-year period except that reports relating solely to candidates for the House of Representative are preserved for 5 years from the date of receipt. Microfilm is preserved indefinitely.

**SYSTEM MANAGER(S) AND ADDRESS:**

The Assistant Staff Director for Disclosure, Federal Election

Commission, Washington, DC 20463, (202/219-3440).

**NOTIFICATION PROCEDURES:**

Refer to Commission access regulations at 11 CFR 1.1 et seq., 41 FR 43064 (1976).

**RECORD ACCESS PROCEDURES:**

Same as above.

**CONTESTING RECORD PROCEDURES:**

Same as above.

**RECORD SOURCE CATEGORIES:**

Reports filed with the FEC.

**FEC 7**

**SYSTEM NAME:**

Certification for primary matching funds and general election campaign funds.

**SYSTEM LOCATION:**

Federal Election Commission, Washington, DC 20463.

**CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:**

Candidates for nomination or election to the Office of President of the United States.

**CATEGORIES OF RECORDS IN THE SYSTEM:**

Certification forms and supporting data requesting matching funds or election funds.

**AUTHORITY FOR MAINTENANCE OF THE SYSTEM:**

26 U.S.C. 9003, 9006; 26 U.S.C. 9033, 9036, 9037.

**ROUTINE USE OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:**

Certification of eligibility for funds by presidential candidates. These files are available for public inspection.

*Routine use for disclosure to the Department of Justice for use in litigation:*

- It shall be a routine use of the records in this system of records to disclose them to the Department of Justice when:
- (a) The agency, or any component thereof; or
  - (b) Any employee of the agency in his or her official capacity; or
  - (c) Any employee of the agency in his or her individual capacity where the Department of Justice has agreed to represent the employee; or
  - (d) The United States, where the agency determines that litigation is likely to affect the agency or any of its components,

is a party to litigation or has an interest in such litigation, and the use of such reports by the Department of Justice is

deemed by the Federal Election Commission to be relevant and necessary to the litigation provided, however, that in each case the agency determines that disclosure of the records to the Department of Justice is a use of the information contained in the records that is compatible with the purpose for which the records were collected.

*Routine use for Agency disclosure in litigation:*

It shall be a routine use of records maintained by this agency to disclose them in a proceeding before a court or adjudicative body before which the agency is authorized to appear when:

- (a) The agency, or any component thereof; or
- (b) Any employee of the agency in his or her official capacity; or
- (c) Any employee of the agency in his or her individual capacity where the agency has agreed to represent the employee; or
- (d) The United States, where the agency determines that litigation is likely to affect the agency, or any of its components,

is a party to litigation or has an interest in such litigation, and the Federal Election Commission determines that, on a case-by-case basis, use of such records is relevant and necessary to the litigation, provided, however, that the agency determines that disclosure of the records is compatible with the purpose for which the records were collected.

**POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:**

**STORAGE:**

Paper records.

**RETRIEVABILITY:**

Indexed by name of candidate.

**SAFEGUARDS:**

Locked filing cabinets.

**RETENTION AND DISPOSAL:**

Indefinite.

**SYSTEMS MANAGER(S) AND ADDRESS:**

Assistant Staff Director for Audit, Federal Election Commission, Washington, DC 20463 (202/219-3440).

**NOTIFICATION PROCEDURES:**

Refer to Commission access regulations at 11 CFR 1.1 et seq., 41 FR 43064 (1976).

**RECORDS ACCESS PROCEDURES:**

Same as above.

**CONTESTING RECORD PROCEDURES:**

Same as above.

**RECORD SOURCE CATEGORIES:**

Certification reports filed with the Commission.

**FEC 8****SYSTEM NAME:**

Payroll records.

**SYSTEM LOCATION:**

Federal Election Commission,  
Washington, DC 20463.

**CATEGORIES OF RECORDS IN THE SYSTEM:**

Varied payroll records, including, among other documents, time and attendance cards; payment vouchers; comprehensive listing of employees; health benefit records; requests for deductions; tax forms; W-2 forms; overtime requests; leave data; and retirement records. Records are used by Commission employees to maintain adequate payroll information for Commission employees, and otherwise by Commission employees who have a need for the record in the performance of their duties.

**AUTHORITY FOR MAINTENANCE OF THE SYSTEM:**

31 U.S.C., generally. Also, 2 U.S.C. 437c(f).

**ROUTINE USES FOR RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:**

In the event that a system of records maintained by this agency to carry out its functions indicated a violation or potential violation of law, whether civil, criminal or regulatory in nature, and whether arising by general statute or particular program statute, or by regulation, rule or order issued pursuant thereto, the relevant records in the system of records may be referred, as a routine use, to the appropriate agency, whether Federal, State, local or foreign, charged with the responsibility of investigating or prosecuting such violation or charged with enforcement or implementation of the statute or rule, regulation or order issued pursuant thereto.

A record from this system of records may be disclosed as a "routine use" to a Federal, State, or local agency maintaining civil, criminal or other relevant enforcement information, such as current licenses, if necessary to obtain information relevant to an agency decision concerning the hiring or retention of an employee, the issuance of a security clearance, the letting of a contract or the issuance of a license, grant or other benefit. A record from this system of records may be disclosed to a Federal agency, in response to its request, in connection with the hiring or retention of an employee, the issuance

of a security clearance, the reporting of an investigation of an employee, the letting of a contract, or the issuance of a license, grant or other benefit by the requesting agency, to the extent that the information is relevant and necessary to the requesting agency's decision in the matter.

A record from this system of records may be disclosed to an authorized appeal grievance examiner, formal complaints examiner, equal employment opportunity investigator, arbitrator or other duly authorized official engaged in investigation or settlement of a grievance, complaint, or appeal filed by an employee. A record from this system of records may be disclosed to the Office of Personnel Management in accordance with the agency's responsibility for evaluation and oversight of Federal personnel management.

A record from this system of records may be disclosed to officers and employees of a Federal agency for purposes of audit.

The information contained in this system of records will be disclosed to the Office of Management and Budget in connection with the review of private relief legislation as set forth in OMB Circular No. A-19 at any stage of the legislative coordination and clearance processes as set forth in that circular.

Records also are disclosed to GAO for audits; to the Internal Revenue Service for investigation; and to private attorneys, pursuant to a power of attorney.

A copy of an employee's Department of the Treasury form W-2, wage and tax statement, also is disclosed to the State and city, or other local jurisdiction which is authorized to tax the employee's compensation. The record will be provided in accordance with a withholding agreement between the State, city, or other local jurisdiction and the Department of the Treasury pursuant to 5 U.S.C. 5516, 5517, or 5520, or, in the absence thereof, in response to a written request from an appropriate official of the taxing jurisdiction to the Assistant Director for Administration; Federal Election Commission, Washington, DC 20463. The request must include a copy of the applicable statute or ordinance authorizing the taxation of compensation and should indicate whether the authority of the jurisdiction to tax the employee is based on place of residence, place of employment, or both.

Pursuant to a withholding agreement between a city and the Department of the Treasury (5 U.S.C. 5520), copies of executed city tax withholding

certificates shall be furnished the city in response to a written request from an appropriate city official to the Assistant Staff Director for Administration.

In the absence of a withholding agreement, the Social Security number will be furnished only to a taxing jurisdiction which has furnished this agency with evidence of its independent authority to compel disclosure of the Social Security number, in accordance with section 7 of the Privacy Act.

**Routine use for disclosure to the Department of Justice for use in litigation:**

It shall be a routine use of the records in this system of records to disclose them to the Department of Justice when:

- (a) The agency, or any component thereof; or
- (b) Any employee of the agency in his or her official capacity; or
- (c) Any employee of the agency in his or her individual capacity where the Department of Justice has agreed to represent the employee; or
- (d) The United States, where the agency determines that litigation is likely to affect the agency or any of its components,

is a party to litigation or has an interest in such litigation, and the use of such reports by the Department of Justice is deemed by the Federal Election Commission to be relevant and necessary to the litigation provided, however, that in each case the agency determines that disclosure of the records to the Department of Justice is a use of the information contained in the records that is compatible with the purpose for which the records were collected.

**Routine use for Agency disclosure in litigation:**

It shall be a routine use of records maintained by this agency to disclose them in a proceeding before a court or adjudicative body before which the agency is authorized to appear when:

- (a) The agency, or any component thereof; or
- (b) Any employee of the agency in his or her official capacity; or
- (c) Any employee of the agency in his or her individual capacity where the agency has agreed to represent the employee; or
- (d) The United States, where the agency determines that litigation is likely to affect the agency, or any of its components,

is a party to litigation or has an interest in such litigation, and the Federal Election Commission determines that, on a case-by-case basis, use of such

records is relevant and necessary to the litigation, provided, however, that the agency determines that disclosure of the records is compatible with the purpose for which the records were collected.

**POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING AND DISPOSING OF RECORDS IN THE SYSTEM:**

**STORAGE:**

Computer disk packs within central processing unit.

**RETRIEVABILITY:**

On line access program utilizing employee social security number.

**SAFEGUARDS:**

Overall password for group number; individual password for each program; knowledge of password limited to appropriate personnel.

**RETENTION AND DISPOSAL:**

Disposition of records shall be in accordance with the HB GSA Records Maintenance and Disposition System (OAD P 1820.2).

**SYSTEM MANAGER(S) AND ADDRESS:**

The Assistant Staff Director for Administration, Federal Election Commission, Washington, DC 20463, (202/219-3440).

**NOTIFICATION PROCEDURES:**

Refer to Commission access regulations at 11 CFR 1.1 et seq., 41 FR 43064 (1976).

**RECORD ACCESS PROCEDURES:**

Same as above.

**CONTESTING RECORD PROCEDURES:**

Same as above.

**RECORD SOURCE CATEGORIES:**

The subject individual; the Federal Election Commission.

**FEC 9**

**SYSTEM NAME:**

Litigation Actions.

**SYSTEM LOCATION:**

Federal Election Commission, Washington, DC 20463.

**CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:**

Individuals who have brought judicial action against the Commission and individuals against whom the Commission has brought judicial action pursuant to 2 U.S.C. 437g or 437h, 26 U.S.C. 9011 or 9041, 5 U.S.C. 552 or any other statute.

**CATEGORIES OR RECORDS IN THE SYSTEM:**

All papers incident to a law suit, including discovery materials, motions, briefs, and orders.

**AUTHORITY FOR MAINTENANCE OF THE SYSTEM:**

2 U.S.C. 437g(a)(6), 437g(a)(8), 437g(a)(11), and 437h.

**ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS, AND THE PURPOSES OF SUCH USES:**

Maintained for historical purposes and for consultation as precedent in subsequent judicial or administrative actions. Civil litigation is handled by the General Counsel's office. Access is limited to FEC staff on a restricted basis.

*Routine use for disclosure to the Department of Justice for use in litigation:*

It shall be a routine use of the records in this system of records to disclose them to the Department of Justice when:

- (a) The agency, or any component thereof; or
- (b) Any employee of the agency in his or her official capacity; or
- (c) Any employee of the agency in his or her individual capacity where the Department of Justice has agreed to represent the employee; or
- (d) The United States, where the agency determines that litigation is likely to affect the agency or any of its components,

is a party to litigation or has an interest in such litigation, and the use of such reports by the Department of Justice is deemed by the Federal Election Commission to be relevant and necessary to the litigation provided, however, that in each case the agency determines that disclosure of the records to the Department of Justice is a use of the information contained in the records that is compatible with the purpose for which the records were collected.

*Routine use for Agency disclosure in litigation:*

It shall be a routine use of records maintained by this agency to disclose them in a proceeding before a court or adjudicative body before which the agency is authorized to appear when:

- (a) The agency, or any component thereof; or
- (b) Any employee of the agency in his or her official capacity; or
- (c) Any employee of the agency in his or her individual capacity where the agency has agreed to represent the employee; or
- (d) The United States, where the agency determines that litigation is likely to affect the agency, or any of its components,

is a party to litigation or has an interest in such litigation, and the Federal Election Commission determines that, on a case-by-case basis, use of such

records is relevant and necessary to the litigation, provided, however, that the agency determines that disclosure of the records is compatible with the purpose for which the records were collected.

**POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:**

**STORAGE:**

Paper records and microfilm.

**RETRIEVABILITY:**

System indexed by name of party litigant and, as applicable, by microfilm roll and frame number.

**SAFEGUARDS:**

This system is kept in locked filing cabinets or in limited access areas under personal surveillance during working hours, and in locked rooms at other times.

**RETENTION AND DISPOSAL:**

Indefinite.

**SYSTEM MANAGER(S) AND ADDRESS:**

The General Counsel, Federal Election Commission, Washington, DC 20463, (202/219-3440).

**NOTIFICATION PROCEDURES:**

Refer to Commission access regulations at 11 CFR 1.1 et seq., 41 FR 43064 (1976).

**RECORD ACCESS PROCEDURES:**

Same as above.

**CONTESTING RECORD PROCEDURES:**

Same as above.

**RECORD SOURCE CATEGORIES:**

Individual party litigants and counsel, court personnel and the Federal Election Commission.

**FEC 10**

**SYSTEM NAME:**

Letter file, Public Communications.

**SYSTEM LOCATION:**

Federal Election Commission, Washington, DC 20463.

**CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:**

Individuals who have written to the FEC requesting answers to specific questions.

**CATEGORIES OF RECORDS IN THE SYSTEM:**

Inquiries by individuals concerning the Federal Election Campaign Act of 1971, as amended.

**AUTHORITY FOR MAINTENANCE OF THE SYSTEM:**

2 U.S.C. 438(a).

**ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:**

Response to inquiries.

*Routine use for disclosure to the Department of Justice for use in litigation:*

It shall be a routine use of the records in this system of records to disclose them to the Department of Justice when:

- (a) The agency, or any component thereof; or
- (b) Any employee of the agency in his or her official capacity; or
- (c) Any employee of the agency in his or her individual capacity where the Department of Justice has agreed to represent the employee; or
- (d) The United States, where the agency determines that litigation is likely to affect the agency or any of its components.

is a party to litigation or has an interest in such litigation, and the use of such reports by the Department of Justice is deemed by the Federal Election Commission to be relevant and necessary to the litigation provided, however, that in each case the agency determines that disclosure of the records to the Department of Justice is a use of the information contained in the records that is compatible with the purpose for which the records were collected.

*Routine use for Agency disclosure in litigation:*

It shall be a routine use of records maintained by this agency to disclose them in a proceeding before a court or adjudicative body before which the agency is authorized to appear when:

- (a) The agency, or any component thereof; or
- (b) Any employee of the agency in his or her official capacity; or
- (c) Any employee of the agency in his or her individual capacity where the agency has agreed to represent the employee; or
- (d) The United States, where the agency determines that litigation is likely to affect the agency, or any of its components,

is a party to litigation or has an interest in such litigation, and the Federal Election Commission determines that, on a case-by-case basis, use of such records is relevant and necessary to the litigation, provided, however, that the agency determines that disclosure of the records is compatible with the purpose for which the records were collected.

**POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING AND DISPOSING OF RECORDS IN THE SYSTEM:**

**STORAGE:**

Paper files.

**RETRIEVABILITY:**

Name of individual.

**RETENTION AND DISPOSAL:**

Retained in-house for one year; shipped afterward to general storage.

**SYSTEM MANAGER(S) AND ADDRESS:**

The Assistant Staff Director for Information, Federal Election Commission, Washington, DC. 20463 (202/219-3440).

**NOTIFICATION PROCEDURES:**

Refer to Commission access regulations at 11 CFR 1.1 et seq., 41 FR 43064 (1976).

**RECORD ACCESS PROCEDURES:**

Same as above.

**CONTESTING RECORD PROCEDURES:**

Same as above.

**RECORD SOURCE CATEGORIES:**

Individuals who request information in writing.

**FEC 11**

**SYSTEM NAME:**

Contributor Name Index System.

**SYSTEM LOCATION:**

Federal Election Commission, Washington, DC 20463.

**CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:**

Individuals who have been listed on campaign finance reports as having given \$200 or more per transaction to a Federal candidate or their supporting political committee.

**CATEGORIES OF RECORDS IN THE SYSTEM:**

On-line disk storage electronic data processing index of names.

**AUTHORITY FOR MAINTENANCE OF THE SYSTEM:**

2 U.S.C. 441a.

**ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:**

Commission staff and the public may use this system to ascertain whether and to what extent named individuals have made contributions to Federal candidates and political committees.

*Routine use for disclosure to the Department of Justice for use in litigation:*

It shall be a routine use of the records in this system of records to disclose them to the Department of Justice when:

- (a) The agency, or any component thereof; or
  - (b) Any employee of the agency in his or her official capacity; or
  - (c) Any employee of the agency in his or her individual capacity where the Department of Justice has agreed to represent the employee; or
  - (d) The United States, where the agency determines that litigation is likely to affect the agency, or any of its components,
- is a party to litigation or has an interest in such litigation, and the use of such reports by the Department of Justice is deemed by Federal Election Commission to be relevant and necessary to the litigation, provided, however, that in each case the agency determines that disclosure of the records to the Department of Justice is a use of the information contained in the records that is compatible with the purpose for which the records were collected.

*Routine use for Agency disclosure in litigation:*

It shall be a routine use of records maintained by this agency to disclose them in a proceeding before a court or adjudicative body before which the agency is authorized to appear when:

- (a) The agency, or any component thereof; or
- (b) Any employee of the agency in his or her official capacity; or
- (c) Any employee of the agency in his or her individual capacity where the agency has agreed to represent the employee; or
- (d) The United States, where the agency determines that litigation is likely to affect the agency, or any of its components,

is a party to litigation or has an interest in such litigation, and the Federal Election Commission determines that, on a case-by-case basis, use of such records is relevant and necessary to the litigation, provided, however, that the agency determines that disclosure of the records is compatible with the purpose for which the records were collected.

**POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING AND DISPOSING OF RECORDS IN THE SYSTEM:**

**STORAGE:**

On-line disk storage electronic data.

**RETRIEVABILITY:**

Indexed by last name of contributor.

**SAFEGUARDS:**

Requests are handled only on an overnight request basis, with Commission staff doing research and retrieval.

**RETENTION AND DISPOSAL:**

Indefinite.

**SYSTEM MANAGER(S) AND ADDRESS:**

The Assistant Staff Director for Data Systems Development Division, Federal Election Commission, Washington, DC 20463, (202/219-3440).

**NOTIFICATION PROCEDURES:**

Refer to Commission access regulations at 11 CFR 1.1 et seq., 41 FR 43064 (1976).

**RECORD ACCESS PROCEDURES:**

Same as above.

**CONTESTING RECORD PROCEDURES:**

Same as above.

**RECORD SOURCE CATEGORIES:**

Individual contributors.

**FEC 12****SYSTEM NAME:**

Inspector General Investigative Files.

**SYSTEM LOCATION:**

Federal Election Commission, Washington, DC 20463.

**CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:**

Individuals who are the subjects of complaints.

**CATEGORIES OF RECORDS IN THE SYSTEM:**

Complaints, referrals from other agencies, investigative notes, interviews, reports, interrogatories and responses thereto.

**AUTHORITY FOR MAINTENANCE OF THE SYSTEM:**

Inspector General Act Amendments of 1988, Public Law 100-504, amending the Inspector General Act of 1978, Public Law 95-402, 5 U.S.C. app.

**ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:**

Material is maintained in the Office of Inspector General's (OIG) investigative files. Access to files is restricted to OIG Staff and then on a need to know basis. Criminal violations are referred to the Justice Department.

**Systems exempted:**

System exempt under 5 U.S.C. 552a(j)(2) and 5 U.S.C. 552a(k)(2). See 11 CFR 1.14.

**POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING AND DISPOSING OF RECORDS IN THE SYSTEM:****STORAGE:**

Paper and computer records.

**RETRIEVABILITY:**

The records are retrieved by the name of the subject of the investigation or by

a unique control number assigned to each investigation.

**SAFEGUARDS:**

The paper records and computer disks are kept in locked cabinets in limited access areas under personal surveillance during working hours and in locked cabinets in a locked room at all other times.

**RETENTION AND DISPOSAL:**

Indefinite.

**SYSTEM MANAGER(S) AND ADDRESS:**

The Inspector General, Federal Election Commission, Washington, DC 20463, (202/219-4267).

**NOTIFICATION PROCEDURES:**

Refer to Commission access regulations at 11 CFR 1.1 et seq., 41 FR 43064 (1976).

**RECORD ACCESS PROCEDURES:**

Same as above.

**CONTESTING RECORD PROCEDURES:**

Same as above.

**RECORD SOURCE CATEGORIES:**

Complaints, subjects, third parties who have been requested to produce relevant information, referring agencies.

**SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:**

With respect to investigations, the system is exempt pursuant to 5 U.S.C. 552a(k)(2).

[FR Doc. 94-26613 Filed 10-26-94; 8:45 am]

BILLING CODE 6715-01-M

**FEDERAL MARITIME COMMISSION**

[Docket No. 94-24]

**South Carolina State Ports Authority Regulation of Stevedore and Marine Terminal Functions; Notice of Filing of Petition for Declaratory Order**

Notice is given that a petition for declaratory order has been filed by The South Carolina State Ports Authority ("Petitioner").

The petitioner requests that the Commission issue a declaratory order endorsing its proposed stevedore licensing guidelines, which would require applicants to bring new business to the Port of Charleston, and which would reserve for petitioner the right to perform public marine terminal operations at its facilities.

Interested persons may submit replies to the Secretary, Federal Maritime Commission, Washington, DC 20573-0001 on or before November 28, 1994, in an original and 15 copies. Replies

shall also be served on counsel for Petitioner: Linette G. Tobin, Garvey, Schubert & Barer, Fifth floor, 1000 Potomac Street, NW., Washington, DC 20007. Replies shall contain the complete factual and legal presentation of the replying party as to the desired resolution of the petition (See 46 CFR 502.68(d)).

Copies of the petition are available for examination at the Washington, DC Office of the Commission, 800 North Capitol Street, NW., Room 1046.

Joseph C. Polking,

Secretary.

[FR Doc. 94-26578 Filed 10-26-94; 8:45 am]

BILLING CODE 6730-01-M

**FEDERAL RESERVE SYSTEM****Commerzbank Aktiengesellschaft, Frankfurt am Main, Federal Republic of Germany; Application to Engage in Nonbanking Activities**

Commerzbank Aktiengesellschaft, Frankfurt am Main, Federal Republic of Germany (Applicant), has applied pursuant to section 4(c)(8) of the Bank Holding Company Act (12 U.S.C. 1843(c)(8)) (BHC Act) and § 225.23(a)(3) of the Board's Regulation Y (12 CFR 225.23(a)(3)) to engage *de novo* through CB Clearing, Inc., Chicago, Illinois (Company), a futures commission merchant (FCM) registered under the Commodity Exchange Act (7 U.S.C. § 1 et seq.), in executing and clearing, clearing without executing, and purchasing and selling through the use of omnibus trading accounts futures and options on futures on nonfinancial commodities that previously have been approved by the Board. Applicant also has applied to engage through Company in executing transactions with respect to the following contracts: Major Market Index options traded on the American Stock Exchange; Standard & Poor's 100 Stock Index options, Standard & Poor's 500 Stock Index options, Long-Term Interest Rate options, Short-Term Interest Rate options, Long-Term U.S. Treasury Index options, and Short-Term U.S. Treasury Index options traded on the Chicago Board Options Exchange; and Deutsche Mark options, Swiss Franc options, Australian Dollar options, British Pound options, Canadian Dollar options, European Currency Unit (ECU) options, French Franc options and Japanese Yen options traded on the Philadelphia Stock Exchange. Applicant proposes to conduct these activities throughout the world.

Section 4(c)(8) of the BHC Act provides that a bank holding company

may, with Board approval, engage in any activity which the Board, after due notice and opportunity for hearing, has determined (by order or regulation) to be so closely related to banking or managing or controlling banks as to be a proper incident thereto. This statutory test requires that two separate tests be met for an activity to be permissible for a bank holding company. First, the Board must determine that the activity is, as a general matter, closely related to banking. Second, the Board must find in a particular case that the performance of the activity by the applicant bank holding company may reasonably be expected to produce public benefits that outweigh possible adverse effects.

A particular activity may be found to meet the "closely related to banking" test if it is demonstrated that banks generally have provided the proposed activity, that banks generally provide services that are operationally or functionally similar to the proposed activity so as to equip them particularly well to provide the proposed activity, or that banks generally provide services that are so integrally related to the proposed activity as to require their provision in a specialized form.

*National Courier Ass'n v. Board of Governors*, 516 F.2d 1229, 1237 (D.C. Cir. 1975). In addition, the Board may consider any other basis that may demonstrate that the activity has a reasonable or close relationship to banking or managing or controlling banks. Board Statement Regarding Regulation Y, 49 FR 806 (1984).

Applicant maintains that the Board previously has determined that the proposed FCM activities are closely related to banking. See *Bank of Montreal*, 79 Federal Reserve Bulletin 1049 (1993); *J.P. Morgan & Co. Incorporated*, 80 Federal Reserve Bulletin 151 (1994) (*J.P. Morgan*). Applicant states that it would perform the proposed FCM activities in a manner consistent with these previous orders. Applicant also maintains that the Board previously has determined by regulation and order that the proposed options execution activities are closely related to banking. See *Manufacturers Hanover Corporation*, 76 Federal Reserve Bulletin 774 (1990); 12 C.F.R. § 225.25 (b)(15). Applicant states that it would perform the proposed options execution activities in accordance with this order and regulation.

In order to approve this proposal, the Board must determine that the proposed activities "can reasonably be expected to produce benefits to the public, such as greater convenience, increased competition, or gains in efficiency, that outweigh possible adverse effects, such

as undue concentration of resources, decreased or unfair competition, conflicts of interests, or unsound banking practices." 12 U.S.C. § 1843(c)(8). Applicant believes that the proposal would produce public benefits that outweigh any potential adverse effects. In particular, Applicant maintains that the proposal will enhance competition and enable Applicant to offer its customers a broader range of services. In addition, Applicant states that the proposed activities will not result in adverse effects such as an undue concentration of resources, decreased or unfair competition, conflicts of interest, or unsound banking practices.

In publishing the proposal for comment, the Board does not take a position on issues raised by the proposal. Notice of the proposal is published solely to seek the views of interested persons on the issues presented by the application and does not represent a determination by the Board that the proposal meets, or is likely to meet, the standards of the BHC Act.

Any comments or requests for hearing should be submitted in writing and received by William W. Wiles, Secretary, Board of Governors of the Federal Reserve System, Washington, D.C. 20551, not later than November 21, 1994. Any request for a hearing on this application must, as required by § 262.3(e) of the Board's Rules of Procedure (12 CFR 262.3(e)), be accompanied by a statement of the reasons why a written presentation would not suffice in lieu of a hearing, identifying specifically any questions of fact that are in dispute, summarizing the evidence that would be presented at a hearing, and indicating how the party commenting would be aggrieved by approval of the proposal.

This application may be inspected at the offices of the Board of Governors or the Federal Reserve Bank of New York.

Board of Governors of the Federal Reserve System, October 21, 1994.

Jennifer J. Johnson,

Deputy Secretary of the Board.

[FR Doc. 94-26605 Filed 10-26-94; 8:45 am]

BILLING CODE 6210-01-F

#### **James D. Masee, et al.; Change in Bank Control Notices; Acquisitions of Shares of Banks or Bank Holding Companies**

The notificants listed below have applied under the Change in Bank Control Act (12 U.S.C. 1817(j)) and § 225.41 of the Board's Regulation Y (12 CFR 225.41) to acquire a bank or bank

holding company. The factors that are considered in acting on the notices are set forth in paragraph 7 of the Act (12 U.S.C. 1817(j)(7)).

The notices are available for immediate inspection at the Federal Reserve Bank indicated. Once the notices have been accepted for processing, they will also be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing to the Reserve Bank indicated for that notice or to the offices of the Board of Governors. Comments must be received not later than November 16, 1994.

**A. Federal Reserve Bank of Minneapolis** (James M. Lyon, Vice President) 250 Marquette Avenue, Minneapolis, Minnesota 55480:

1. *James D. Masee and Wade R. Schmidt*, both of Appleton, Minneapolis; to acquire a total of 100 percent of the voting shares of MPS Investment Company, Appleton, Minnesota, and thereby indirectly acquire Farmers and Merchants State Bank of Appleton, Appleton, Minnesota.

Board of Governors of the Federal Reserve System, October 21, 1994.

Jennifer J. Johnson,

Deputy Secretary of the Board.

[FR Doc. 94-26606 Filed 10-26-94; 8:45 am]

BILLING CODE 6210-01-F

#### **Whitney Holding Corporation, et al.; Formations of; Acquisitions by; and Mergers of Bank Holding Companies**

The companies listed in this notice have applied for the Board's approval under section 3 of the Bank Holding Company Act (12 U.S.C. 1842) and § 225.14 of the Board's Regulation Y (12 CFR 225.14) to become a bank holding company or to acquire a bank or bank holding company. The factors that are considered in acting on the applications are set forth in section 3(c) of the Act (12 U.S.C. 1842(c)).

Each application is available for immediate inspection at the Federal Reserve Bank indicated. Once the application has been accepted for processing, it will also be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing to the Reserve Bank or to the offices of the Board of Governors. Any comment on an application that requests a hearing must include a statement of why a written presentation would not suffice in lieu of a hearing, identifying specifically any questions of fact that are in dispute and summarizing the evidence that would be presented at a hearing.

Unless otherwise noted, comments regarding each of these applications must be received not later than November 21, 1994.

**A. Federal Reserve Bank of Atlanta** (Zane R. Kelley, Vice President) 104 Marietta Street, N.W., Atlanta, Georgia 30303:

1. *Whitney Holding Corporation*, New Orleans, Louisiana; to acquire 100 percent of the voting shares of Whitney Bank of Alabama, Mobile, Alabama, a *de novo* bank.

**B. Federal Reserve Bank of Chicago** (James A. Bluemle, Vice President) 230 South LaSalle Street, Chicago, Illinois 60690:

1. *First National Independent Bancorp, Inc.*, La Grange, Illinois, and Wesco Investment Company, La Grange, Illinois; to become a bank holding company by acquiring 51 percent of the voting shares of FNBC of La Grange, Inc., La Grange, Illinois, and thereby indirectly acquire Mokena State Bank, Mokena, Illinois; First National Bank of La Grange, La Grange, Illinois; and West Chicago State Bank, West Chicago, Illinois.

2. *Oak Bancorporation*, Oakland, Iowa; to acquire 100 percent of the voting shares of Security Bancorp, Stanton, Iowa, and thereby indirectly acquire Security State Bank, Stanton, Iowa.

**C. Federal Reserve Bank of St. Louis** (Randall C. Sumner, Vice President) 411 Locust Street, St. Louis, Missouri 63166:

1. *American Bancshares, Inc.*, Highland, Illinois; to become a bank holding company by acquiring 100 percent of the voting shares of American Bank of Illinois in Highland, Highland, Illinois.

**D. Federal Reserve Bank of Kansas City** (John E. Yorke, Senior Vice President) 925 Grand Avenue, Kansas City, Missouri 64198:

1. *Berlau Bancshares, Inc.*, Prairie Village, Kansas; to become a bank holding company by acquiring 100 percent of the voting shares of Brooke State Bank, Jewell, Kansas.

**E. Federal Reserve Bank of Dallas** (Genie D. Short, Vice President) 2200 North Pearl Street, Dallas, Texas 75201-2272:

1. *Texas Financial Bancorporation, Inc.*, Minneapolis, Minnesota; to acquire 100 percent of the voting shares of acquire Fulton State, Fulton, Illinois; Monmouth Trust and Savings Bank, Monmouth, Illinois; Monmouth Financial Services, Inc., Minneapolis, Minnesota; and First National Bank of Rosenberg, Rosenberg, Texas.

Board of Governors of the Federal Reserve System, October 21, 1994.

Jennifer J. Johnson,

Deputy Secretary of the Board.

[FR Doc. 94-26607 Filed 10-26-94; 8:45 am]

BILLING CODE 6210-01-F

## GENERAL SERVICES ADMINISTRATION

### Public Buildings Service; Record of Decision; New United States Courthouse-Federal Building in Sacramento, CA

The United States General Services Administration (GSA) announces its decision, in accordance with the National Environmental Policy Act (NEPA) and the Regulations issued by the Council on Environmental Quality, November 29, 1978, to construct a new United States Courthouse-Federal Building (USCT-FB) in Sacramento, California. The site is bordered by H Street to the North, I Street to the South, 5th Street to the West, and 6th Street to the East. The purpose of the new USCT-FB is to relieve overcrowded conditions at the existing court facilities in the City of Sacramento and to provide space for anticipated future growth. The proposed project is anticipated to be ready for occupancy in 1997-98. The existing courthouse facilities are too small to meet the year 2000 and 2020 space requirements. Additionally, the existing facilities do not meet guidelines for court facilities set forth in the "U.S. Courts Design Guide" (February 1993). Structural restrictions such as obstructing columns and inadequate ceiling heights prevent the use of full-size courtrooms in the existing facilities. There is not sufficient space in the current courthouse to accommodate an increase in the number of courtrooms and the configuration of courtrooms to meet the court design guidelines. In addition, security in and around the building is inadequate.

#### I. Criteria for Evaluating EIS Alternatives

Selection of an alternative site involves the weighing and balancing of many complex, interrelated and often competing policy factors. An alternative superior to others in one environmental respect may be otherwise inferior in another. Several factors were of key importance in evaluating each of the alternatives. These are identified below.

A. The first project criterion is to provide for the expansion of the federal courts in the Sacramento vicinity. Current facilities housed in the John E. Moss Federal Building-US Courthouse

are insufficient. Leasing additional space to make up for the shortfall at the Moss Building would not be an efficient means of providing court space. Alternative project sites were therefore examined for their ability to meet existing court needs as well as their suitability for future expansion.

B. The second project criterion is to promote local government redevelopment goals, which can often be greatly assisted by the implementation of large projects such as the high-profile federal building.

C. The third project criterion is the minimization of adverse environmental effects.

D. The fourth project criterion is attractive location. Some sites are more attractive due to their proximity to public amenities, the City's Central Business District, and retail areas.

#### II. Alternatives Considered

In accordance with the National Environmental Policy Act (NEPA), GSA has considered a range of alternatives to the preferred alternative that could feasibly attain the basic objectives of the proposed project. In addition to the preferred alternative, four other alternatives (a reduced intensity alternative, the Lot B alternative, the expansion alternative and the no action alternative) have been analyzed within the EIS and are representative of a reasonable range of alternatives.

##### A. Preferred Alternative

The preferred alternative site, which is owned by both the Southern Pacific Railroad and the City of Sacramento, encompasses approximately 2.50 acres. The site is bounded by H Street to the North, I Street to the South, 5th Street to the West and 6th Street to the East, within the City of Sacramento. The block is currently irregular in shape and must be reconfigured as a standard city block by realigning and extending 5th and H Streets. The site is a full City block, which provides the space required to meet both current court facility needs and the projected court needs through the year 2020.

The preferred site is located within the boundaries of the Merged Downtown Redevelopment Project Area, and is also within the boundaries of the proposed Railyards Specific Plan. This alternative is consistent with redevelopment plans for the Railyards area and will provide a catalyst for development in the Railyards. The project site promotes local land use and redevelopment goals. It is located in proximity to existing and light rail transits system and is near the path of its planned extension. This location will

promote use of a transportation means that is environmentally superior to single occupancy vehicle. By virtue of its proximity of the County Jail and the Hall of Justice, the location presents the potential for operational efficiencies that are not present at the other alternatives. The proximity of these buildings to each other would make the transportation of incarcerated individuals both easier and safer. Additionally, the preferred alternative is located in proximity to the City's new Central Library, located at 8th and I Streets, Downtown Plaza, a regional shopping center located between 4th and 7th Streets along K Street and Plaza Park, located at 8th and I Streets. These locational amenities add to the attraction of the preferred alternative site.

There are no wetlands on the project site nor is the site within the 100-year floodplain. Sacramento is located within Seismic Zone 3 on a scale of 1 to 4, with 4 as having the highest risk of seismic events and potential severity. No known active faults or Alquist-Priolo Special Study Zones occur in or adjacent to the City of Sacramento. An Alquist-Priolo Zone is a designation given by the State Geologist who assures that homes, offices, public buildings, and other structures for human occupancy are not built on active faults. The designation requires that a geological investigation be conducted before a local government can approve a development project located within the special study zone.

#### *B. The Reduced Intensity Alternative*

The reduced intensity alternative is identical to the preferred alternative except that a wing or annex would not be constructed. The building constructed under this alternative would remain at approximately 380,100 square through the year 2020. As new courtrooms are needed by the Eastern District, approximately the top seven floors would be converted from office space to courtroom space as under the preferred alternative. Under the reduced intensity alternative, however, the federal workers displaced by this conversion would move into lease quarters in the Sacramento area instead of being accommodated on site. The reduced intensity alternative is found to be infeasible because it does not provide for long-term growth of the federal courts. The building proposed under the reduced intensity alternative would not provide adequate space through the year 2020. In addition, as conversion from office to courtroom space takes place, federal workers would have to move

into leased space or additional space would have to be constructed off-site.

#### *C. Lot B Alternative*

Under this alternative, a building similar to that described in the "Preferred Alternative" section would be constructed on the City of Sacramento's Lot B, which is bounded by H Street on the north, I Street on the south, 10th Street on the west and 11th Street on the east. This site, which is owned by the City of Sacramento is currently used for City employee parking. Land uses surrounding the two story parking structure include residential and motel uses to the north, City Hall office buildings to the west, a high rise parking structure with ground level commercial structures to the south, restaurant, commercial and residential structures to the east, and Plaza Park and the Sacramento Central Library to the southwest. Like the preferred alternative site, the Lot B site is owned by the City and is of adequate size to meet current and future court needs. It is also located within the City's Central Business District and is in proximity to light rail, the City's new library and Plaza Park. The site is not, however, located as conveniently close to the County jail as the preferred alternative site. The Lot B Alternative is, however, infeasible as the State of California has recently selected this site for the location of a new State office building and the City has agreed to sell the property to the State. The Lot B site is, therefore, not available for the Courthouse.

#### *D. Expansion Alternative*

The John E. Moss Federal Building is a nine-story federal office building located at 650 Capitol Mall in downtown Sacramento. Under this project alternative, an annex would be constructed against the south wall of the Moss Building. A parking lot for federal employees now occupies the proposed annex site. The land uses surrounding the site consist of the City's Lot A parking garage to the north, high density residential uses (apartments and townhouses) to the south, and State of California offices to the east and the IBM and Wells Fargo towers to the west. Under this alternative, an approximately 250,000 square foot annex to the existing John E. Moss Federal Building-US Courthouse would be constructed against the south wall of the Moss Building. The proposed annex would occupy the approximately 20,000 square foot parking area to the south of the Building. It would house a new district courtroom, a new and a relocated magistrate courtroom, a jury assembly

area, lobbies and corridors, elevators and ancillary facilities. The proposed annex would be 13 floors in height. Parking for 250 cars would be provided in a subterranean two-level parking garage beneath the annex. Approximately 28,000 cubic yards of material would have to be excavated in order to accommodate a parking area of this size. Because this site could not meet the courts projected space needs over the current planning period, other space would eventually have to be leased or constructed. The expansion alternative is infeasible because it does not provide adequate space to meet the court's current or projected needs.

#### *E. No Action Alternative*

Under the no action alternative, the City of Sacramento would retain possession of the proposed site, and no Federal building would be constructed there, or any other location. The U.S. Court for the Eastern District of California would either reduce its space needs in the Sacramento area, or accommodate its future growth by some other means. The projected increase in the federal presence in the Sacramento area is not contingent upon the construction of a Courthouse/Federal Building. The rate of growth in all categories of federal employees (including judicial and executive branch agencies) is projected to be the same, regardless of whether the proposed building is constructed.

### **III. Mitigation Measures**

All practicable means to avoid or minimize impacts to the area are being considered in the development of the project. GSA received a number of comments and mitigation suggestions from concerned citizens, and interested and responsible local, state, and Federal agencies.

Significant impacts were identified and mitigation measures were set forth in the EIS. The mitigation measures proposed in the EIS that can be implemented were adopted by GSA.

#### *A. Air Quality*

There are several potential areas of impact to air quality. Construction activities will exceed the SMAQMD NO<sub>x</sub> and SMAQMD PM<sub>10</sub> emission thresholds. This will be significant and unavoidable. The construction management plan developed for the project will reduce vehicle emission by reducing vehicle idling time and vehicle miles traveled. Specifically it will:

1. Route construction trips to avoid congested streets. Construction traffic ingress and egress will be controlled so as to avoid long queues of construction

vehicles entering and leaving the site. Vehicles will enter and leave via the staging area. Appropriate traffic controls will be established on public roadways where project traffic enters and leaves the site.

2. Electrical power for construction activities will be obtained from power poles instead of electrical generators (when feasible).

3. Methanol or natural gas will be used for mobile construction equipment instead of diesel (when feasible).

4. Trucks will not idle for more than two minutes.

5. Active portions of the project site will be watered twice daily.

6. Non-toxic soil stabilizers will be applied to graded areas to be inactive for 10 days or more.

7. Excavation and grading will be suspended when the wind speed (as instantaneous gusts) exceeds 25 miles per hour.

8. Trucks carrying earth material off-site will be covered.

9. Paved streets adjacent to the construction site will be swept as needed to remove dust and silt that may have accumulated as a result of construction activities, and all construction requiring heavy equipment will be curtailed during second stage smog alerts.

Mitigation Measures are feasible and required, but the impact is unavoidable. The primary source of construction-related NO<sub>x</sub> emissions are gasoline and diesel-powered heavy duty mobile construction equipment. The above mitigation measures will reduce the short-term significant impact of construction activities by restricting use of mobile construction equipment such that NO<sub>x</sub>, ROC and CO concentrations from Project construction are minimized. These measures, however, will only partially reduce the impact. The impact remains significant and unavoidable.

The project's direct and indirect emissions are less than the de minimis thresholds, as defined in Section 176 of the 1990 Amendments to the Clean Air Act. Therefore, the subject project is exempt from the final conformity rule and a conformity determination need to be prepared. The information has been provided to the regional office of the Environmental Protection Agency.

#### B. Noise

Implementation of this alternative would expose surrounding land uses to short-term noise levels in excess of City threshold levels. This impact is considered significant and unavoidable. Site preparation and construction activities shall comply with the City of

Sacramento Noise Ordinance limiting construction activities to the hours between 7 a.m. and 6 p.m., Monday through Friday, and 9 a.m. and 6 p.m. on Saturday as a maximum. All construction equipment fixed or mobile shall be in proper operating condition and fitted with standard silencing features. Prior to construction activities, a solid wood construction barrier will be erected around the exterior perimeter of the project sites to minimize noise intrusion into surrounding residential land uses. An outside construction manager will ensure that all noise mitigation measures are implemented. In addition, the construction manager will handle any complaints regarding noise that may arise as a result of construction. The mitigation measure will reduce, but not entirely eliminate, construction noise impacts resulting from the project. The impact remains significant and unavoidable.

#### C. Archaeological and Historical

The implementation of the preferred alternative will have an impact on archaeological and historic resources. The American Railway Express Building is a building which has been determined eligible, by consensus, for inclusion on the National Register of Historic Places. A portion of the structure which is the loading dock has been removed by the City after the concurrence of the State Historic Preservation Officer and Advisory Council. This is considered a significant unavoidable impact. The loading dock structure was recorded through mapping, photography, textual description, and drawings along with a narrative description and history of the structure.

Mitigation has GSA consulting with the State Historic Preservation Officer to seek ways to avoid or reduce the effect on historic properties. In addition, GSA will cooperate to the extent feasible, in plans to preserve the historic structure which would be affected by the proposed project. The mitigation measure is feasible and will reduce impacts to historical resources through recordation. However, impacts to the physical structure through demolition cannot be reduced to a less-than-significant level.

Another potential impact is the scale and style of the proposed courthouse may not be compatible with the surrounding historically significant structures. This is considered a significant unavoidable impact. By using the *Secretary of the Interior's Standards for Rehabilitation and Guidelines for Rehabilitation of Historic Buildings* as a resource document, the

project will employ project design standards which make thorough use of existing historic context. The project design standards for new construction will consider the existing historic context in determining: mass, size, scale, materials, texture, setback, and architectural features. The mitigation measure is feasible and will partially reduce compatibility impacts, but not to a less-than-significant level.

The General Services Administration believes that there are no outstanding issues to be resolved with respect to the proposed project. For additional information associated with the new U.S. Courthouse-Federal Building may be directed to Mr. Lou Lopez, Planning Staff (9PL), U.S. General Services Administration, 525 Market Street, San Francisco, CA 94105, (415) 744-5256.

Dated: October 13, 1994.

Aki K. Nakao,

Acting Regional Administrator (9A).

[FR Doc. 94-26576 Filed 10-26-94; 8:45 am]

BILLING CODE 6820-BR-M

#### Interagency Committee for Medical Records (ICMR); Stocking Change and Revision of SF 527, Medical Record—Group Muscle Strength, Joint R.O.M. Girth and Length Measurements

AGENCY: General Services Administration.

ACTION: Notice.

**SUMMARY:** The General Services Administration/ICMR is changing the stocking requirement of SF 527, Medical Record—Group Muscle Strength, Joint R.O.M. Girth and Length Measurements. This form is now authorized for local reproduction. You can request camera copy of SF 527 from General Services Administration (GARM), Attn: Barbara Williams, (202) 501-0581.

This form also is revised to:

1. Delete the line that extended from the caption to the arrow in captions "Date" and "Indicate Side Tested" on both sides of the form.

2. To delete "grade; SSAN; rank; rate;" from "PATIENT'S IDENTIFICATION" item and replace with "ID no. (SSN or other);".

FOR FURTHER INFORMATION CONTACT: Ms. Barbara Williams, General Services Administration, (202) 501-0581.

DATES: Effective October 27, 1994.

Dated: October 18, 1994.

Theodore D. Freed,

Chief, Forms Management Branch.

[FR Doc. 94-26575 Filed 10-26-94; 8:45 am]

BILLING CODE 6820-34-M

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### New Electronic Initiative for Disseminating and Sharing Grant Information

**AGENCY:** Department of Health and Human Services (HHS).

**ACTION:** Notice.

**SUMMARY:** The Department is piloting a free, on-line grant information service called GrantsNet, for finding and exchanging information about HHS and other Federal grant programs.

**FOR FURTHER INFORMATION CONTACT:**

Ms. Suzanne M. Neill, Division of Grants Policy and Oversight, Room 517-D, 200 Independence Avenue SW., Washington, DC 20201. Telephone: (202) 690-5731. Internet: sneill@os.dhhs.gov.

**SUPPLEMENTARY INFORMATION:** The Department of Health and Human Services has been rapidly improving its information resources and grant activities to incorporate total quality management and electronic technologies. As part of this process, HHS is piloting an on-line grant information service that will serve the general public, grantee organizations, and government grant-making agencies. This new service, GrantsNet, is a free public-access computer network for finding and exchanging information about HHS and other Federal grant programs. Anyone having a personal computer with internet capability will be able to access GrantsNet. Conceptually, GrantsNet has two components: (1) An on-line informational reference service using gopher server technology; and (2) an interactive mailing list service which groups subscribers with common interests into computer-managed mailing lists for sharing of information and dialogue on certain subjects.

This mission of GrantsNet is to serve as a vehicle and catalyst for continuous improvement and innovation in Federal grants management practices, policies, and information dissemination. It will provide a medium for the sharing of ideas, successes, news, lessons learned, and an archival reference library of grant-related legislation, regulations, and policies. GrantsNet will also provide a yellow-page style directory of granting offices, grants management staff and grant program personnel.

The major thrust of GrantsNet is to allow members of the public to cut through government red tape—to find the information they want, when they want it, and whom to directly contact for additional information. As such, it is one of the 11 NETWORKS created under the auspices of Vice President Gore's National Performance Review (NPR). The aims of the NETWORKS are to provide government-wide information and resources in an on-line, easily accessible, and meaningful manner.

#### When Will It Be Implemented?

HHS has established a gopher and world wide web (WWW) server to facilitate the GrantsNet mission and vision, assisted by the Parklawn Computer Center which provides selected communication services. The Department is taking a phased approach to the implementation of GrantsNet. It is anticipated that GrantsNet will be up and running by the end of October 1994, with fiscal year 1995 serving as the pilot-testing period for populating the gopher information service with grant resource data pertinent to HHS and further developing the interactive mailing list service. Once success of the system has been established and tested, HHS intends to expand the scope of GrantsNet to governmentwide.

Development and implementation of GrantsNet are carried out by the GrantsNet Core Team which is managed and directed by the Office of Grants and Acquisition Management in the Office of the Secretary. The Chair of the GrantsNet Core Team is Suzanne Neill. Also, as a complement to the Core Team, HHS intends to establish an Advisory Team comprised of individuals from other Federal agencies. By doing so, interagency collaboration and insights to shaping the development of GrantsNet will be gained.

#### For Further Information

To be placed on a mailing list for receiving news and updates on GrantsNet, send your name, organization, mailing address, internet address, and phone number to: Suzanne M. Neill, Internet: sneill@os.dhhs.gov, OR, Charles Bish, Internet: cbish@os.dhhs.gov.

Moreover, HHS recognizes that for GrantsNet to become a practical and user-friendly information service to the Federal grantee community and to the general public, coordination with interested parties and feedback from

users will be important. To that end, the GrantsNet Core Team is interested in any questions or suggestions you may have. This includes recommendations for improving GrantsNet services, as well as the identification of additional grants information, resources, and/or activities that you would like HHS to post. Please address your comments to the GrantsNet Core Team Chair.

Dated: October 20, 1994.

**Terrence J. Tychan,**

*Deputy Assistant Secretary for Grants and Acquisition Management.*

[FR Doc. 94-26566 Filed 10-26-94; 8:45 am]

BILLING CODE 4150-04-M

## Food and Drug Administration

### Advisory Committee Information Hotline

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) has established an Advisory Committee Information Hotline (the hotline) using a voice-mail telephone system. The hotline provides the public with access to the most current information available on FDA advisory committee meetings. The advisory committee hotline, which will disseminate current information and information updates, can be accessed by dialing a toll free number.

**FOR FURTHER INFORMATION CONTACT:** Donna M. Combs, Committee Management Office (HFA-306), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-2765.

**SUPPLEMENTARY INFORMATION:** The Advisory Committee Information Hotline can be accessed by dialing 1-800-741-8138 or 301-443-0572. Each advisory committee is assigned a 5-digit number. This 5-digit number will appear in each individual notice of meeting. The hotline will enable the public to obtain information about a particular advisory committee by using the committee's 5-digit number. Information in the hotline is preliminary and may change before a meeting is actually held. The hotline will be updated when such changes are made. The following is a list of each advisory committee's 5-digit number to be used when accessing the hotline:

Committee Name

Number

OFFICE OF THE COMMISSIONER

Board of Tea Experts .....

12601

Committee Name	Number
National Task Force on AIDS Drug Development .....	12602
Science Board to the Food and Drug Administration .....	12603
CENTER FOR BIOLOGICS EVALUATION AND RESEARCH (CBER)(All CBER committees use the same 5-digit number)	
Allergenic Products Advisory Committee .....	12388
Biological Response Modifiers Advisory Committee .....	12388
Blood Products Advisory Committee .....	12388
Vaccines and Related Biological Products Advisory Committee .....	12388
CENTER FOR DRUG EVALUATION AND RESEARCH	
Anesthetic and Life Support Drugs Advisory Committee .....	12529
Anti-Infective Drugs Advisory Committee .....	12530
Antiviral Drugs Advisory Committee .....	12531
Arthritis Advisory Committee .....	12532
Cardiovascular and Renal Drugs Advisory Committee .....	12533
Dermatologic Drugs Advisory Committee .....	12534
Drug Abuse Advisory Committee .....	12535
Endocrinologic and Metabolic Drugs Advisory Committee .....	12536
Fertility and Maternal Health Drugs Advisory Committee .....	12537
Gastrointestinal Drugs Advisory Committee .....	12538
Generic Drugs Advisory Committee .....	12539
Medical Imaging Drugs Advisory Committee .....	12540
Nonprescription Drugs Advisory Committee .....	12541
Oncologic Drugs Advisory Committee .....	12542
Peripheral and Central Nervous System Drugs Advisory Committee .....	12543
Psychopharmacologic Drugs Advisory Committee .....	12544
Pulmonary-Allergy Drugs Advisory Committee .....	12545
CENTER FOR FOOD SAFETY AND APPLIED NUTRITION	
Food Advisory Committee .....	10564
CENTER FOR DEVICES AND RADIOLOGICAL HEALTH	
Device Good Manufacturing Practice Advisory Committee .....	12398
National Mammography Quality Assurance Advisory Committee .....	12397
Technical Electronic Product Radiation Safety Standards Committee .....	12399
Medical Devices Advisory Committee .....	
Anesthesiology and Respiratory Therapy Devices Panel .....	12624
Circulatory System Devices Panel .....	12625
Clinical Chemistry and Clinical Toxicology Devices Panel .....	12514
Dental Products Panel .....	12518
Ear, Nose, and Throat Devices Panel .....	12522
Gastroenterology-Urology Devices Panel .....	12523
General and Plastic Surgery Devices Panel .....	12519
General Hospital and Personal Use Devices Panel .....	12520
Hematology and Pathology Devices Panel .....	12515
Immunology Devices Panel .....	12516
Microbiology Devices Panel .....	12517
Neurological Devices Panel .....	12513
Obstetrics-Gynecology Devices Panel .....	12524
Ophthalmic Devices Panel .....	12396
Orthopedic and Rehabilitation Devices Panel .....	12521
Radiological Devices Panel .....	12526
CENTER FOR VETERINARY MEDICINE	
Veterinary Medicine Advisory Committee .....	12546
NATIONAL CENTER FOR TOXICOLOGICAL RESEARCH	
Ranch Hand Advisory Committee .....	12560
Science Advisory Board to the National Center for Toxicological Research .....	12559

The hotline will provide the most recent information available on upcoming advisory committee meetings, guidance for making an oral presentation during the open public hearing portion, and procedures on obtaining copies of transcripts of advisory committee meetings. Because the hotline will communicate the most current information available about any particular advisory committee meeting,

the establishment of this system will provide interested parties with timely and equal access to such information. The hotline should also conserve agency resources by reducing the current volume of inquires individual FDA offices and employees must handle concerning advisory committee schedules and procedures.

Dated: October 20, 1994.

Linda A. Suydam,  
Interim Deputy Commissioner for Operations.  
[FR Doc. 94-26604 Filed 10-26-94; 8:45 am]

BILLING CODE 4160-01-F

[Docket No. 85D-0505]

**Guideline for Adverse Experience Reporting for Licensed Biological Products; Availability****AGENCY:** Food and Drug Administration, HHS.**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a guideline entitled "Guideline for Adverse Experience Reporting for Licensed Biological Products." The purpose of this guideline is to assist manufacturers of biological products in developing and implementing procedures to report to FDA adverse experiences associated with biological products. Elsewhere in this issue of the *Federal Register*, FDA is issuing a final rule amending the biologics regulations to which this guideline applies.

**ADDRESSES:** Submit written requests for single copies of "Guideline for Adverse Experience Reporting for Licensed Biological Products" to the Congressional and Consumer Affairs Branch (HFM-12), Food and Drug Administration, 1401 Rockville Pike, suite 200 North, Rockville, MD 20852-1448, 301-594-2000. Send two self-addressed adhesive labels to assist that office in processing your requests. Persons with access to the INTERNET may request this document from "CBER-INFO@A1.CBER.FDA.GOV." The document may also be obtained by calling the CBER FAX Information System at 301-594-1939 from a FAX machine with a touch tone phone attached or built in. Submit written comments on the guideline to the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857. Requests and comments should be identified with the docket number found in brackets in the heading of this document. A copy of "Guideline for Adverse Experience Reporting for Licensed Biological Products" and received comments are available for public examination in the Docket Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

**FOR FURTHER INFORMATION CONTACT:** Paula McKeever, Center for Biologics Evaluation and Research (HFM-635), Food and Drug Administration, suite 200 North, 1401 Rockville Pike, Rockville, MD 20852-1448, 301-594-3074.

**SUPPLEMENTARY INFORMATION:** In the *Federal Register* of March 29, 1990 (55 FR 11611), FDA issued a proposed rule

that would require manufacturers of licensed biological products to report to FDA certain adverse experiences associated with their products. In the same issue of the *Federal Register* (55 FR 11655), FDA published a notice announcing the availability of a draft guideline for reporting adverse experiences associated with licensed biological products, FDA offered the public 60 days for comment on the proposed rule and draft guideline.

Elsewhere in this issue of the *Federal Register*, FDA is issuing a final rule which, upon the effective date, will require manufacturers of licensed biological products to report to FDA: (1) Within 15 working days all adverse experiences associated with the use of a biological product that are both serious and unexpected; (2) within 15 working days any significant increase in the frequency of a serious, but expected, adverse experience and any significant increase in frequency of therapeutic failures; and (3) periodically all other adverse experiences and product distribution and disposition data. This notice is to announce the availability of a guideline based on the draft guideline made available in 1990. The guideline offers guidance for meeting the reporting requirements of 21 CFR 600.80 and 600.81 and for meeting the vaccines adverse experience reporting requirements in accordance with section 2125 of the Public Health Service Act as amended by the National Childhood Vaccine Injury Act of 1986.

The guidelines was prepared by the Division of Biostatistics and Epidemiology, Office of Establishment Licensing and Product Surveillance, Center for Biologics Evaluation and Research, FDA. In developing the guideline, consideration was given to the comments received on the proposed rule and on the draft guideline.

Changes from the draft guideline are generally editorial in nature or made to conform to amendments made in the final rule discussed elsewhere in this issue of the *Federal Register*. The guideline has also been formatted to be more consistent with the similar guideline, "Guideline for Postmarketing Reporting of Adverse Drug Experiences," applicable to reporting adverse experiences associated with human drugs.

Elsewhere in this issue of the *Federal Register*, FDA is also issuing a proposed rule that would revise and update the reporting requirements for adverse experiences related to both biological products and human drugs. When FDA issues the final rule based on that proposed rule, FDA will also issue a notice of availability of revised

guidelines relating to biological products and human drugs to be consistent with the final rule. Comments received in response to the proposed rule will be considered for the next revision of the guidelines applicable to biological products and human drugs.

Guidelines provide general information to persons dealing with FDA and do not include decisions or advice on particular situations. A person may follow a guideline or may follow different procedures or practices. When different procedures or practices are chosen, a person may, but is not required to, discuss the matter in advance with FDA to prevent the expenditure of money and effort on an activity that may later be determined to be unacceptable.

A guideline represents the position of FDA on a procedure or practice at the time of its issuance. However, a guideline does not bind the agency, and it does not create or confer any rights, privileges, or benefits for or on any person. FDA may, at its discretion, recommend or initiate legal or administrative action against a person or product with respect to an action taken in conformity with a guideline provided that the legal or administrative action is consistent with applicable statutes and regulations.

Interested persons may submit written comments on the guideline to the Dockets Management Branch (address above). These comments will be considered in determining whether additional revision of the guideline is appropriate. Two copies of any comments are to be submitted, except individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The guideline and received comments may be seen in the Dockets Management Branch, between 9 a.m. and 4 p.m., Monday through Friday.

Dated: October 13, 1994.

**William K. Hubbard,***Interim Deputy Commissioner for Policy.*

[FR Doc. 94-26484 Filed 10-26-94; 8:45 am]

BILLING CODE 4160-01-F-M

[Docket No. 94M-0349]

**Ciba Corning Corp.; Premarket Approval of ACS™ PSA +D****AGENCY:** Food and Drug Administration, HHS.**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing its

approval of the application by Ciba Corning Corp., Medfield, MA, for premarket approval, under section 515 of the Federal Food, Drug, and Cosmetic Act (the act), of ASC™ PSA +D. FDA's Center for Devices and Radiological Health (CDRH) notified the applicant, by letter on September 2, 1994, of the approval of the application.

**DATES:** Petitions for administrative review by November 28, 1994.

**ADDRESSES:** Written requests for copies of the summary of safety and effectiveness data and petitions for administrative review to the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857.

**FOR FURTHER INFORMATION CONTACT:**

Peter E. Maxim, Center for Devices and Radiological Health (HFZ-440), Food and Drug Administration, 2098 Gaither Rd., Rockville, MD 20850, 301-594-1293.

**SUPPLEMENTARY INFORMATION:** On June 26, 1992, Ciba Corning Diagnostics Corp., Medfield, MA 02052-1688, submitted to CDRH an application for premarket approval of ASC™ PSA +D. The device is a two-site chemiluminometric assay and is indicated for the quantitative, serial determination of prostate-specific antigen (PSA) in serum and to aid in the management of patients with prostate cancer using the Ciba Corning Automated Chemiluminescence System (ACS). In accordance with the provisions of section 515(c)(2) of the act (21 U.S.C. 360e(c)(2)) as amended by the Safe Medical Devices Act of 1990, this PMA was not referred to the Immunology Devices Panel, an FDA advisory panel, for review and recommendation because the information in the PMA substantially duplicates information previously reviewed by this panel. On September 2, 1994, CDRH approved the application by a letter to the applicant from the Director of the Office of Device Evaluation, CDRH.

A summary of the safety and effectiveness data on which CDRH based its approval is on file in the Dockets Management Branch (address above) and is available from that office upon written request. Requests should be identified with the name of the device and the docket number found in brackets in the heading of this document.

**Opportunity for Administrative Review**

Section 515(d)(3) of the act (21 U.S.C. 360e(d)(3)) authorizes any interested person to petition, under section 515(g)

of the act (21 U.S.C. 360e(g)), for administrative review of CDRH's decision to approve this application. A petitioner may request either a formal hearing under part 12 (21 CFR part 12) of FDA's administrative practices and procedures regulations or a review of the application and CDRH's action by an independent advisory committee of experts. A petition is to be in the form of a petition for reconsideration under § 10.33(b) (21 CFR 10.33(b)). A petitioner shall identify the form of review requested (hearing or independent advisory committee) and shall submit with the petition supporting data and information showing that there is a genuine and substantial issue of material fact for resolution through administrative review. After reviewing the petition, FDA will decide whether to grant or deny the petition and will publish a notice of its decision in the **Federal Register**. If FDA grants the petition, the notice will state the issue to be reviewed, the form of review to be used, the persons who may participate in the review, the time and place where the review will occur, and other details.

Petitioners may, at any time on or before November 28, 1994, file with the Dockets Management Branch (address above) two copies of each petition and supporting data and information, identified with the name of the device and the docket number found in brackets in the heading of this document. Received petitions may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

This notice is issued under the Federal Food, Drug, and Cosmetic Act (secs. 515(d), 520(h) (21 U.S.C. 360e(d), 360j(h))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10) and redelegated to the Director, Center for Devices and Radiological Health (21 CFR 5.53).

Dated: October 13, 1994.

**Joseph A. Levitt,**

*Deputy Director for Regulations Policy, Center for Devices and Radiological Health.*

[FR Doc. 94-26673 Filed 10-26-94; 8:45 am]

BILLING CODE 4160-01-F

**Advisory Committee Meeting; Amendment of Notice**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing an amendment to the notice of the joint meeting of the Nonprescription Drugs and the Pulmonary-Allergy Drugs

Advisory Committees, which was announced in the **Federal Register** of July 7, 1994 (59 FR 34847). The amendment is being made to add an additional topic to the agenda of the open session and to add a closed session for the Nonprescription Drugs Advisory Committee. There are no other changes. This amendment will be announced at the beginning of the open portion of the meeting.

**FOR FURTHER INFORMATION CONTACT:** Lee L. Zwanziger or Leander B. Madoo, Center for Drug Evaluation and Research (HFD-9), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-5455.

**SUPPLEMENTARY INFORMATION:** In the **Federal Register** of July 7, 1994, FDA announced that a joint meeting of the Nonprescription Drugs and the Pulmonary-Allergy Drugs Advisory Committees would be held on November 14, 1994, to be extended to November 15, 1994, if sufficient interest in participation was expressed. On page 34847, in column 1, the "Type of meeting and contact person" portion of the meeting is amended as follows:

*Type of meeting and contact person.*  
Open committee discussion, November 14, 1994, 8:30 a.m. to 4 p.m.; open public hearing, 4 p.m. to 5 p.m., unless public participation does not last that long; closed committee deliberations for Nonprescription Drugs Advisory Committee only, 5 p.m. to 5:30 p.m.; open committee discussion, November 15, 1994, 8:30 a.m. to 4 p.m.; Lee L. Zwanziger or Leander B. Madoo, Center for Drug Evaluation and Research (HFD-9), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-4695.

On page 34847, in column 2, the "Open committee discussion" portion of this meeting is amended as follows:

*Open committee discussion.* On November 14, 1994, possibly extended to November 15, 1994, the committees will jointly discuss over-the-counter (OTC) drug products for the treatment of asthma and will address topics such as: (1) OTC bronchodilator drug products currently available and possible pending changes in their marketing status; (2) whether there is a population for which OTC antiasthma drug products are appropriate; (3) the general question of whether antiasthma drug products should be available OTC; (4) antiasthma drug products currently available by prescription only that could be considered for OTC status; and (5) data requirements necessary to support conversion of prescription antiasthma drug products to OTC status. Public comments are available for inspection in

docket no. 94N-0232 at the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857. If the meeting is extended to November 15, 1994, the committees will hear a report by FDA personnel of a meta-analysis of data on the use of antihistamines in the common cold.

After the "open committee discussion" portion, a "closed committee deliberations" portion is added as follows:

**Closed committee deliberations.** The Nonprescription Drugs Advisory Committee will discuss trade secret and/or confidential commercial information relevant to pending investigational new drug applications. This portion of the meeting will be closed to permit discussion of this information (5 U.S.C. 552b(c)(4)).

Each public advisory committee meeting listed above may have as many as four separable portions: (1) An open public hearing, (2) an open committee discussion, (3) a closed presentation of data, and (4) a closed committee deliberation. Every advisory committee meeting shall have an open public hearing portion. Whether or not it also includes any of the other three portions will depend upon the specific meeting involved. The dates and times reserved for the separate portions of each committee meeting are listed above.

The open public hearing portion of each meeting shall be at least 1 hour long unless public participation does not last that long. It is emphasized, however, that the 1 hour time limit for an open public hearing represents a minimum rather than a maximum time for public participation, and an open public hearing may last for whatever longer period the committee chairperson determines will facilitate the committee's work.

Public hearings are subject to FDA's guideline (subpart C of 21 CFR part 10) concerning the policy and procedures for electronic media coverage of FDA's public administrative proceedings, including hearings before public advisory committees under 21 CFR part 14. Under 21 CFR 10.205, representatives of the electronic media may be permitted, subject to certain limitations, to videotape, film, or otherwise record FDA's public administrative proceedings, including presentations by participants.

Meetings of advisory committees shall be conducted, insofar as is practical, in accordance with the agenda published in this Federal Register notice. Changes in the agenda will be announced at the beginning of the open portion of a meeting.

Any interested person who wishes to be assured of the right to make an oral presentation at the open public hearing portion of a meeting shall inform the contact person listed above, either orally or in writing, prior to the meeting. Any person attending the hearing who does not in advance of the meeting request an opportunity to speak will be allowed to make an oral presentation at the hearing's conclusion, if time permits, at the chairperson's discretion.

The agenda, the questions to be addressed by the committee, and a current list of committee members will be available at the meeting location on the day of the meeting.

Transcripts of the open portion of the meeting may be requested in writing from the Freedom of Information Office (HFI-35), Food and Drug Administration, rm. 12A-16, 5600 Fishers Lane, Rockville, MD 20857, approximately 15 working days after the meeting, at a cost of 10 cents per page. The transcript may be viewed at the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857, approximately 15 working days after the meeting, between the hours of 9 a.m. and 4 p.m., Monday through Friday. Summary minutes of the open portion of the meeting may be requested in writing from the Freedom of Information Office (address above) beginning approximately 90 days after the meeting.

The Commissioner has determined for the reasons stated that those portions of the advisory committee meetings so designated in this notice shall be closed. The Federal Advisory Committee Act (FACA) (5 U.S.C. app. 2, 10(d)), permits such closed advisory committee meetings in certain circumstances. Those portions of a meeting designated as closed, however, shall be closed for the shortest possible time, consistent with the intent of the cited statutes.

The FACA, as amended, provides that a portion of a meeting may be closed where the matter for discussion involves a trade secret; commercial or financial information that is privileged or confidential; information of a personal nature, disclosure of which would be a clearly unwarranted invasion of personal privacy; investigatory files compiled for law enforcement purposes; information the premature disclosure of which would be likely to significantly frustrate implementation of a proposed agency action; and information in certain other instances not generally relevant to FDA matters.

Examples of portions of FDA advisory committee meetings that ordinarily may be closed, where necessary and in

accordance with FACA criteria, include the review, discussion, and evaluation of drafts of regulations or guidelines or similar preexisting internal agency documents, but only if their premature disclosure is likely to significantly frustrate implementation of proposed agency action; review of trade secrets and confidential commercial or financial information submitted to the agency; consideration of matters involving investigatory files compiled for law enforcement purposes; and review of matters, such as personnel records or individual patient records, where disclosure would constitute a clearly unwarranted invasion of personal privacy.

Examples of portions of FDA advisory committee meetings that ordinarily shall not be closed include the review, discussion, and evaluation of general preclinical and clinical test protocols and procedures for a class of drugs or devices; consideration of labeling requirements for a class of marketed drugs or devices; review of data and information on specific investigational or marketed drugs and devices that have previously been made public; presentation of any other data or information that is not exempt from public disclosure pursuant to the FACA, as amended; and, deliberation to formulate advice and recommendations to the agency on matters that do not independently justify closing.

This notice is issued under section 10(a)(1) and (2) of the Federal Advisory Committee Act (5 U.S.C. app. 2), and FDA's regulations (21 CFR part 14) on advisory committees.

Dated: October 20, 1994.

Linda A. Suydam,  
Interim Deputy Commissioner for Operations.  
[FR Doc. 94-26672 Filed 10-26-94; 8:45 am]  
BILLING CODE 4160-01-F

## Health Resources and Services Administration

### Program Announcement, Proposed Project Requirements and Review Criteria for Cooperative Agreements for the National AIDS Education and Training Centers Program for FY 1995

The Health Resources and Services Administration (HRSA) announces that applications will be accepted for fiscal year 1995 for Cooperative Agreements for the National AIDS Education and Training Centers (AETCs) Program (formerly the AIDS Regional Education and Training Centers (AETCs)) Program, authorized under section 776(a), title VII of the Public Service (PHS) Act, as amended by the Health Professions

Education Extension Amendments of 1992, Pub. L. 102-408, dated October 13, 1992. These centers will constitute a national network which will conduct targeted, multidisciplinary education and training programs for health care providers within designated geographic areas, with the principal focus on areas heavily impacted by the HIV epidemic. Comments are invited on the proposed project requirements and review criteria stated below.

#### Eligibility and Purpose

The Secretary may make awards and enter into contracts to assist public and nonprofit private entities and schools and academic health science centers in meeting the costs of projects

(1) To train the faculty of schools of, and graduate departments or programs of, medicine, nursing, osteopathic medicine, dentistry, public health, allied health, and mental health practice to teach health professions students to provide for the health care needs of individuals with HIV disease;

(2) To train practitioners to provide for the health care needs of such individuals;

(3) With respect to improving clinical skills in the diagnosis, treatment, and prevention of such disease, to educate and train the health professionals and clinical staff of schools of medicine, osteopathic medicine, and dentistry; and

(4) To develop and disseminate curricula and resource materials relating to the care and treatment of individuals with such disease and the prevention of the disease among individuals who are at risk of contracting the disease.

Specifically for the National AETC Program, these awards will be made as above and will include community based organizations (CBOs) and community health clinics affiliated with accredited public and nonprofit private entities—

1. To train health personnel, focusing on practitioners in Title XXVI programs (Ryan White CARE Act), in the diagnosis, treatment, and prevention of Human Immunodeficiency Virus (HIV) infection and disease; and to provide supplementary and/or complementary training to the faculty of schools of, and graduate departments or programs of medicine, nursing, dentistry, public health, mental health practice and allied health personnel;

2. To train and motivate the above practitioners and other community providers to care for the health needs of individuals with HIV disease;

3. To teach health professions students and residents to provide for the

health care needs of individuals with HIV disease; and

4. To develop and disseminate to health providers curricula and resource materials relating to the care and treatment of individuals with HIV disease and the prevention of HIV among individuals who are at risk of contracting the disease; and to organize plans for information dissemination of HIV-related information.

#### Strategic Directions for the National AETC Program for FY 1995

In 1987, the National AETC Program was initially designed to provide information on the prevalence of AIDS and identification of groups at increased risk of HIV infection. In the second project period which began in 1991, emphasis was placed on providing training of health care professionals in the prevention, early diagnosis, and treatment of HIV infection. Currently, HRSA funds 17 AETCs. As of June 1994, over 400,000 health professionals had received training.

In FY 1995, the National AETC Program will focus the majority of resources on those Eligible Metropolitan Areas (EMAs) with the highest prevalence of HIV/AIDS; however, consideration will be given to AETCs in rural areas. The AETCs will be required to spend the majority of their funds on information dissemination and the training (especially clinical training) of primary care health professionals, including physicians, registered nurses, dentists, physician assistants, nurses with advanced training (e.g., nurse practitioners, clinical nurse specialists and nurse midwives) and dental hygienists. Additionally, the AETCs will focus on mental health providers and allied health personnel. Emphasis will be placed on training in Ryan White CARE ACT programs and health professional schools and academic health centers.

#### Funding

Approximately \$16,287,000 will be available in FY 1995 for this program. It is anticipated that approximately 10 to 15 new awards will be made ranging from \$500,000 to \$2,500,000.

#### Period of Support

The period of support should not exceed 3 years from June 1, 1995 through May 31, 1998, and is subject to annual approval by the Secretary and the availability of appropriations for the fiscal year involved. Funding of the awards may be available in the future for no more than 2 additional years, for a total funding period of 5 years.

Interested applicants are strongly encouraged, but are not required, to send a letter of intent postmarked no later than November 28, 1994 to: Juanita Koziol, RN, MS, CS, Health Professions HIV Education Branch, National AIDS Education and Training Centers Program, Bureau of Health Professions, Health Resources and Services Administration, Parklawn Building, Room 9A-39, 5600 Fishers Lane, Rockville, Maryland 20857. Telephone: (301) 443-6364, FAX: (301) 443-8890.

#### Statutory Funding Preferences

In making awards, preference will be given to qualified projects which will—

(1) Train, or result in the training of, health professionals who will provide treatment for minority individuals with HIV disease and other individuals who are at high risk of contracting such disease; and

(2) Train, or result in the training of, minority health professionals and minority allied health professionals to provide treatment for individuals with such disease.

#### Proposed Project Requirements

The focus in FY 1995 will be on primary care providers in high HIV/AIDS prevalence areas, with an emphasis on living persons infected with HIV. However, consideration will be given to rural areas. The project requirements are designed to direct Federal resources where the greatest needs exist. To accomplish this, each project must define a geographic region and identify the types of providers to be targeted for training within that region.

#### A. Definition of AETCs

All applicants are encouraged to form AETCs composed of as many states/territories/commonwealths as can be managed completely and efficiently. There are four options for defining an AETC region. An applicant may propose, with appropriate documentation:

1. An AETC composed only of a single state/territory/ commonwealth as a region if that region contains two or more Ryan White CARE Act Title I Eligible Metropolitan Areas (EMAs) or if the AETC currently is established as a single state AETC;

2. An AETC composed of multiple, contiguous states (Hawaii and Alaska may be included) if it justifies its boundaries with the inclusion of one EMA and specific local epidemiological data equivalent to at least 10,000 living HIV-infected persons (with a prevalence of at least 2,500 living AIDS cases and 7,500 other HIV infected persons). Supporting documentation may include

rates of HIV/AIDS infection, or proxy indicators such as STD, TB, and substance abuse, CDC heel stick study data, teenage pregnancy etc.;

3. An AETC for rural regions if it encompasses at least three states with contiguous boundaries (Hawaii and Alaska may be included) and contains at least one EMA, although the prevalence of living HIV infected persons totals less than 10,000; or

4. An AETC specifically in the District of Columbia that either stands alone or is incorporated in a consortium arrangement with another AETC.

At least 50 percent of project funds must be expended for training activities in high AIDS prevalence areas, i.e.: as defined as EMAs in the Ryan White CARE ACT, Title I. If this is not done, appropriate justification from regional epidemiological data and the needs assessment must be provided.

#### B. Performance Expectations

Each AETC must provide or perform the following. These items are essential for consideration for this cooperative agreement.

1. Submission of a coordinated plan, including a clear statement of resources available from the region's EMA(s), for the network that has been created for dissemination of state-of-the-art information to health professions schools and organizations, HIV care providers and CBOs, including organizations of people living with AIDS (PLWA) in the AETC's proposed region; the methodology (e.g., electronic bulletin boards, print material and teleconferencing, etc.) should be described as well as the types of education materials to be distributed in concert with other PHS agencies and health professions' schools and organizations.

2. A comprehensive clinical training plan, of which a minimum of 50 percent of the Federal funds devoted to training is directed toward primary care providers, i.e., physicians, registered nurses, dentists, physician assistants, nurses with advanced training (e.g., nurse practitioners, clinical nurse specialists and nurse midwives) and dental hygienists.

3. A training plan for other health professionals including, but not limited to, mental health care providers, case managers, substance abuse counselors and other allied health personnel;

4. Linkages to other organizations in the following priority order: (a) Ryan White CARE ACT, Titles I, II, including Special Programs of National Significance (SPNS), IIIb and IVd funded health services programs, and the Hemophilia Programs; (b) health

professions schools, academic centers, and national health professions organizations, including minority professional groups; (c) Federally supported substance abuse programs (e.g.: NIDA & SAMHSA) and community substance abuse programs; (d) PHS funded Area Health Education Centers (AHECs), migrant centers (e.g., sec. 329(a)(1), community health centers (e.g., sec. 330(a), and homeless centers (e.g., sec. 340), mental health providers (e.g.: SAMHSA grantees), Federally supported STD and prevention activities (e.g.: CDC, etc.), providers in prisons, family planning programs and HRSA supported maternal and child health programs, State and local health agencies and health care facilities involved in providing care for HIV infected individuals in order to fill any gaps in training; (e) other community based HIV-related organizations (including those formed by PLWA); AETC projects also are encouraged to collaborate with (f) national networks of AIDS clinical trials such as the adult and pediatric AIDS Clinical Trials Group (ACTG), the Community Programs for Clinical Research on AIDS (CPCRA), AMFAR and the Robert Wood Johnson Foundation.

5. An updated needs-assessment of the education and training needs of the primary care providers within the proposed service area and which is based upon epidemiological data for that service area.

6. A plan for outreach to minorities, including involvement of minority providers, providers who serve minority populations, minority professional organizations, and minority health care delivery systems;

7. A plan for program assessment and data collection on program and trainees which can be used for regional and national evaluative purposes; and

8. Plan for non-Federal funding during the 3-year project period.

#### Proposed Review Criteria

The following review criteria are proposed for FY 1995:

Applications will be reviewed and rated according to the applicant's ability to meet the following:

1. The completeness and pertinence of the needs assessment to the proposed region and the degree of linkage between its findings and the plans for information dissemination and training for National AETC Program Levels I through III described in the program guidelines;

2. The degree of emphasis on linkages with Ryan White CARE ACT programs I, II (including Special Programs of National Significance (SPNS)), IIIb and

IVd, health professions schools and academic health centers, and other collaborations as described under Proposed Project Requirements above;

3. The extent to which the training plans meet the national priorities (prevention, substance abuse, cultural competence, tuberculosis, providers in prisons, implementation of the PHS recommendations of protocol, AIDS Clinical Trials Group (ACTG 076), and psychosocial issues) of the National AETC Program;

4. The completeness and appropriateness of the plan for information dissemination among key HIV contacts as defined under Proposed Project Requirements above;

5. The completeness and appropriateness of the training plans for National AETC Program Levels I, II and III;

6. The organization of the AETC; the administration and management of the AETC and its relationship to its component parts, i.e.: Consortia members and/or subcontractors;

7. The appropriateness of the size and configuration of the AETC; the appropriateness and cost-effectiveness of the budget; the amount of support contributed by the proposed awardee institution, including in-kind support;

8. The completeness and appropriateness of the data management and evaluation plans; and

9. The potential for the project to operate on a partially self-sustaining basis during the 3-year period of support.

Interested persons are invited to comment on the proposed project requirements and review criteria. The comment period is 30-days. All comments received on or before November 28, 1994 will be considered before the final project requirements and review criteria are established.

Written comments should be addressed to: Marc L. Rivo, M.D., M.P.H., Director, Division of Medicine, Bureau of Health Professions, Health Resources and Services Administration, Parklawn Building, Room 9A-20, 5600 Fishers Lane, Rockville, MD 20857.

All comments received will be available for public inspection and copying at the Division of Medicine, Bureau of Health Professions, at the above address, weekdays (Federal holidays excepted) between the hours of 8:30 a.m. and 5:00 p.m.

#### National Health Objectives for the Year 2000

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of Healthy People 2000, a

PHS-led national activity for setting priority areas. The Cooperative Agreements for the National AIDS Education and Training Centers Program is related to the priority area of Educational and Community-Based programs. Potential applicants may obtain a copy of *Healthy People 2000* (Full Report; Stock No. 017-001-00474-0) or *Healthy People 2000* (Summary Report; Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, D.C. 20402-9325 (Telephone 202-783-3238).

#### Education and Service Linkage

As part of its long-range planning, HRSA will be targeting its efforts to strengthening linkages between U.S. Public Health Service education programs and programs which provide comprehensive primary care services to the underserved.

#### Smoke-Free Workplace

The PHS strongly encourages all grant and cooperative agreement recipients to provide a smoke-free workplace and promote the non-use of all tobacco products. This is consistent with the PHS mission to protect and advance the physical and mental health of the American people.

#### Definitions

As used in this notice:

(1) The term *HIV disease* means infection with the human immunodeficiency virus, and includes any condition arising from such infection.

(2) The term *human immunodeficiency virus* means the etiologic agent for acquired immune deficiency syndrome.

#### Substantial Federal Involvement

Substantial involvement will occur in the following areas:

1. The development of a plan for the proposed AETC region for the dissemination of state-of-the-art diagnostic and therapeutic clinical guidelines and algorithms, with a particular emphasis on prevention and early intervention strategies;
2. The determination of National AETC Program training priorities;
3. Collaboration with Ryan White CARE ACT programs; health professions schools and academic health centers;
4. The development of a relationship between the National AETC Program and national health professional organizations and national organizations of PLWA.

5. The design or direction of activities to develop the plans for information dissemination and training.

6. The approval of key AETC project staff with particular emphasis on recruitment of minority faculty; and

7. The review of consortia arrangements and major contracts and/or agreements with subcontractors.

8. The collaboration with other HRSA AIDS and AIDS related programs, multiple PHS agencies (NIH, SAMHSA, CDC, FDA and AHCPR) and CBOs including organizations of PLWA.

#### Additional Information

Requests for technical or programmatic information should be directed to Juanita Koziol, RN, MS, CS, at the address listed above.

#### Application Requests

Requests for application materials and questions regarding grants policy and business management issues should be directed to: Mrs. Wilma Johnson (D-35), Deputy Chief, Grants Management Branch, Bureau of Health Professions, Health Resources and Services Administration, Parklawn Building, Room 8C-26, 5600 Fishers Lane, Rockville, Maryland 20857, Telephone: (301) 443-6857, FAX: (301) 443-6343.

Completed applications should be returned to the Grants Management Branch at the above address.

#### Paperwork Reduction Act

The standard application form PHS 6025-1, HRSA Competing Training Grant Application, General Instructions and supplement for this program have been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act. The OMB clearance number is 0915-0060.

#### Application Deadline Date

The application deadline date is December 13, 1994. Applications shall be considered as meeting the deadline if they are either:

- (1) Received on or before the established deadline date, or
- (2) Sent on or before the established deadline date and received in time for orderly processing. (Applicants should request a legibly dated U.S. Postal Service postmark or obtain a legibly dated receipt from a commercial carrier or U.S. Postal Service. Private metered postmarks shall not be acceptable as proof of timely mailing.)

Late applications not accepted for processing will be returned to the applicant.

This program is listed at 93.145 in the Catalog of Federal Domestic Assistance and 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: September 6, 1994.

Ciro V. Sumaya,

M.D., M.P.H.T.M., Administrator.

[FR Doc. 94-26569 Filed 10-26-94; 8:45 am]

BILLING CODE 4160-15-P

#### National Institutes of Health

#### National Institute of Environmental Health Sciences; Notice of Closed Meeting

Pursuant to Section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting:

*Name of Committee:* Environmental Health Sciences Review Committee.

*Date:* November 21-22, 1994.

*Time:* 8:30 a.m. to adjournment.

*Place:* National Institute of Environmental Health Sciences, Building 101 Conference Room, South Campus, Research Triangle Park, North Carolina.

*Contact Person:* Dr. Ethel Jackson, Scientific Review Administrator, P.O. Box 12233, Research Triangle Park, NC 27709, (919) 541-7826.

*Purpose:* To review and evaluate grant applications.

The meeting will be closed in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5, U.S.C. Applications and the discussions could reveal confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

(Catalog of Federal Domestic Assistance Program Nos. 93.113, Biological Response to Environmental Health Hazards; 93-114, Applied Toxicological Research and Testing; 93-115, Biometry and Risk Estimation; 93-894, Resource and Manpower Development, National Institutes of Health)

Dated: October 19, 1994.

Susan K. Feldman,

Committee Management Officer, NIH.

[FR Doc. 94-26564 Filed 10-26-94; 8:45 am]

BILLING CODE 4140-01-M

#### Division of Research Grants; Notice of Closed Meetings

Pursuant to Section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following Division of Research Grants Special Emphasis Panels (SEPs) meetings:

*Purpose/Agenda:* To review Small Business Innovation Research Program grant applications.

*Name of SEP:* Behavioral and Neurosciences.

*Date:* November 9-10, 1994.

*Time:* 9:00 a.m.

*Place:* ANA Hotel, Washington, DC.

*Contact Person:* Dr. Anita Sostek, Scientific Review Admin., 5333 Westbard Ave., Room 319C, Bethesda, MD 20892, (301) 594-7358.

*Name of SEP:* Multidisciplinary Sciences.

*Date:* November 15-16, 1994.

*Time:* 10:00 a.m.

*Place:* Mclean Hilton, Tysons Corner, VA.

*Contact Person:* Dr. Melvin Ketchel, Scientific Review Admin., 5333 Westbard Ave., Room 2A14, Bethesda, MD 20802, (301) 594-7391.

*Name of SEP:* Clinical Sciences.

*Date:* November 16, 1994.

*Time:* 8:00 a.m.

*Place:* Holiday Inn, Chevy Chase, MD.

*Contact Person:* Dr. Gopal Sharma, Scientific Review Administrator, 5333 Westbard Ave., Room 219C, Bethesda, MD 20892, (301) 594-7130.

*Name of SEP:* Clinical Sciences.

*Date:* November 17, 1994.

*Time:* 8:00 a.m.

*Place:* Holiday Inn, Chevy Chase, MD.

*Contact Person:* Dr. Gopal Sharma, Scientific Review Administrator, 5333 Westbard Ave., Room 219C, Bethesda, MD 20892, (301) 594-7130.

*Name of SEP:* Multidisciplinary Sciences.

*Date:* November 30, 1994.

*Place:* NIH, Westwood Building, Room 2A17, Telephone Conference.

*Contact Person:* Dr. Richard Panniers, Scientific Review Administrator, 5333 Westbard Ave., Room 2A17, Bethesda, MD 20892, (301) 594-7348.

*Purpose/Agenda:* To review individual grant applications.

*Name of SEP:* Clinical Sciences.

*Date:* November 14, 1994.

*Time:* 8:30 a.m.

*Place:* NIH, Westwood Building, Room 203B, Telephone Conference.

*Contact Person:* Dr. H.M. Stiles, Scientific Review Administrator, 5333 Westbard Ave., Room 203B, Bethesda, MD 20892, (301) 594-7194.

*Name of SEP:* Biological & Physiological Sciences.

*Date:* November 14, 1994.

*Time:* 1:00 p.m.

*Place:* National Airport, Arlington, VA.

*Contact Person:* Dr. Everett Sinnott, Scientific Review Administrator, 5333 Westbard Ave., Room 349, Bethesda, MD 20892, (301) 594-7220.

*Name of SEP:* Biological & Physiological Sciences.

*Date:* November 14, 1994.

*Time:* 2:00 p.m.

*Place:* NIH, Westwood Building, Room 225B, Telephone Conference.

*Contact Person:* Dr. David Redmondini, Scientific Review Administrator, 5333 Westbard Ave., Room 225B, Bethesda, MD 20892, (301) 594-7202.

*Name of SEP:* Microbiological and Immunological Sciences.

*Date:* November 15, 1994.

*Time:* 11:00 a.m.

*Place:* NIH, Westwood Building, Room A23, Telephone Conference.

*Contact Person:* Dr. Anita Weinblatt, Scientific Review Administrator, 5333 Westbard Ave., Room A23, Bethesda, MD 20892, (301) 594-7175.

*Name of SEP:* Chemistry and Related Sciences.

*Date:* November 16, 1994.

*Time:* 1:00 p.m.

*Place:* NIH, Westwood Building, Room 1A26, Telephone Conference.

*Contact Person:* Dr. Martin Padarathsingh, Scientific Review Admin., 5333 Westbard Ave., Room 1A26, Bethesda, MD 20892, (301) 594-7192.

*Name of SEP:* Biological Physiological Sciences.

*Date:* November 17, 1994.

*Time:* 2:00 p.m.

*Place:* NIH Westwood Building, Room 225B, Telephone Conference.

*Contact Person:* Dr. David Redmondini, Scientific Review Administrator, 5333 Westbard Ave., Room 225B, Bethesda, MD 20892, (301) 594-7202.

*Name of SEP:* Chemistry and Related Science.

*Date:* November 17, 1994.

*Time:* 11:00 a.m.

*Place:* NIH, Westwood Building, Room 337, Telephone Conference.

*Contact Person:* Dr. Mike Radtke, Scientific Review Administrator, 5333 Westbard Ave., Room 337, Bethesda, MD 20892, (301) 594-7212.

*Name of SEP:* Clinical Sciences.

*Date:* November 18, 1994.

*Time:* 1:00 p.m.

*Place:* NIH, Westwood Building, Room 349, Telephone Conference.

*Contact Person:* Ms. Jo Pelham, Scientific Review Administrator, 5333 Westbard Ave., Room 349, Bethesda, MD 20892, (301) 594-7254.

*Name of SEP:* Biological & Physiological Sciences.

*Date:* November 18, 1994.

*Time:* 2:00 p.m.

*Place:* NIH, Westwood Building, Room 225B, Telephone Conference.

*Contact Person:* Dr. David Redmondini, Scientific Review Administrator, 5333 Westbard Ave., Room 225B, Bethesda, MD 20892, (301) 594-7202.

*Name of SEP:* Multidisciplinary Sciences.

*Date:* November 20-23, 1994.

*Place:* Penn View Inn, Philadelphia, PA.

*Contact Person:* Dr. Richard Panniers, Scientific Review Admin., 5333 Westbard Ave., Room 2A17, Bethesda, MD 20892, (301) 594-7348.

*Name of SEP:* Multidisciplinary Sciences.

*Date:* November 22, 1994.

*Time:* 2:00 p.m.

*Place:* NIH, Westwood Building, Room 2A14, Telephone Conference.

*Contact Person:* Dr. Melvin Ketchel, Scientific Review Administrator, 5333 Westbard Ave., Room 2A14, Bethesda, MD 20892, (301) 594-7391.

*Name of SEP:* Chemistry and Related Sciences.

*Date:* November 30, 1994.

*Time:* 2:00 p.m.

*Place:* NIH, Westwood Building, Room 328, Telephone Conference.

*Contact Person:* Dr. Paul Strudler, Scientific Review Admin., 5333 Westbard Ave., Room 328, Bethesda, MD 20892, (301) 594-7152.

*Name of SEP:* Multidisciplinary Sciences

*Date:* November 30, 1994.

*Time:* 8:30 a.m.

*Place:* Univ. of California, Irvine, CA.

*Contact Person:* Dr. Marjam Behar, Scientific Review Administrator, 5333 Westbard Ave., Room 2A11A, Bethesda, MD 20892, (301) 594-7376.

*Name of SEP:* Clinical Sciences.

*Date:* November 18, 1994.

*Time:* 1:00 p.m.

*Place:* NIH, Westwood Building, Room 349, Telephone Conference.

*Contact Person:* Ms. Jo Pelham, Scientific Review Administrator, 5333 Westbard Ave., Room 349, Bethesda, MD 20892, (301) 594-7254.

The meetings will be closed in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5, U.S.C. Applications and/or proposals and discussions could reveal confidential trade secrets or commercial property such as patentable material and personal information concerning individuals associated with the applications and/or proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy. (Catalog of Federal Domestic Assistance Program Nos. 93.306, 93.333, 93.337, 93.393-93.396, 93.837-93.844, 93.846-93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: October 20, 1994.

**Susan K. Feldman,**

*Committee Management Officer, NIH*

[FR Doc. 94-26565 Filed 10-26-94; 8:45 am]

BILLING CODE 4140-01-M

## Public Health Service

### National Institutes of Health; Statement of Organization, Functions, and Delegations of Authority

Part H, Chapter HN (National Institutes of Health) of the Statement of Organization, Functions, and Delegations of Authority for the Department of Health and Human Services (40 FR 22859, May 27, 1975, as amended most recently at 59 FR 42066, August 16, 1994) is amended to reflect the reorganization of the National Institute of Dental Research (NIDR) (HNP). This reorganization will align NIDR's organizational structure with that of other Institutes to assure proper comparability and recognition of organizations and positions by both the dental community and personnel of other Government organizations. The reorganization consists of the following: (1) Realign the Office of Administrative

Management (HNP13) and Office of Planning, Evaluation and Communications (HNP14) in the Office of the Director (HNP1); (2) establish the Division of Intramural Research (HNP2); (3) transfer the functions of the Intramural Research Program (IRP) (HNP-2) to the Division of Intramural Research and abolish the IRP; (4) establish the Division of Extramural Research (HNP4); (5) transfer the functions of the Extramural Program (EP) (HNP-4) to the Division of Extramural Research and abolish the EP; (6) establish the Division of Epidemiology and Oral Disease Prevention (HNP5); and (7) transfer the functions of the Epidemiology and Oral Disease Prevention Program (EODPP) (HNP-5) to the Division of Epidemiology and Oral Disease Prevention and abolish the EODPP.

*Section HN-B, Organization and Functions*, is amended as follows: (1) Under the heading *National Institute of Dental Research (NIDR)*, delete the titles and functional statements for the *Intramural Research Program (HNP-2)*, the *Extramural Program (HNP-4)*, and the *Epidemiology and Oral Disease Prevention Program (HNP-5)* in their entirety and insert the following:

**Office of Administrative Management (HNP13)**

(1) Advises the Director, Deputy Director, Program Directors, and other key officials on managerial and administrative matters affecting the planning and execution of NIDR programs; (2) plans, directs, and conducts administrative management activities of the NIDR including the areas of financial management, personnel management, management analysis, and office services; (3) interprets, analyzes, and implements legislation and/or Departmental and NIH directives affecting administrative policies, administrative orders, and new concepts affecting the overall mission of the NIDR; (4) develops policies, guidelines, and procedures on matters relating to the administrative management activities of the Institute; and (5) serves as the Institute focal point for the coordination, preparation, and analysis of a wide variety of programmatic reports and other documents associated with NIH, PHS, DHHS, and other Federal agencies.

**Office of Planning, Evaluation and Communications (HNP14)**

(1) Advises the Director on science program and policy activities related to strategic planning, evaluation, program analysis, legislation, public information, and communications and data systems,

and directs the Institute's efforts in these areas; and (2) maintains NIDR's research project information systems and serves as the Institute focus for automated data processing systems and information technology, including local area networks.

**Division of Intramural Research (HNP2)**

(1) Plans and conducts the Institute's basic and clinical research program directed toward increasing fundamental knowledge of oral diseases and the senses of taste and smell; the biochemistry, structure, function and development of bone, teeth, salivary glands, and connective tissues; the role of bacteria and viruses in oral disease, genetic disorders and tumors of the oral cavity; and studies the cause and treatment of acute and chronic pain and new diagnostic methods; (2) provides dental care for selected inpatients and ambulatory patients of Institutes conducting clinical research in the Warren Grant Magnuson Clinical Center; (3) evaluates research efforts and establishes program priorities; (4) allocates funds, space, and personnel ceilings to ensure maximum utilization of available resources in the attainment of Institute objectives and integrates new research activities into the program structure; (5) collaborates with other NIH Institutes and external research institutions and maintains an awareness of national research efforts in program areas; and (6) provides advice on intramural research and science in general to the Institute Director.

**Division of Extramural Research (HNP4)**

(1) Plans and directs the Institute's programs that support research and research training through grants and contracts in oral biology, periodontal diseases, dental caries, nutrition and fluoride; craniofacial development and disorders; biomaterials, biology of the pulp and implants; oral soft tissue diseases; pain and oral motor and sensory function; salivary glands and saliva; and behavioral and social sciences and oral epidemiology, to ensure maximum utilization of available resources in attainment of institute objectives; (2) provides essential initial scientific review for applications assigned to the Institute and assures effective and proper grants and contracts management; (3) assesses the need for research and research training in a broad spectrum of scientific program areas; (4) determines program priorities and recommends funding levels; (5) collaborates with Institute and NIH intramural programs and

maintains an awareness of related national research efforts in program areas; (6) provides advice on extramural research and science in general to the Institute Director, staff, and advisory groups by preparing reports and analyses to facilitate the implementation of their responsibilities; (7) establishes and maintains effective relationships with dental schools and research institutions, professional dental organizations, and other agencies and organizations concerned with extramural programs; and (8) consults with other Federal and public agencies, voluntary health organizations, professional associations, and private sector organizations in identifying research needs and developing programs to meet those needs.

**Division of Epidemiology and Oral Disease Prevention (HNP5)**

Serves as the Federal focus for research in the fields of orofacial epidemiology and disease prevention. (1) Plans, develops, directs, and performs epidemiologic investigations of oral and maxillofacial health and diseases, as well as oral manifestations of systemic disorders; (2) identifies biological, behavioral, social, environmental, and material risk factors for orofacial diseases and conditions; (3) identifies and tests molecular and cellular markers, clinical indices, imaging techniques, behavioral and social factors, environmental indicators, and other approaches for assessing the presence and course of orofacial disorders, treatment compliance and outcome, and the onset of systemic diseases via *in vitro*, animal model, and human population studies; (4) performs research in the areas of diseases diagnosis, etiology, prognosis, and treatment; prevention and health promotion; delivery of care; utilization of services; risk-benefit assessment; and decision systems; (5) develops current estimates for, and monitors trends in, levels and distribution of orofacial health status and diseases; (6) compiles, maintains, and analyzes databases, disease registries, and data banks on orofacial health status in the U.S. general population and particular subpopulations; (7) facilitates the diffusion, dissemination, and transfer of knowledge related to oral disease prevention and health promotion, and evaluates that process in terms of such factors as feasibility, acceptability, effectiveness, and long-term adoption of intervention strategies for improving oral health practices, utilization of dental services, and oral health status; (8) fosters the transmission of scientific knowledge to the research, public, and

practitioner communities; (9) identifies emerging orofacial health problems and issues in populations, evaluates the sources and implications of trends in the orofacial health status of populations, and uses results to help develop research priorities for the division and Institute; (10) offers training programs related to the mission of the division; (11) provides technical assistance to other NIDR program components, NIH, PHS, DHHS, and Federal and non-Federal agencies, and professional groups; (12) prepares analyses and reports to assist Institute staff and advisory groups in carrying out their responsibilities; (13) consults with health organizations and professional associations in identifying research needs and developing programs to meet them; and (14) provides advice on the program and science in general to the Institute Director.

Dated: October 12, 1994.

Harold Varmus,

Director, NIH.

[FR Doc. 94-26563 Filed 10-26-94; 8:45 am]

BILLING CODE 4140-01-M

### National Institutes of Health; Privacy Act of 1974; New System of Records

AGENCY: Public Health Service, DHHS.

ACTION: Notification of a new system of records.

**SUMMARY:** In accordance with the requirements of the Privacy Act, the Public Health Service (PHS) is publishing a notice of a new system of records, 09-25-0169, "Medical Staff Credentials Files, HHS/NIH/CC." We are also proposing routine uses for this new system.

**DATES:** PHS invites interested parties to submit comments on the proposed internal and routine uses on or before November 28, 1994. PHS has sent a report of a New System to the Congress and to the Office of Management and Budget (OMB) on October 14, 1994. This system of records will be effective 40 days from the date of publication unless PHS receives comments on the routine uses which would result in a contrary determination.

**ADDRESSES:** Please submit comments to: NIH Privacy Act Officer, Building 31, Room 3B03, 9000 Rockville Pike, Bethesda, MD 20892, 301-496-2832.

Comments received will be available for inspection at this same address from 9 a.m. to 3 p.m., Monday through Friday.

**FOR FURTHER INFORMATION CONTACT:** Chief, Medical Record Department, Warren G. Magnuson Clinical Center,

National Institutes of Health, Building 10, Room 1N208, 9000 Rockville Pike, Bethesda, Maryland 20892, 301-496-2292.

The numbers listed above are not toll free.

**SUPPLEMENTARY INFORMATION:** The National Institutes of Health (NIH) proposes to establish a new system of records: 09-25-0169, "Medical Staff Credentials Files, HHS/NIH/CC." This system of records will be used by NIH staff to: (1) Maintain information used in the credentialing and privileging of active medical staff members at the Warren G. Magnuson Clinical Center; (2) document patient care privileges for active members of the medical staff; (3) provide information about active and non-active members of the medical staff to authorized individuals; and (4) report to the National Practitioner Data Bank as required by the provisions of Title IV of Public Law 99-660, as amended.

The system will comprise records that contain medical staff names, date of birth, home address and telephone number, office address and telephone number, citizenship, visa information, appointment date, hospital-wide computer access privileges, Institute/Center/Division designation, branch/lab, type of medical staff membership, privilege delineation, professional degree(s) including school of attendance and graduation dates, foreign medical examinations, specialty board certifications, licensing information (including state of licensure and license number), record or disciplinary actions, documentation of training, and admitting privileges.

The amount of information recorded on each individual will be only that which is necessary to accomplish the purposes of the system. Records are established from forms and documentation submitted by individual medical staff members to the Medical Record Department.

The records in this system will be maintained in a secure manner compatible with their content and use. NIH and Contractor staff will be required to adhere to the provisions of the Privacy Act and the HHS Privacy Act regulations. The System Manager will control access to the data. Only authorized users whose official duties require the use of such information will have regular access to the records in this system. Authorized users are HHS employees and Contractor staff responsible for implementing the medical staff credentials data system.

Records will be stored on paper forms in file folders and on computer disk. Manual and computerized records will

be maintained in accordance with the standards of Chapter 45-13 of the HHS General Administration Manual, "Safeguarding Records Contained in Systems of Records," supplementary Chapter PHS hf: 45-13, the Department's Automated Information System Security Program Handbook, and the National Institute of Standards and Technology Federal Information Processing Standards (FIPS Pub. 41 and FIPS Pub. 31).

Data stored in computers is accessed through a network system by use of a password known only to authorized users. Rooms where records are stored are locked when not in use. During regular business hours, rooms are unlocked by entry is controlled by on-site personnel.

The routine uses proposed for this system are compatible with the stated purposes of the system. The first routine use permitting disclosure to a congressional office is proposed to allow subject individuals to obtain assistance from their representatives in Congress, should they so desire. Such disclosure would be made only pursuant to a request of the individual. The second routine use of this system allows disclosure to the Department of Justice to defend the Federal Government, the Department, or employees of the Department in the event of litigation. The third routine use allows referral to the appropriate agency in the event that a system of records maintained by this agency to carry out its functions indicates a violation or potential violation of law. The fourth routine use allows disclosure of records to contractors for the purpose of processing or refining records in the system. The fifth routine use permits disclosure to representatives of the Joint Commission on Accreditation of Healthcare Organizations for the purpose of conducting quality assurance reviews and inspections of the Warren G. Magnuson Clinical Center credentialing policies and procedures. The sixth routine use permits disclosure to State medical boards for purposes of professional quality assurance activities. The seventh routine use allows disclosure to health care facilities for the purpose of verifying that an individual to whom they intend to grant medical staff or patient care privileges has or previously held such privileges at the Warren G. Magnuson Clinical Center.

The following notice is written in the present, rather than future tense, in order to avoid the unnecessary expenditure of public funds to republish the notice after the system has become effective.

Dated: October 18, 1994.

Ellen Wormser,  
Director, Office of Organization and  
Management Systems.

09-25-0169

**SYSTEM NAME:**

Medical Staff-Credentials Files, HHS/  
NIH/CC.

**SECURITY CLASSIFICATION:**

None.

**SYSTEM LOCATION:**

Medical Record Department, Warren  
G. Magnuson Clinical Center, National  
Institutes of Health, Building 10, Room  
1N208, 9000 Rockville Pike, Bethesda,  
Maryland 20892.

Write to the System Manager at the  
address below for a list of Contractor  
locations, including the address of any  
Federal Records Center where records  
from this system may be stored.

**CATEGORIES OF INDIVIDUALS COVERED BY THE  
SYSTEM:**

Individuals who have been approved  
as members of the medical staff at the  
Warren G. Magnuson Clinical Center.

**CATEGORIES OF RECORDS IN THE SYSTEM:**

Medical staff names, date of birth,  
home address and telephone number,  
office address and telephone number,  
citizenship, visa information,  
appointment date, hospital-wide  
computer access privileges, Institute/  
Center/Division designation, branch/lab,  
type of medical staff membership,  
privilege delineation, professional  
degree(s) including school of attendance  
and graduation dates, foreign medical  
examinations, specialty board  
certifications, licensing information  
(including state of licensure and license  
number), record of disciplinary actions,  
documentation of training, and  
admitting privileges.

**AUTHORITY FOR MAINTENANCE OF THE SYSTEM:**

Authority for collecting the requested  
information is contained in section 301  
(42 U.S.C. 241) of the Public Health  
Service Act, as amended, outlining the  
authority of the Secretary to, within the  
Public Health Service (PHS), promote  
the coordination of various research and  
associated activities, including for  
purposes of study, admitting and  
treating individuals at PHS facilities.  
Section 402(b) of the Public Health  
Service Act (42 U.S.C. 282(b)), as  
amended, outlining the authority of the  
Director of the National Institutes of  
Health (NIH) with respect to the  
admission and treatment of individuals  
at NIH facilities for purposes of study.

**PURPOSE(S):**

These records are used to: (1)  
Maintain information used in the  
credentialing and privileging of active  
medical staff members at the Warren G.  
Magnuson Clinical Center; (2) document  
patient care privileges for active  
members of the medical staff; (3)  
provide information about active and  
non-active members of the medical staff  
to authorized individuals; and (4) report  
to the National Practitioner Data Bank as  
required by the provisions of Title IV of  
Pub. L. 99-660, as amended.

**ROUTINE USES OF RECORDS MAINTAINED IN THE  
SYSTEM, INCLUDING CATEGORIES OF USERS AND  
THE PURPOSES OF SUCH USE:**

1. Disclosure may be made to a  
congressional office from the record of  
an individual in response to an inquiry  
from the congressional office made at  
the request of that individual.

2. The Department of Health and  
Human Services (HHS) may disclose  
information from this system of records  
to the Department of Justice, or to a  
court or other tribunal, when (a) HHS,  
or any component thereof; or (b) any  
HHS employee in his or her official  
capacity; or (c) any HHS employee in  
his or her individual capacity where the  
Department of Justice (or HHS, where it  
is authorized to do so) has agreed to  
represent the employee; or (d) the  
United States or any agency thereof  
where HHS determines that the  
litigation is likely to affect HHS or any  
of its components, is a party to  
litigation, and HHS determines that the  
use of such records by the Department  
of Justice, court or other tribunal is  
relevant and necessary to the litigation  
and would help in the effective  
representation of the governmental  
party, provided, however, that in each  
case HHS determines that such  
disclosure is compatible with the  
purpose for which the records were  
collected.

3. In the event that a system of records  
maintained by this agency to carry out  
its functions indicates a violation or  
potential violation of law, whether civil,  
criminal, or regulatory in nature, and  
whether arising by general statute or  
particular program statute, or by  
regulation, rule or order issued pursuant  
thereto, the relevant records in the  
system of records may be referred to the  
appropriate agency, whether Federal,  
State, or local, charged with enforcing or  
implementing the statute or rule,  
regulation or order issued pursuant  
thereto.

4. NIH may disclosure records to  
Department contractors and  
subcontractors for the purpose of  
collecting, compiling, aggregating,

analyzing, or refining records in the  
system. Contractors maintain, and are  
also required to ensure that  
subcontractors maintain, Privacy Act  
safeguards with respect to such records.

5. NIH may disclose information to  
representatives of the Joint Commission  
on Accreditation of Healthcare  
Organizations for the purpose of  
conducting quality assurance reviews  
and inspections of the Warren G.  
Magnuson Clinical Center credentialing  
policies and procedures.

6. NIH disclose information from this  
system of records to State medical  
boards for purposes of professional  
quality assurance activities.

7. NIH may disclose information from  
this system of records to health care  
facilities for the purpose of verifying  
that an individual to whom they intend  
to grant medical staff or patient care  
privileges has or previously held such  
privileges at the Warren G. Magnuson  
Clinical Center.

**POLICIES AND PRACTICES FOR STORING,  
RETRIEVING, ACCESSING, RETAINING, AND  
DISPOSING OF RECORDS IN THE SYSTEM:**

**STORAGE:**

Records are stored on paper forms in  
file folders and on computer disks.

**RETRIEVABILITY:**

Records are retrieved by name, date of  
birth, type of medical staff membership,  
Institute/Center/Division and licensing  
status.

**SAFEGUARDS:**

1. *Authorized users:* Data on the  
computer network system is accessed by  
a password known only to authorized  
users who are NIH employees and  
Contractor staff responsible for  
implementing the medical staff  
credentials data system. Access to  
information is thus limited to those with  
a need to know.

2. *Physical safeguards:* Rooms where  
records are stored are locked when not  
in use. During regular business hours  
rooms are unlocked but entry is  
controlled by on-site personnel.

3. *Procedural and technical  
safeguards:* Access to files is strictly  
controlled by the system manager.  
Names and other identifying particulars  
are deleted when data from original  
records are encoded for analysis. Data  
stored in computers is accessed through  
a network system by use of a password  
known only to authorized users. All  
authorized users of personal  
information in connection with the  
performance of their jobs (see  
Authorized Users, above) protect  
information from public view and from  
unauthorized personnel entering an

unsupervised office. These practices are in compliance with the standards of Chapter 45-13 of the HHS General Administration Manual, "Safeguarding Records Contained in Systems of Records," supplementary Chapter PHS hf: 45-13, and the Department's Automated Information System Security Program Handbook, and the National Institute of Standards and Technology Federal Information Processing Standards (FIPS Pub. 41 and FIPS Pub. 31).

#### RETENTION AND DISPOSAL:

Records are retained and disposed of under the authority of the NIH Records Control Schedule contained in NIH Manual Chapter 1743, Appendix 1—"Keeping and Destroying Records" (HHS Records Management Manual, Appendix B-361), item 2300-293-4, "Medical Staffs' Credential Files," which allows inactive records to be transferred to the Federal Records Center at five year intervals and to be destroyed after thirty years. Refer to the NIH Manual Chapter for specific disposition instructions.

#### SYSTEM MANAGER AND ADDRESS:

Chief, Medical Record Department, Warren G. Magnuson Clinical Center, National Institutes of Health, Building 10, Room 1N208, 9000 Rockville Pike, Bethesda, Maryland 20892.

#### NOTIFICATION PROCEDURES:

To determine if a record exists, write to the System Manager at the above address. The requester must provide tangible proof of identity (e.g., driver's license). If no identification papers are available, the requester must verify his or her identity by providing either a notarization of the request or a written certification that the requester is who he or she claims to be and understands that the knowing and willful request for acquisition of a record pertaining to an individual under false pretenses is a criminal offense under the Act, subject to a five thousand dollar fine.

#### RECORD ACCESS PROCEDURES:

Write to the System Manager specified above to attain access to records and provide the same information as that required under the Notification Procedures. Requesters should also reasonably specify the record contents being requested. Individuals may also request an accounting of disclosure of their records, if any.

#### CONTESTING RECORD PROCEDURES:

Contact the System Manager specified above and reasonably identify the record, specify the information to be

contested, the corrective action sought, and your reasons for requesting the correction, along with supporting information to show how the record is inaccurate, incomplete, untimely or irrelevant. The right to contest records is limited to information which is incomplete, irrelevant, incorrect, or untimely (obsolete).

#### RECORD SOURCE CATEGORIES:

Subject individual.

#### SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:

None.

[FR Doc. 94-26626 Filed 10-26-94; 8:45 am]

BILLING CODE 4140-01-M

### Social Security Administration

#### Privacy Act of 1974; Report of New Systems of Records

AGENCY: Social Security Administration (SSA), HHS.

ACTION: Notification of new systems of records and new routine uses.

**SUMMARY:** In accordance with the Privacy Act of 1974 (5 U.S.C. 552a(e)(4)), we are notifying the public of our intent to establish two new systems of records. The proposed systems are entitled "SSA-Initiated Personal Earnings and Benefit Estimate Statement (SIPEBES) History File, HHS/SSA/OSR, 09-60-0224" and "SSA-Initiated Personal Earnings and Benefit Estimate Statement Address System for Certain Territories, HHS/SSA/OSR, 09-60-0225." For convenience we will refer to these systems as the "History File" and the "Territory Address System," respectively.

We are also proposing to establish routine uses of the information to be maintained in the two systems. The proposed routine uses are discussed below.

We invite public comment on this publication.

**DATES:** We filed a report of the proposed systems of records with the Senate Committee on Governmental Affairs, the House Committee on Government Operations, and the Office of Management and Budget, Office of Information and Regulatory Affairs, on October 3, 1994. The proposed systems, including the proposed routine uses, will become effective as proposed, without further notice, on November 12, 1994, unless we receive comments on or before that date which would warrant preventing the systems from taking effect.

**ADDRESSES:** Interested individuals may comment on this proposal by writing to

the SSA Privacy Officer, 3-D-1 Operations Building, 6401 Security Boulevard, Baltimore, Maryland 21235. All comments received will be available for public inspection at the above address.

**FOR FURTHER INFORMATION CONTACT:** Mr. Peter J. Benson, Office of Policy, 6401 Security Boulevard, Baltimore, Maryland 21235; telephone 410-965-1736.

#### SUPPLEMENTARY INFORMATION:

##### I. Description of the Proposed Systems of Records

Section 1143(c) of the Social Security Act requires SSA to phase in a program, beginning not later than October 1, 1999, for mailing a PEBES annually to everyone:

- (a) Who has reached at least age 25,
- (b) Who has had some earnings reported to his/her Social Security number (SSN),
- (c) Who is not receiving benefits under Title II of the Social Security Act, and
- (d) For whom SSA can determine a mailing address.

The phasing in requires SSA to furnish PEBES by not later than September 30, 1995, to everyone who has reached age 60 by October 1, 1994, who is currently not receiving title II benefits, for whom some earnings have been reported, and for whom a current mailing address can be established; and from October 1, 1994, to September 30, 1999, to everyone who attains age 60 during that period and who meets the other criteria for receiving the PEBES. The PEBES will be sent in the fiscal year (October 1 through September 30) in which the individual attains age 60.

The two systems together will enable SSA to mail Personal Earnings and Benefit Estimate Statements (PEBES) to certain individuals, pursuant to section 1143 of the Social Security Act (42 U.S.C. 1320b-13).

SSA has previously maintained current address information only for those persons currently entitled to monthly Social Security benefits. Therefore, SSA must obtain address information for everyone to whom SSA will be required to mail a PEBES.

As discussed below, SSA will use different sources for obtaining the address information that will be maintained in the systems.

**A. History File.** For persons living within a State of the United States or the District of Columbia, SSA will use address information obtained from the Internal Revenue Service (IRS), reflecting addresses taken from Federal income tax returns. SSA will maintain

this address information obtained from IRS in the History File.

After the PEBES have been released in a given mailing cycle, SSA will inevitably receive inquiries from some individuals about their PEBES, or alleging that they did not receive a PEBES. The History File will enable SSA to verify whether a PEBES was released to that person, when, to what address, and what address source was used. The History File will also permit statistical studies involving the PEBES system.

**B. Territory Address System.** For persons living in Puerto Rico or in a territory of the United States who are not required to file Federal income tax returns, SSA must obtain their addresses from sources other than the IRS. SSA will obtain this information from the Commonwealth and Territorial governments. SSA must maintain these data until needed for a PEBES mailing. We therefore are establishing the Territory Address System of records for that purpose. After an address is identified from the Territory Address System and a PEBES is mailed, the address information will be maintained in the History File.

## II. Collection and Maintenance of Data in the Systems

Information for the History File (each individual's address information, other personal information, and information about the PEBES mailing) will be obtained from IRS and from sources within SSA, respectively.

Information for the Territory Address System will be obtained primarily from the Commonwealth and Territorial governments, possibly supplemented from other sources.

## III. Proposed Routine Use Disclosures of Data in the Systems

We are proposing to establish the following routine use disclosures of the information that will be maintained in the two systems. The routine use disclosures are identical for both systems except as noted. Information may be disclosed as follows:

1. *Information may be disclosed to contractors and other Federal agencies, as necessary, to assist SSA in the efficient administration of its programs. We contemplate disclosing information under this routine use only in situations in which SSA may enter a contractual or similar agreement with a third party to assist in accomplishing an agency function relating to this system of records.*

*Wage and other information which is subject to the disclosure provisions of the Internal Revenue Code (IRC, 26*

*U.S.C. 6103) will not be disclosed under this routine use unless disclosure is expressly permitted by the IRC.*

Contractors will safeguard information disclosed to them consistent with the requirements of the Privacy Act.

We contemplate disclosing information under this routine use only when SSA enters into a contractual or similar agreement with a third party to help SSA maintain the proposed systems or to carry out the PEBES mailing program.

In administering our program, we often find that it is more efficient to use an outside contractor to carry out some of our functions. This proposed routine use would allow us to disclose information from the system under these circumstances.

2. *Information may be disclosed to a congressional office in response to an inquiry from the congressional office made at the request of the subject of the record.*

*Wage and other information which is subject to the disclosure provisions of the Internal Revenue Code (IRC, 26 U.S.C. 6103) will not be disclosed under this routine use unless disclosure is expressly permitted by the IRC.*

We contemplate disclosing information under this routine use only in situations in which the individual asks his/her Member of Congress to intercede in an SSA matter on his/her behalf. Information will be disclosed from the proposed systems only when the Member of Congress inquires and presents evidence that he/she is acting on behalf of the individual whose record is requested.

3. *Information may be disclosed to the Department of Justice (DOJ), a court, or other tribunal, or another party before such tribunal, when:*

(1) *SSA, or any component thereof; or*  
(2) *any SSA employee in his/her official capacity; or*

(3) *any SSA employee in his/her individual capacity when DOJ (or SSA, when it is authorized to do so) has agreed to represent the employee; or*

(4) *the United States or any agency thereof when SSA determines that the litigation is likely to affect the operations of SSA or any of its components, is a party to litigation or has an interest in such litigation, and SSA determines that the use of such records by DOJ, the court or other tribunal, or other party before the tribunal is relevant and necessary to the litigation, provided, however, that in each case SSA determines that such disclosure is compatible with the purposes for which the records were collected.*

*Wage and other information which is subject to the disclosure provisions of the Internal Revenue Code (IRC, 26 U.S.C. 6103) will not be disclosed under this routine use unless disclosure is expressly permitted by the IRC.*

This proposed routine use would permit us to disclose information from the proposed systems when an SSA component and/or employee is involved in litigation involving information in the proposed system. The routine use would also permit disclosure when SSA brings suit or when another party brings suit and SSA has an interest in the litigation.

4. *Information may be disclosed to the Office of the President for responding to an individual pursuant to an inquiry received from that individual or from a third party on his or her behalf.*

*Wage and other information which is subject to the disclosure provisions of the Internal Revenue Code (IRC, 26 U.S.C. 6103) will not be disclosed under this routine use unless disclosure is expressly permitted by the IRC.*

We contemplate disclosing information under this routine use in situations in which that individual or someone else on the individual's behalf asks the President to intercede in an SSA matter pertaining to the individual. Information may be disclosed from the proposed systems when the Office of the President inquires and presents evidence that it is acting on behalf of the individual whose record is requested.

5. *Nontax return information, the disclosure of which is not expressly restricted by Federal law, may be disclosed to the General Services Administration and the National Archives and Records Administration under 44 U.S.C. 2904 and 2906, as amended by the National Archives and Records Administration Act of 1984, for the use of those agencies in conducting records management studies.*

*Wage and other information which is subject to the disclosure provisions of the Internal Revenue Code (IRC, 26 U.S.C. 6103) will not be disclosed under this routine use unless disclosure is expressly permitted by the IRC.*

The Administrator of the General Services Administration (GSA) and the Archivist of the National Archives and Records Administration (NARA) are charged by 44 U.S.C. 2904 with promulgating safeguards, procedures, and guidelines regarding records management and conducting records management studies. Section 2906 of that law, also amended by the NARA Act of 1984, provides that GSA and NARA are to have access to Federal agencies' records and that agencies are to cooperate with GSA and NARA. In

carrying out these responsibilities, it may be necessary for GSA and NARA to have access to these two proposed systems of records. In such instances, the routine use will facilitate disclosure.

6. Information may be disclosed to the Internal Revenue Service (IRS) for auditing SSA's compliance with the safeguard provisions of the Internal Revenue Code of 1986, as amended.

This routine use applied only to the History File which maintains some information obtained from the IRS. As necessary, the routine use will allow disclosure to IRS to ensure that SSA is in compliance with safeguard standards.

#### IV. Compatibility of the Proposed Routine Uses

Both the Privacy Act of 1974 (5 U.S.C. 552a(a)(7) and (b)(3)) and our disclosure regulations (20 CFR part 401) permit us to disclose information under a routine use for a purpose which is compatible with the purposes for which we collected the information. Paragraph 401.310(c) of the regulations permits us to disclose information under a routine use to administer our programs. Section 401.205 of the regulations requires us to disclose information when a law specifically requires the disclosure.

The proposed routine uses numbered 1, 2, 3, 4, and 6, described above, will facilitate SSA's administration of its programs. Routine use number 5 will allow GSA or NARA to inspect our records, as required by 44 U.S.C. 2904 and 2906, when those agencies conduct records management studies. Thus, all the routine uses are appropriate and meet the criteria in the Privacy Act and SSA's regulations.

#### V. Safeguards

We will employ a number of security measures to minimize the risk of unauthorized access to or disclosure of personal data in the two proposed systems. These measures include the use of passwords and access codes to enter the computer system which will maintain the data, and storage of the computerized records in secured areas which are accessible only to employees who require the information in performing their official duties. SSA employees who have access to the data will be informed of the criminal penalties of the Privacy Act for unauthorized access to or disclosure of information maintained in the system.

In addition, any contract which SSA may sign with a third party in order to carry out the required mailings will stipulate that (a) the contractor must establish safeguards to protect the personal information temporarily in its custody, in accordance with Privacy Act

requirements; (b) the contractor may use the information only as necessary in fulfilling the contract; and (c) the contractor is subject to criminal penalties for violations of the Privacy Act.

#### VI. Effect of the Proposed Systems of Records on Individual Rights

As discussed above, the proposed systems of records will enable SSA to mail PEBES. Recipients will benefit from the PEBES because these statements will help them plan their finances and check the accuracy of SSA's records. The routine uses will benefit individuals by helping SSA run its programs smoothly.

SSA will adhere to all provisions of the Privacy Act, Social Security Act, and other applicable laws in our maintenance and use of the information. Thus, we do not anticipate that the system will have any adverse effect on individuals' rights.

Dated: October 3, 1994.

Shirley S. Chater,

Commissioner of Social Security.

09-60-0224

#### SYSTEM NAME:

SSA-Initiated Personal Earnings and Benefit Estimate Statement (SIPEBES) History File, HHS/SSA/OSR.

#### SECURITY CLASSIFICATION:

None.

#### SYSTEM LOCATION:

Social Security Administration, Office of Systems, 6401 Security Boulevard, Baltimore, MD 21235.

#### CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Any person:

- Who lives in a state or territory of the United States or the District of Columbia;
- Who has reached age 25;
- Who has had earnings posted to his/her Social Security number (SSN);
- Who is not receiving benefits under title II of the Social Security Act; and
- For whom the Social Security Administration (SSA) can determine the current mailing address.

#### CATEGORIES OF RECORDS IN THE SYSTEM:

This system contains the following information about each individual:

- Name;
- SSN;
- Address to which the PEBES was mailed;
- Date of birth;
- Sex;
- Disposition code (to indicate earnings discrepancy or refusal);

- Date of SIPEBES issuance;
- Whether the PEBES was issued at the individual's request or SSA's initiative;
- Primary language (English or Spanish);
- Address source (IRS, the individual, or other);
- IRARN-CD (a code reserved for future use);
- PROC-CD (a code reserved for future use).

#### AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

Sections 205(a), 205(c)(2), and 1143 of the Social Security Act (42 U.S.C. 405(a), 405(c)(2), and 1320b-13); the Federal Records Act of 1950 (64 Stat. 583), as amended.

#### PURPOSES:

This system is used for the following purposes:

- To establish and retrieve specific records for PEBES processing;
- To identify whether or when a person has previously received an SIPEBES;
- To help SSA respond to PEBES inquiries; and
- To conduct statistical studies.

#### ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

Disclosure may be made for routine uses as indicated below:

1. Information may be disclosed to contractors and other Federal agencies, as necessary, to assist SSA in the efficient administration of its programs. We contemplate disclosing information under this routine use only in situations in which SSA may enter a contractual or similar agreement with a third party to assist in accomplishing an agency function relating to this system of records.

Wage and other information which is subject to the disclosure provisions of the Internal Revenue Code (IRC, 26 U.S.C. 6103) will not be disclosed under this routine use unless disclosure is expressly permitted by the IRC.

2. Information may be disclosed to a congressional office in response to an inquiry from the congressional office made at the request of the subject of the record.

Wage and other information which is subject to the disclosure provisions of the Internal Revenue Code (IRC, 26 U.S.C. 6103) will not be disclosed under this routine use unless disclosure is expressly permitted by the IRC.

3. To the Department of Justice (DOJ), a court, or other tribunal, or another party before such tribunal, when:

- (1) SSA, or any component thereof; or

(2) Any SSA employee in his/her official capacity; or

(3) Any SSA employee in his/her individual capacity when DOJ (or SSA, when it is authorized to do so) has agreed to represent the employee; or

(4) The United States or any agency thereof when SSA determines that the litigation is likely to affect the operations of SSA or any of its components,

is a party to litigation or has an interest in such litigation, and SSA determines that the use of such records by DOJ, the court or other tribunal, or the other party before the tribunal is relevant and necessary to the litigation, provided, however, that in each case SSA determines that such disclosure is compatible with the purposes for which the records were collected.

Wage and other information which is subject to the disclosure provisions of the Internal Revenue Code (IRC, 26 U.S.C. 6103) will not be disclosed under this routine use unless disclosure is expressly permitted by the IRC.

4. Information may be disclosed to the Office of the President for responding to an individual pursuant to an inquiry received from that individual or from a third party on his or her behalf.

Wage and other information which is subject to the disclosure provisions of the Internal Revenue Code (IRC, 26 U.S.C. 6103) will not be disclosed under this routine use unless disclosure is expressly permitted by the IRC.

5. Nontax return information, the disclosure of which is not expressly restricted by Federal law, may be disclosed to the General Services Administration and the National Archives and Records Administration under 44 U.S.C. 2904 and 2906, as amended by the National Archives and Records Administration Act of 1984, for the use of those agencies in conducting records management studies.

Wage and other information which is subject to the disclosure provisions of the Internal Revenue Code (IRC, 26 U.S.C. 6103) will not be disclosed under this routine use unless disclosure is expressly permitted by the IRC.

6. Information may be disclosed to the Internal Revenue Service (IRS) for auditing SSA's compliance with the safeguard provisions of the Internal Revenue Code of 1986, as amended.

**POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, AND DISPOSING OF RECORDS IN THE SYSTEM:**

**STORAGE:**

Records may be stored in magnetic media (e.g., magnetic tape and disc), microfilm, or paper.

**RETRIEVABILITY:**

Data will be retrieved from the system by SSN and name.

**SAFEGUARDS:**

Safeguards for automated records have been established in accordance with the Department of Health and Human Services (HHS) Information Resources Management Manual, Part 6, Automated Information Systems Security Program Handbook. This includes maintaining the magnetic tapes and discs within an enclosure attended by security guards. Anyone entering or leaving this enclosure must have a special badge issued only to authorized personnel.

For computerized records electronically transmitted between Central Office and Field Office locations (including organizations administering SSA programs under contractual agreements), safeguards include a lock/unlock password system, exclusive use of leased telephone lines, a terminal-oriented transaction matrix, and an audit trail. All microfilm and paper files are accessible only by authorized personnel who have a need for the information in performing their official duties.

SSA's terminals are equipped with physical key locks. The terminals are also fitted with adapters to permit the future installation of data encryption devices and devices to permit the identification of terminal users.

Contractors will safeguard information disclosed to them consistent with the requirements of the Privacy Act.

**RETENTION AND DISPOSAL:**

All tapes, discs, and microfilm files are updated periodically. Out-of-date magnetic tapes and discs are erased. Out-of-date microfilm is shredded.

SSA retains correspondence one year when it concerns documents returned to an individual, denials of confidential information, release of confidential information to an authorized third party, and undeliverable material; for four years when it concerns information and evidence pertaining to coverage, wage, and self-employment determinations or when it affects future coverage, wage, and self-employment determinations. Correspondence is destroyed, when appropriate, by shredding. Magnetic media records are maintained indefinitely.

**SYSTEM MANAGER(S) AND ADDRESS:**

Director, Office of Pre-Claims Requirements, Office of Systems Requirements, Social Security

Administration, 6401 Security Boulevard, Baltimore, MD 21235.

**NOTIFICATION PROCEDURE:**

An individual can determine if this system contains a record pertaining to him/her by providing his/her name, signature, and SSN, or, if the SSN is not known, name, signature, date and place of birth, mother's birth name, and father's name to the address shown above under "System manager" and by referring to this system. (Furnishing the SSN is voluntary, but it will enable an easier and faster search for an individual's record.)

An individual requesting notification of records in person need not furnish any special documents of identity. Documents which one would normally carry on one's person are sufficient (e.g., credit cards, driver's license, or voter registration card). An individual requesting notification via mail or telephone must furnish a minimum of his/her name, date of birth, and address in order to establish identity, plus any additional information which may be requested. These procedures conform with HHS Regulations, 45 CFR part 5b.

**RECORD ACCESS PROCEDURES:**

Same as notification procedures. Also, requesters should reasonably identify the record contents they are seeking. These procedures conform with HHS Regulations, 45 CFR part 5b.

**CONTESTING RECORD PROCEDURES:**

Same as notification procedures. Also, requesters should reasonably identify the record, specify the information they are contesting and state the corrective action sought and the reasons for the correction with supporting justification. These procedures conform with HHS Regulations, 45 CFR part 5b.

**RECORD SOURCE CATEGORIES:**

Information in this system is obtained from the Numident File of the SSA system of records entitled "Master File of Social Security Number Holders, HHS/SSA/OSR (09-60-0058)"; and from the IRS.

**SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:**

None.

09-60-0225

**SYSTEM NAME:**

SSA-Initiated Personal Earnings and Benefit Estimate Statement Address System for Certain Territories. HHS/SSA/OSR.

**SECURITY CLASSIFICATION:**

None.

**SYSTEM LOCATION:**

Social Security Administration, Office of Systems, 6401 Security Boulevard, Baltimore, MD 21235.

Records may also be located at contractor sites. Contact the system manager at the address below for contractor addresses.

**CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:**

Any person:

- Who lives in Guam, Puerto Rico, or the United States Virgin Islands,
- Who has reached age 25,
- Who has had earnings posted to his/her SSN,
- Who is not receiving benefits under Title II of the Social Security Act, and
- From whom SSA can determine the current mailing address.

**CATEGORIES OF RECORDS IN THE SYSTEM:**

This system contains the following information about each individual:

- Name;
- Sex;
- SSN;
- Address;
- Whether a PEBES was issued at the individual's request or SSA's initiative;
- A country name code.

**AUTHORITY FOR MAINTENANCE OF THE SYSTEM:**

Sections 205(a), 205(c)(2), and 1143 of the Social Security Act (42 U.S.C. 405(a), 405(c)(2), and 1320b-13); the Federal Records Act of 1950 (64 Stat. 583).

**PURPOSES:**

The system is used for the following purposes:

- To establish and retrieve specific records for PEBES processing for individuals living in the specified areas;
- To help SSA respond to PEBES inquiries; and
- To conduct statistical studies.

**ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:**

Disclosure may be made from routine uses as indicated below:

1. Information may be disclosed to contractors and other Federal agencies, as necessary, to assist SSA in the efficient administration of its programs. We contemplate disclosing information under this routine use only in situations in which SSA may enter a contractual or similar agreement with a third party to assist in accomplishing an agency function relating to this system of records.

2. Information may be disclosed to a congressional office in response to an inquiry from the congressional office made at the request of the subject of the record.

3. Information may be disclosed to the Department of Justice (DOJ), a court, or other tribunal, or another party before such tribunal, when:

- (1) SSA, or any component thereof; or
- (2) Any SSA employee in his/her official capacity; or
- (3) Any SSA employee in his/her individual capacity when DOJ (or SSA, when it is authorized to do so) has agreed to represent the employee; or
- (4) The United States or any agency thereof when SSA determines that the litigation is likely to affect the operation of SSA or any of its components.

is a party to litigation or has an interest in such litigation, and SSA determines that the use of such records by DOJ, the court or other tribunal, or the other party before the tribunal is relevant and necessary to the litigation, provided, however, that in each case SSA determines that such disclosure is compatible with the purposes for which the records were collected.

4. Information may be disclosed to the Office of the President for responding to an individual pursuant to an inquiry received from that individual or from a third party on his or her behalf.

5. Nontax return information, the disclosure of which is not expressly restricted by Federal law, may be disclosed to the General Services Administration and the National Archives and Records Administration under 44 U.S.C. 2904 and 2906, as amended by the National Archives and Records Administration Act of 1984, for the use of those agencies in conducting records management studies.

**POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, AND DISPOSING OF RECORDS IN THE SYSTEM:****STORAGE:**

Records will be stored in magnetic media (e.g., magnetic tape and disc).

**RETRIEVABILITY:**

Data will be retrieved from the system by SSN, name, and date of issuance of the PEBES.

**SAFEGUARDS:**

Safeguards for automated records have been established in accordance with the Department of Health and Human Services (HHS) Information Resources Management Manual, Part 6, Automated Information Systems Security Program Handbook. This includes maintaining the magnetic tapes and discs within an enclosure attended by security guards, Anyone entering or leaving this enclosure must have a special badge issued only to authorized personnel.

For computerized records electronically transmitted between

Central Office and Field Office locations (including organizations administering SSA programs under contractual agreements), safeguards include a lock/unlock password system, exclusive use of leased telephone lines, a terminal-oriented transaction matrix, and an audit trail. All microfilm and paper files are accessible only by authorized personnel who have a need for the information in performing their official duties.

SSA's terminals are equipped with physical key locks. The terminals are also fitted with adapters to permit the future installation of data encryption devices and devices to permit the identification of terminal users.

**RETENTION AND DISPOSAL:**

All tapes, discs, and microfilm files are updated periodically. Out-of-date magnetic tapes and discs are erased. Out-of-date microfilm is shredded.

SSA retains correspondence one year when it concerns documents returned to an individual, denials of confidential information, release of confidential information to an authorized third party, and undeliverable material; for four years when it concerns information and evidence pertaining to coverage, wage, and self-employment determinations or when it affects future claims development, especially coverage, wage, and self-employment determinations. Correspondence is destroyed, when appropriate, by shredding. Magnetic media records are maintained indefinitely.

**SYSTEM MANAGERS(S) AND ADDRESS:**

Director, Office of Pre-Claims Requirements, Office of Systems Requirements, Social Security Administration, 6401 Security Boulevard, Baltimore, MD 21235.

**NOTIFICATION PROCEDURE:**

An individual can determine if this system contains a record pertaining to him/her by providing his/her name, signature, and SSN, or, if the SSN is not known, name, signature, date and place of birth, mother's birth name, and father's name to the address shown above under "System manager" and by referring to this system. (Furnishing the SSN is voluntary, but it will enable an easier and faster search for an individual's record.)

An individual requesting notification of records in person need not furnish any special documents of identity. Documents which one would normally carry on one's person are sufficient (e.g., credit cards, driver's license, or voter registration card). An individual requesting notification via mail or

telephone must furnish a minimum of his/her name, date of birth, and address in order to establish identity, plus any additional information which may be requested. These procedures conform with HHS Regulations, 45 CFR Part 5b.

**RECORD ACCESS PROCEDURES:**

Same as notification procedures. Also, requesters should reasonably identify the record contents they are seeking. These procedures conform with HHS Regulations, 45 CFR Part 5b.

**CONTESTING RECORD PROCEDURES:**

Same as notification procedures. Also, requesters should reasonably identify the record, specify the information they are contesting and state the corrective action sought and the reasons for the correction with supporting justification. These procedures conform with HHS Regulations, 45 CFR part 5b.

**RECORD SOURCE CATEGORIES:**

Information in this system is obtained from the Commonwealth of Puerto Rico and the Territories of Guam and the United States Virgin Islands.

**SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:**

None.

[FR Doc. 94-26627 Filed 10-26-94; 8:45 am]

BILLING CODE 4190-29-M

**DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT**

**Government National Mortgage Association**

[Docket No. R-94-1698; FR-3555-N-06]

**Government National Mortgage Association; Multiclass Securities Program; Announcement of OMB Control Number**

AGENCY: Government National Mortgage Association, HUD.

ACTION: Supplemental Notice for GNMA Multiclass Securities Program; Announcement of OMB control number.

**SUMMARY:** On September 30, 1994 (59 FR 50148), the Department published in the *Federal Register*, a Supplemental Notice for GNMA Multiclass Securities Program, in which it referred to a Notice published in the *Federal Register* on May 26, 1994 (59 FR 27290), which implemented a new program under which GNMA would guarantee multiclass mortgage-backed securities. The May 26, 1994 Notice provided for implementation in two stages, the initial stage and the full participation stage. The program is intended to benefit

borrowers using federally insured or guaranteed mortgages by increasing investment demand for GNMA guaranteed mortgage-backed securities ("MBS") that are backed by these mortgages, thus reducing financing costs for these mortgages; and raise revenues through the receipt of guarantee and other fees by GNMA.

The September 30, 1994 Notice and a Notice of Proposed Information Collection Requirements to OMB, published on September 28, 1994 (59 FR 49410), identified that this program under which GNMA would guarantee multiclass mortgage-backed securities, contained information collection requirements, but that no person would be subjected to a penalty for failure to comply with these information collection requirements until they had been approved and assigned an OMB control number.

The purpose of this document is to announce the OMB control number for the GNMA Multiclass Securities Program.

**DATES:** Approved: October 3, 1994, for use through May 31, 1995.

**FOR FURTHER INFORMATION CONTACT:** Guy S. Wilson, Vice President, Government National Mortgage Association, Room 6151, 451 Seventh Street, S.W., Washington, D.C. 20410-9000, telephone (202) 401-8970. Hearing or speech-impaired individuals may call HUD's TDD number (202) 708-3649. (These telephone numbers are not toll-free.)

**SUPPLEMENTARY INFORMATION:**

Accordingly, the OMB control number for the Government National Mortgage Association; Multiclass Securities Program; Notice of Proposed Information Collection Requirements to OMB Notice published September 28, 1994 (59 FR 49410), and for the Supplemental Notice for the Government National Mortgage Association Guaranteed Multiclass Securities, published September 30, 1994 (59 FR 50148), is 2503-0030.

Dated: October 24, 1994.

**Camille E. Acevedo,**

*Assistant General Counsel for Regulations.*

[FR Doc. 94-26616 Filed 10-26-94; 8:45 am]

BILLING CODE 4210-01-P

**DEPARTMENT OF THE INTERIOR**

**Bureau of Land Management**

[NM-932-1310-01; TXNM 89085]

**Proposed Reinstatement of Terminated Oil and Gas Lease; New Mexico**

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice.

**SUMMARY:** Under the provisions of Public Law 97-451, a petition for reinstatement of Oil and Gas Lease TXNM 89085, Sabine County, Texas, was timely filed and was accompanied by all required rentals and royalties accruing from June 1, 1994, the date of the termination. No valid lease has been issued affecting the land. The lessee has agreed to new lease terms for rentals and royalties at rates of \$10.00 per acre, or fraction thereof, and 16 $\frac{2}{3}$  percent, respectively. Payment of a \$500.00 administrative fee has been made. Having met all the requirements for reinstatement of the lease as set in Section 31(d) and (e) of the Mineral Leasing Act of 1920, as amended (30 U.S.C. 188(d) and (e)), the Bureau of Land Management is proposing to reinstate the lease effective June 1, 1994, subject to the original terms and conditions of the lease and the increased rental and royalty rates cited above, and the reimbursement for cost of publication of this Notice.

**FOR FURTHER INFORMATION CONTACT:** Angela Trujillo, BLM, New Mexico State Office, (505) 438-7592.

Dated: October 20, 1994.

Angela Trujillo,

*Chief, Lease Maintenance Unit.*

[FR Doc. 94-26629 Filed 10-26-94; 8:45 am]

BILLING CODE 4310-FB-M

[AZ-942-05-1420-00]

**Arizona; Notice of Filing of Plats of Survey**

October 17, 1994.

1. The plats of survey of the following described lands were officially filed in the Arizona State Office, Phoenix, Arizona, on the dates indicated:

A plat representing the dependent resurvey of a portion of the north boundary and a portion of the subdivisional lines; and the subdivision of section 2, and the metes-and-bounds survey in section 2, Township 10 North, Range 10 East, Gila and Salt River Meridian, Arizona, was accepted August 30, 1994, and was officially filed September 1, 1994.

This plat was prepared, at the request of Eastern Arizona College, to facilitate a land exchange.

A plat, in 3 sheets, representing the dependent resurvey of a portion of the east boundary and a portion of the subdivisional lines; and the subdivision of certain sections, and metes-and-bounds surveys in Township 20 North, Range 26 East, Gila and Salt River Meridian, Arizona, was accepted July 5, 1994, and was officially filed July 14, 1994.

This plat was prepared at the request of the Navajo and Hopi Indian Relocation Committee.

A plat, in 4 sheets, representing the dependent resurvey of portions of the north boundary (First Standard Parallel North), east boundary and subdivisional lines; and the completion survey of a portion of the subdivisional lines and the survey of the subdivision of section 16, Township 5 North, Range 10 West, Navajo Special Meridian, Arizona, was accepted August 16, 1994, and was officially filed August 15, 1994.

This plat was prepared at the request of the Bureau of Indian Affairs, Navajo Area Office.

A plat representing the dependent resurvey of a portion of the subdivisional lines; and a metes-and-bounds survey of Parcel A in sections 23 and 24, Township 13 South, Range 19 East, Gila and Salt River Meridian, Arizona, was accepted August 2, 1994, and was officially filed August 11, 1994.

This plat was prepared at the request of the Bureau of Land Management, San Pedro Project Office, Safford District.

A plat representing the dependent resurvey of a portion of the subdivisional lines; and the subdivision of section 8, and a metes-and-bounds survey in section 8, Township 21 North, Range 18 West, Gila and Salt River Meridian, Arizona, was accepted August 22, 1994, and was officially filed August 25, 1994.

This plat was prepared at the request of the Bureau of Land Management, Kingman Resource Area.

A plat representing the dependent resurvey of Mineral Survey Numbers 694 and 695 in Township 13 North, Range 1 West, Gila and Salt River Meridian, Arizona, was accepted September 19, 1994, and was officially filed September 22, 1994.

This plat was prepared at the request of the United States Forest Service, Prescott National Forest.

2. These plats will immediately become the basic records for describing the land for all authorized purposes. These plats have been placed in the open files and are available to the public for information only.

3. All inquiries relating to these lands should be sent to the Arizona State Office, Bureau of Land Management, P.O. Box 16563, Phoenix, Arizona 85011.

James P. Kelley,

Chief Cadastral, Surveyor of Arizona.

[FR Doc. 94-26574 Filed 10-26-94; 8:45 am]

BILLING CODE 4310-32-M

[OR-943-1430-01; GP5-006; OR 51332]

### Proposed Withdrawal and Opportunity for Public Meeting; Oregon

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice.

**SUMMARY:** The U.S. Department of Agriculture, Forest Service, proposes to withdraw 86.85 acres of National Forest System land to protect the cultural resource sites at Wocas Point in the Winema National Forest. This notice closes the land for up to two years from mining. The land will remain open to mineral leasing.

**DATES:** Comments and requests for a public meeting must be received by January 25, 1995.

**ADDRESSES:** Comments and meeting requests should be sent to the Oregon/Washington State Director, BLM, P.O. Box 2965, Portland, Oregon 97208-2965.

**FOR FURTHER INFORMATION CONTACT:** Donna Kauffman, BLM Oregon/Washington State Office, 503-280-7162.

**SUPPLEMENTARY INFORMATION:** On September 30, 1994, the U.S. Department of Agriculture, Forest Service, filed an application to withdraw the following described National Forest System land from location and entry under the United States mining laws (30 U.S.C. Ch. 2), but not the mineral leasing laws, subject to valid existing rights:

#### Willamette Meridian

##### Winema National Forest

T. 31 S., R. 9 E.,

Sec. 30, lots 2 and 3, and N $\frac{1}{2}$ NE $\frac{1}{4}$ SW $\frac{1}{4}$ .

The area described contains 86.85 acres in Klamath County.

The purpose of the proposed withdrawal is to protect the cultural resource sites at Wocas Point.

For a period of 90 days from the date of publication of this notice, all persons who wish to submit comments, suggestions, or objections in connection with the proposed withdrawal may present their views in writing to the State Director at the address indicated above.

Notice is hereby given that an opportunity for a public meeting is afforded in connection with the proposed withdrawal. All interested parties who desire a public meeting for the purpose of being heard on the proposed withdrawal must submit a written request to the State Director at the address indicated above within 90 days from the date of publication of this notice. Upon determination by the authorized officer that a public meeting will be held, a notice of the time and place will be published in the *Federal Register* at least 30 days before the scheduled date of the meeting.

The application will be processed in accordance with the regulations set forth in 43 CFR part 2300.

For a period of two years from the date of publication of this notice in the *Federal Register*, the land will be segregated as specified above unless the application is denied or canceled or the withdrawal is approved prior to that date. The temporary uses which may be permitted during this segregative period are other National Forest management activities, including permits, licenses, and cooperative agreements, that are compatible with the intended use under the discretion of the authorized officer.

Dated: October 19, 1994.

Robert D. DeViney, Jr.,

Acting Chief, Branch of Lands and Minerals Operations.

[FR Doc. 94-26619 Filed 10-26-94; 8:45 am]

BILLING CODE 4310-33-P

### INTERSTATE COMMERCE COMMISSION

[Finance Docket No. 32601]

#### South Central Florida Express, Inc.—Trackage Rights Exemption—Florida East Coast Railway Company

South Central Florida Express, Inc., (SCFE) has filed a verified notice under 49 CFR 1180.2(d)(7) to acquire local trackage rights from Florida East Coast Railway Company (FEC) over the 20.6-mile segment of FEC's Fort Pierce-Lake Harbor Branch between milepost K-49.8, at Canal Point, FL, and the end of the line near milepost K-70.4, the interchange point with SCFE at Lake Harbor, FL. The transaction was to have been consummated on October 24, 1994.

As a condition to this exemption, any employees adversely affected by the trackage rights will be protected under *Norfolk and Western Ry. Co.—Trackage Rights—BN, 354 I.C.C. 605 (1978)*, as modified in *Mendocino Coast Ry., Inc.—Lease and Operate, 360 I.C.C. 653 (1980)*.

If the verified notice contains false or misleading information, the exemption is void *ab initio*. Petitions to reopen the proceeding to revoke the exemption under 49 U.S.C. 10505(d) may be filed at any time. The filing of a petition to reopen will not stay the exemption's effectiveness. An original and 10 copies of all pleadings, referring to Finance Docket No. 32601, must be filed with the Office of the Secretary, Case Control Branch, Interstate Commerce Commission, Washington, DC 20423. In addition, a copy of each pleading must be served on Mark H. Sidman, WEINER, BRODSKY, SIDMAN & KIDER, P.C., 1350 New York Ave., NW., Suite 800, Washington, DC 20005.

Decided: October 21, 1994.

By the Commission, David M. Konschnik, Director, Office of Proceedings.

Vernon A. Williams,

Acting Secretary.

[FR Doc. 94-26623 Filed 10-26-94; 8:45 am]

BILLING CODE 7035-01-P

## DEPARTMENT OF JUSTICE

### Antitrust Division

#### Notice Pursuant to the National Cooperative Research and Production Act of 1993—Corporation for Open Systems International

Notice is hereby given that, on June 13, 1994, pursuant to Section 6(a) of the National Cooperative Research and Production Act of 1993, 15 U.S.C. 4301 *et seq.* ("the Act"), the Corporation for Open Systems International ("COS") has filed written notifications simultaneously with the Attorney General and the Federal Trade Commission disclosing certain information. The notifications were filed for the purpose of extending the Act's provisions limiting the recovery of antitrust plaintiffs to actual damages under specified circumstances. Specifically, the changes are as follows: (1) JP Morgan ceased membership in COS effective June 1, 1994; (2) COS was advised that the name of the National Bureau of Standards, a member of COS, was changed to National Institute of Standards and Technology; (3) COS has established the SONET Interoperability Forum (the "Forum") to conduct research regarding bandwidth and network management interoperability of products implementing SONET (Synchronous Optical Network), an international specification for bandwidth and network management; (4) The following organizations became Associates of the Forum on the dates indicated: ADC Telecommunications,

Inc., Richardson, TX, on March 16, 1994; Applied Innovation, Inc., Columbus, OH, on March 22, 1994; DSC Communications, Petaluma, CA, on June 13, 1994; Fujitsu NTS, Transmission Systems Division, Richardson, TX, on April 21, 1994; NEC America, Inc., Herndon, VA, on March 24, 1994; Newbridge Networks, Inc., Herndon, VA, on April 21, 1994; Sprint Corporation, Westwood, KS, on April 6, 1994; SWL Inc., Telecommunications Division, Columbia, MD, on April 21, 1994; and Tellabs Operations, Inc., Lisle, IL, on April 21, 1994; (5) The following organizations became Auditing Members of the Forum on the dates indicated: ANDO Corporation, Rockville, MD, on April 1, 1994; MARBEN Products, Inc., Los Gatos, CA, on May 2, 1994; Open Con Systems, Inc., Piscataway, NJ, on April 21, 1994; and Pulse Communications, Inc., Herndon, VA, on May 31, 1994; (6) FTT Consultants, Inc., Roswell, GA, became a participant in the COS X.500 Integration Pilot Project on May 25, 1994; (7) The ISDN Executive Council (the "Council") has established the ISDN Solutions '94 project. ISDN Solutions '94 involves research regarding and the development of simplified procedures for ordering and providing ISDN network services, including documentation of switch translations for equipment implementing the National ISDN-1 specification, as well as promotion of the benefits of ISDN technology. The following organizations became Patrons of ISDN Solutions '94 on the dates indicated: Adtran, Huntsville, AL, on April 29, 1994; Cincinnati Bell Telephone, Cincinnati, OH, on April 29, 1994; Controlware Communications Systems, Inc., Neptune, NJ, on April 26, 1994; Fujitsu Network Switching, Raleigh, NC, on April 29, 1994; Gandalf, Nepean, Ontario, CANADA, on April 12, 1994; and TELES GmbH, Berlin, GERMANY, on June 6, 1994.

No other changes have been made in either the membership or planned activities of COS. Membership in COS remains open, and COS intends to file additional written notifications disclosing all changes in membership.

On May 14, 1986, COS filed its original notification pursuant to Section 6(a) of the Act. The Department of Justice published a notice in the **Federal Register** pursuant to Section 6(b) of the Act on June 11, 1986, (51 FR 21260).

The last notification was filed with the Department on March 31, 1994. A notice was published in the **Federal**

**Register** pursuant to Section 6(b) of the Act on April 28, 1994 (59 FR 21999).

**Constance K. Robinson,**

*Director of Operations, Antitrust Division.*

[FR Doc. 94-26634 Filed 10-26-94; 8:45 am]

BILLING CODE 4410-01-M

#### Notice Pursuant to the National Cooperative Research and Production Act of 1993—the Precision Laser Machining Technology Reinvestment Project

Notice is hereby given that, on August 24, 1994, pursuant to Section 6(a) of the National Cooperative Research and Production Act of 1993, 15 U.S.C. 4301 *et seq.* ("the Act"), TRW Inc., on behalf of members of the Precision Machining Technology Reinvestment Project ("PLM TRP"), filed notifications simultaneously with the Attorney General and the Federal Trade Commission disclosing (1) the identities of the parties to and (2) the nature and objectives of the project. The notifications were filed for the purpose of invoking the Act's provisions limiting the recovery of antitrust plaintiffs to actual damages under specified circumstances. Pursuant to Section 6(b) of the Act, the identities of the parties are: TRW Inc., Redondo Beach, CA; The Boeing Company, Seattle, WA; Caterpillar Inc., Mossville, IL; Cummins Engine Company, Inc., Columbus, IN; Edison Welding Institute, Columbus, OH; Fibertek, Inc., Herndon, VA; General Electric Aircraft Engines, Cincinnati, OH; General Electric CRD, Schenectady, NY; Hughes Aircraft Company, Malibu, CA; the University of Illinois, Champaign, IL; Newport News Shipbuilding, Newport News, VA; Northrup Corporation, Electronics Systems Division, Hawthorne, CA; Penn State University, State College, PA; Process Equipment Company, Tipp City, OH; SDL, Inc., San Jose, CA; United Technologies Corporation, East Hartford, CT; and Utilase Systems, Inc., Detroit, MI. The objective of PLM TRP is to provide the most advanced and affordable US military systems, and the most competitive commercial products in the global marketplace for the automotive, aerospace (platforms and propulsion systems), heavy equipment, and shipbuilding industries through a new generation of laser machine tools and advanced laser manufacturing processes. To accomplish this objective, a consortium of industrial laser users, process developers, system integrators, and technology developers has been established forming a fully integrated team. This will avoid inefficient duplication of effort and expense while

performing research in this area, collection, exchange and, where appropriate, dissemination of the research results, to work closely with various governmental and private agencies and perform further acts allowed by the Act that would advance the PLM TRP's objectives.

Membership in PLM TRP remains open, and TRW intends to file additional written notifications disclosing all changes in membership.

Information regarding participation in the project may be obtained from: Dr. Leonard J. Marabella, Bldg. R1/1196, One Space Park, Redondo Beach, CA 90278.

Constance K. Robinson,  
Director of Operations, Antitrust Division.  
[FR Doc. 94-26633 Filed 10-26-94; 8:45 am]  
BILLING CODE 4410-01-M

#### Notice Pursuant to the National Cooperative Research and Production Act of 1993; Spinal Implant Manufacturers Group

Notice is hereby given that, on August 31, 1994, pursuant to Section 6(a) of the National Cooperative Research and Production Act of 1993, 15 U.S.C. 4301 et seq. ("the Act"), the Spinal Implant Manufacturers Group ("SIMG") has filed written notifications simultaneously with the Attorney General and the Federal Trade Commission disclosing changes in its membership. The notifications were filed for the purpose of extending the Act's provisions limiting the recovery of antitrust plaintiffs to actual damages under specified circumstances. Specifically, DePuy Motech, Warsaw, IN has been added as a member. AMS and Aesculap have resigned as members. Stryker Instruments is now being represented by one of its subsidiaries, Stryker/Osteonics, Allendale, NJ.

No other changes have been made in either the membership or planned activity of the group research project. Membership in this group research project remains open, and SIMG intends to file additional written notification disclosing all changes in membership.

On December 8, 1993, SIMG filed its original notification pursuant to Section 6(a) of the Act. The Department of Justice published a notice in the Federal Register pursuant to Section 6(b) of the Act on January 14, 1994 (59 FR 2439).

Constance K. Robinson,  
Director of Operations, Antitrust Division.  
[FR Doc. 94-26632 Filed 10-26-94; 8:45 am]  
BILLING CODE 4410-01-M

#### NATIONAL SCIENCE FOUNDATION

##### Meeting of Global Learning and Observations To Benefit the Environment (GLOBE)

Global Learning and Observations to Benefit the Environment (GLOBE): Announcement of Opportunity for Science/Education Teams. POC Contact Technical Representative: Barrett Rock, 202-395-7600. The Government is interested in receiving proposals that address the development of services and materials to support scientific measurements, environmental education, teacher training, and program evaluation as part of the GLOBE Program. The GLOBE Program is an international education and science program that will involve students all over the Earth in measuring their local environment and creating a global set of data to be shared via the Internet that will be used to create global environmental images for the students and by environmental scientists. GLOBE is driven in part by the measurement needs of scientists and will be structured to teach students about the Earth's environment, thereby generating increased interest in science and awareness of the changing global environment. A public briefing will be held from 10:00 to 12:00 on November 3, 1994, in the Auditorium of the Department of Commerce, which is entered on 14th St. between Constitution Ave. and E St. in Washington, DC. Organizations planning to attend should provide a list of attendees, limit two per organization, to John Schmidt, 202-395-7600, FAX 202-395-7611. The Program Announcement, which contains a detailed description of the competition, will be released on or about October 28, 1994; deadline for receipt of proposals is December 15, 1994. Any award is subject to availability of funds. Proposals will be evaluated by a peer review panel, which will meet in January, 1995. Written requests for copies of the announcement should be directed to Dr. Barrett Rock. The GLOBE Program, 744 Jackson Place, NW., Washington, DC 20503. For information on how to obtain the Program Announcement electronically from the National Science Foundation, contact: [stis@nsf.gov](mailto:stis@nsf.gov) (Internet), 703-306-0214 (voice mail), or 703-306-0090 (TDD). All proposals submitted by responsible sources will be considered.

Dated: October 24, 1994.

Michael Mayhew,  
Program Director for Geophysics.  
[FR Doc. 94-26651 Filed 10-26-94; 8:45 am]  
BILLING CODE 7555-01-M

##### Special Emphasis Panel in Geosciences; Notice of Meeting

In accordance with the Federal Advisory Committee Act (Pub. L. 92-463, as amended), the National Science Foundation announces the following meeting:

*Name:* Special Emphasis Panel in Geosciences (#1756).  
*Date and Time:* November 14, 1994; 8:30 a.m. to 5:00 p.m.  
*Place:* Room 118, St James Hotel, 950 24th St. NW., Washington, DC 20037.  
*Type of Meeting:* Closed.  
*Contact Person:* Dr. Joan R. Mitchell, OCE Room 725, National Science Foundation, 4201 Wilson Blvd., Arlington, VA 22230. Telephone: (703) 306-1560.

*Purpose of Meeting:* To provide advice and recommendations concerning proposal submitted to NSF for financial support.

*Agenda:* To review and evaluate OCE's Research Experiences for Undergraduate (REU) proposals as part of the selection process for awards.

*Reasons for Closing:* The proposals being reviewed include information of a proprietary or confidential nature, including technical information; financial data, such as salaries; and personal information concerning individuals associated with the proposals. These matters are exempt under 5 U.S.C. 552(b)(3), (4) and (6) of the Government in the Sunshine Act.

Dated: October 24, 1994.

M. Rebecca Winkler,  
Committee Management Officer.  
[FR Doc. 94-26654 Filed 10-26-94; 8:45 am]  
BILLING CODE 7555-01-M

##### Special Emphasis Panel in Human Resource Development; Notice of Meeting

In accordance with the Federal Advisory Committee Act (Pub. L. 92-463, as amended), the National Science Foundation announces the following meeting:

*Name:* Special Emphasis Panel in Human Resources Development (#1199).  
*Date and Time:* November 17 & 18, 1994—8:30 am—5:00 pm.  
*Place:* National Science Foundation, 4201 Wilson Blvd, Arlington, VA.  
*Type of Meeting:* Closed.  
*Contact Person:* Lawrence Scadden & Mary Kohlerman, National Science Foundation, 4201 Wilson Blvd., Arlington, VA 22230. Telephone: (703) 306-1636.

*Purpose of Meeting:* To provide advice and recommendations concerning proposals submitted to NSF for financial support.

**Agenda:** To review and evaluate Programs for Persons with Disabilities proposals as part of the selection process for awards.

**Reason for Closing:** The proposals being reviewed include information of a proprietary or confidential nature, including technical information; financial data, such as salaries; and personal information concerning individuals associated with the proposals. These matters are exempt under 5 U.S.C. 552(b)(c), and (4) and (6) of the Government in the Sunshine Act.

Dated: October 24, 1994.

**M. Rebecca Winkler,**

*Committee Management Officer.*

[FR Doc. 94-26655 Filed 10-26-94; 8:45 am]

BILLING CODE 7555-01-M

### Advisory Panel for Instrumentation and Instrument Development; Notice of Meeting

In accordance with the Federal Advisory Committee Act (Pub. L. 92-463, as amended), the National Science Foundation announces the following meeting:

**Name:** Advisory Panel for Instrumentation and Instrument Development (#1215).

**Date and Time:** November 17-18, 1994.

**Place:** Georgetown Suite, 1111 30th, NW., Washington, DC.

**Type of Meeting:** Closed.

**Contact Person:** Dr. Michael Lamvik and Dr. John Cross, Program Director, Instrumentation and Instrument Development, Room 615, National Science Foundation, 4201 Wilson Boulevard, Arlington, VA 22230. Telephone: (703) 306-1472.

**Agenda:** To review and evaluate Instrumentation and Instrument Development proposals as part of the selection process for awards.

**Reason for Closing:** The proposals being reviewed include information of a proprietary or confidential nature, including technical information; financial data, such as salaries and personal information concerning individuals associated with the proposals. These matters are exempt under 5 U.S.C. 552(b)(c) (4) and (6) of the Government in the Sunshine Act.

Dated: October 24, 1994.

**M. Rebecca Winkler,**

*Committee Management Officer.*

[FR Doc. 94-26656 Filed 10-26-94; 8:45 am]

BILLING CODE 7555-01-M

### Office of Polar Programs; Arctic Social Science Program; Notice of Meeting

In accordance with the Federal Advisory Committee Act (Pub. L. 92-463, as amended), the National Science Foundation announces the following meeting:

**Name:** Special Emphasis Panel in Polar Program (#1209).

**Date and Time:** November 21, 1994; 8:20 AM to 5:00 PM.

**Place:** Room 730, National Science Foundation, 4201 Wilson Boulevard, Arlington, VA.

**Type of Meeting:** Closed.

**Contact Person:** Dr. Noel Broadbent, National Science Foundation, 4201 Wilson Boulevard, Arlington, VA 22230. Telephone: (703) 306-1031.

**Purpose of Meeting:** To provide advice and recommendations concerning proposals submitted to NSF for financial support.

**Agenda:** To review and evaluate Arctic Social Science proposals as part of the selection process for awards.

**Reason for Closing:** The proposals being reviewed include information of a proprietary or confidential nature, including technical information; financial data, such as salaries; and personal information concerning individual associated with the proposals. These matters are exempt under 5 U.S.C. 552(b)(c), (4) and (6) of the Government in the Sunshine Act.

Dated: October 24, 1994.

**M. Rebecca Winkler,**

*Committee Management Officer.*

[FR Doc. 94-26657 Filed 10-26-94; 8:45 am]

BILLING CODE 7555-01-M

### Membership of National Science Foundation's Senior Executive Service Performance Review Board

**AGENCY:** National Science Foundation.

**ACTION:** Announcement of Membership of the National Science Foundation's Senior Executive Service Performance Review Board.

**SUMMARY:** This announcement of the membership of the National Science Foundation's Senior Executive Service Performance Review Board is made in compliance with 5 U.S.C. 4314(c)(4).

**ADDRESSES:** Comments should be addressed to Director, Division of Human Resource Management, National Science Foundation, Room 315, 4201 Wilson Boulevard, Arlington, VA 22230.

**FOR FURTHER INFORMATION CONTACT:** Mr. John F. Wilkinson, Jr. at the above address or (703) 306-1180.

**SUPPLEMENTARY INFORMATION:** The membership of the National Science Foundation's Senior Executive Service Performance Review Board is as follows:

Mary E. Clutter, Assistant Director for Biological Sciences, Chairperson  
William C. Harris, Assistant Director for Mathematical and Physical Sciences  
Joseph L. Kull, Chief Financial Officer  
Constance K. McLindon, Director, Office of Information and Resource Management  
Nathaniel G. Pitts, Director, Office of Science and Technology Infrastructure

Luther S. Williams, Assistant Director for Education and Human Resources

Dated: October 20, 1994.

**John F. Wilkinson, Jr.,**

*Director, Division of Human Resource Management.*

[FR Doc. 94-26652 Filed 10-26-94; 8:45 am]

BILLING CODE 7555-01-M

### Membership of National Science Foundation's Office of Inspector General Senior Executive Service Performance Review Board

**AGENCY:** National Science Foundation.

**ACTION:** Announcement of Membership of the National Science Foundation's Performance Review Board for Office of Inspector General Senior Executive Service positions.

**SUMMARY:** This announcement of the membership of the National Science Foundation's Office of Inspector General Senior Executive Service Performance Review Board is made in compliance with 5 U.S.C. 4314(c)(4).

**ADDRESSES:** Comments should be addressed to Director, Division of Human Resource Management, National Science Foundation, Room 315, 4201 Wilson Boulevard, Arlington, VA 22230.

**FOR FURTHER INFORMATION CONTACT:** Mr. John F. Wilkinson, Jr. at the above address or (703) 306-1180.

**SUPPLEMENTARY INFORMATION:** The membership of the National Science Foundation's Office of Inspector General Senior Executive Service Performance Review Board is as follows:

Richard N. Zare, Chairman, Audit and Oversight Committee, National Science Board, Chairperson  
Constance K. McLindon, Director, Office of Information and Resource Management, Executive Secretary  
William C. Harris, Assistant Director for Mathematical and Physical Sciences

Dated: October 21, 1994.

**John F. Wilkinson, Jr.,**

*Director, Division of Human Resource Management.*

[FR Doc. 94-26653 Filed 10-26-94; 8:45 am]

BILLING CODE 7555-01-M

### NUCLEAR REGULATORY COMMISSION

[Docket Nos. 50-317 and 50-318]

### Baltimore Gas and Electric Company; Environmental Assessment and Finding of No Significant Impact

The U.S. Nuclear Regulatory Commission (the Commission) is

considering issuance of an exemption from certain requirements of 10 CFR Part 50, Appendix A, General Criterion 2, "Design Bases For Protection Against Natural Phenomena," to Baltimore Gas and Electric Company (the licensee), for the Calvert Cliffs Nuclear Power Plant, Unit Nos. 1 and 2, located at the licensee's site in Calvert County, Maryland.

#### Environmental Assessment

##### Identification of Proposed Action

The proposed exemption would allow relief from General Design Criterion 2 (GDC-2) during the upgrading of the Unit 2 emergency diesel generator (EDG) No. 21. The proposed exemption will permit the temporary removal of a steel missile door which provides missile protection for the No. 21 EDG, which will be out-of-service to allow for modifications which will increase its load capacity, and also provides missile protection to portions of the support systems for EDGs Nos. 11 and 12. EDGs Nos. 11 and 12 are required to be operable to support the operation of Unit 1 (Modes 1, 2, or 3). In addition, EDG No. 12 is a swing EDG and is required to be operable for Unit 2 when the unit is shutdown or in refueling (Mode 5 or 6).

The upgrading of the Unit 2 EDG will be performed during the upcoming Unit 2 refueling outage (RFO-10). RFO-10 is scheduled to commence on March 17, 1995, and be completed in late May 1995. The steel missile door will be required to be removed about four times during the outage. The licensee estimates that each of the removals will last for about 24 hours, which will result in a total removal time of about 100 hours during the scheduled 65 day RFO-10.

##### Need for the Proposed Action

The proposed temporary exemption is needed to permit the completion of highly desirable upgrade to the Unit 2 EDG No. 21 without requiring a dual unit shutdown.

##### Environmental Impacts of the Proposed Action

The proposed exemption does not involve any measurable environmental impact during normal operation of Unit 1 or the shutdown/refueling of Unit 2 since the plant configuration is changed only minimally for short periods of time when the missile door will be removed and overall plant operation is not changed. The likelihood of tornado-generated or other high wind-generated missile damage during the time the exemption would be in effect and which

could affect equipment required to be operable to avoid radiological impact is low. Also, the licensee indicates that the missile door will be reinstalled whenever severe weather conditions arise. Thus, the proposed temporary exemption would not significantly affect the probability or consequences of potential reactor accidents and would not otherwise affect radiological plant effluents. Consequently, the Commission concludes that there are no significant radiological impacts associated with the proposed exemption.

With regard to potential nonradiological impacts, the proposed exemption involves features located entirely within the owner-controlled area defined in 10 CFR Part 20. The EDG upgrade project activities do not affect nonradiological plant effluents and has no other environmental impact. Therefore, the staff concludes that there are no significant nonradiological environmental impacts associated with the proposed exemption.

##### Alternatives to the Proposed Action

The principal alternative to requesting the temporary exemption for implementation of the EDG upgrade would be to comply with the restrictive requirements of GDC-2. However, this alternative would not significantly enhance the protection of the environment, and would result in a significant loss of power generation since a dual outage would be required.

##### Alternate Use of Resources

This action does not involve the use of any resources not previously considered in the April 1973 Final Environmental Statements for the Calvert Cliffs Nuclear Power Plant, Unit Nos. 1 and 2.

##### Agencies and Persons Consulted

The NRC staff consulted the State of Maryland, Department of Natural Resources, regarding the environmental impact of this proposed action. The State of Maryland had no comments.

##### Finding of No Significant Impact

Based upon the foregoing environmental assessment, the staff concludes that the proposed action will not have a significant effect on the quality of the human environment and has determined, therefore, not to prepare an environmental impact statement for the proposed exemption.

For further details with respect to this action, see the application dated August 4, 1994, 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 located at Calvert County Library, Prince Frederick, Maryland 20678.

Dated at Rockville, Maryland, this 17th day of October 1994.

For the Nuclear Regulatory Commission.

Ledyard B. Marsh,

Director, Project Directorate I-I, Division of Reactor Projects—I/II, Office of Nuclear Reactor Regulation.

[FR Doc. 94-26648 Filed 10-26-94; 8:45 am]

BILLING CODE 7590-01-M

## SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-34860; International Series Release No. 733; File No. S7-8-90]

### Order Approving Proposed Amendment to the Options Price Reporting Authority's National Market System Plan for the Purpose of Establishing a Fee To Be Paid by Persons Other Than Vendors Who Provide a Data Control Service to OPRA Subscribers

October 19, 1994.

On June 27, 1994, the Options Price Reporting Authority ("OPRA")<sup>1</sup> filed with the Securities and Exchange Commission ("Commission" or "SEC") pursuant to Section 11Aa3-2 under the Securities Exchange Act of 1934 ("Act")<sup>2</sup> a proposed amendment to its National Market System Plan for the purpose of establishing a Data Control Service Agreement and a Control Service Fee for persons other than vendors who provide a data control service to OPRA subscribers and exempting subscribers who receive the feed from OPRA's Subscriber Indirect Access Fee. On August 30, 1994, OPRA filed with the Commission a letter amendment revising the amendment to clarify that OPRA vendors who provide data control services to their data feed customers are not considered to be Control Service Providers required to enter into a Data Control Service Agreement or pay a Control Service

<sup>1</sup> 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, 1991).

The plan provides 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").

<sup>2</sup> 15 U.S.C. 78k-1.

Fee.<sup>3</sup> The proposed amendment was published for comment in the *Federal Register*.<sup>4</sup> One comment letter was received. For the reasons discussed below, the Commission is approving the proposed amendment.

### I. Background

Recent developments in computer and communications technology have led an increasing number of OPRA subscribers to receive options information by means of high speed, data feed transmissions from vendors. Historically, OPRA vendors have provided a controlled and formatted transmission of options information to most subscribers, but have also provided an uncontrolled, bulk, data feed transmission to an increasing number of subscribers. As a result of the trend toward data feed transmission, a new type of service provider—the data control service provider—has appeared. Such a provider controls the access and entitlement of subscribers' devices in respect of market information received in the form of a data feed transmission. Unlike vendors, data control service providers are not currently subject to a contract with OPRA nor are they required to contribute toward OPRA's overall administrative costs, despite the fact that, like vendors, they are in the business of redistributing options information.

### II. Description

The proposed amendment establishes a Control Service Fee to be paid by persons other than vendors who provide a data control service to OPRA subscribers. The monthly fee of \$2,800 is the same as that currently paid by vendors under their agreement with OPRA. The control service fee is intended to cover OPRA's additional administrative costs and to allocate a portion of OPRA's overall costs to those persons who utilize options market information for commercial purposes.

The proposed amendment also establishes a Data Control Service Agreement that will serve as a contract between a Control Service Provider and OPRA. This agreement imposes requirements on Control Service Providers intended to assure the reliability and integrity of the services they provide. It will require Control Service Providers to provide OPRA with a complete description of the systems

and procedures to be utilized by them in controlling subscribers' access to options information, as well as a current list of subscribers and their entitlements.

The amendment also provides that OPRA's Subscriber Indirect Access Fee, which is payable by subscribers who receive uncontrolled data feed transmissions of options information from vendors, will not apply to subscribers whose receipt of a data feed transmission is under the control of a Control Service Provider.

Finally, the Indirect (Vendor Pass-Through) Circuit Connection Rider to OPRA's Subscriber Agreement would be amended to relieve controlled data feed subscribers of the obligation to report device counts to OPRA. Since vendors and Control Service Providers are or will be required to provide this information to OPRA, there is no need to obtain it from the subscribers.

### III. Summary of Comments

As noted above, the Commission received one comment letter.<sup>5</sup> Reuters, a vendor that distributes OPRA information, assumed that the purpose of the amendment was to replace the indirect access fee (paid by subscribers who receive an uncontrolled data feed of information from vendors) with a charge to vendors who control the data delivered to a subscriber. As the letter amendment (cited on page 2 of this order) makes clear, only data control service providers *who are not vendors* will be required to enter into a Data Control Service Agreement and pay the Control Service Fee. No new or additional fees are to be imposed on vendors under this amendment.

### IV. Discussion

The Commission believes the proposed amendment is consistent with the Act and the rules and regulations thereunder applicable to OPRA and, in particular, with Sections 11A(a)(1)(C)(ii) and (D) of the Act. Section 11A(a)(1)(C)(ii) provides for the availability to brokers, dealers, and investors of information with respect to quotations for and transactions in securities. Section 11A(a)(1)(D) provides for the linking of all markets for qualified securities through communications and data processing facilities to foster efficiency, enhance competition, increase the information available to brokers, dealers, and investors, facilitate the offsetting of investor's orders, and contribute to the best execution of such orders. Further,

the Commission believes that the amendment is consistent with Rule 11Aa3-2(c)(2) in that it is 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.

The new Data Control Service Provider Agreement and accompanying fee will help OPRA to assure the reliability and integrity of the service that these providers offer OPRA customers. The Agreement will permit OPRA to know the exact number of entitlements a subscriber has arranged for with the Control Service Provider. This will eliminate the need for the Indirect Access Fee, currently paid by those subscribers who receive an uncontrolled data feed whether they have one entitlement or 100. The Control Service Fee, payable by the Provider, will be the same as the fee charged to vendors, thus promoting uniformity and equality in pricing options information.

It is therefore ordered, pursuant to Section 11A(a)(3)(B) of the Act, that the amendments to the OPRA Plan be, and hereby are, approved.

For the Commission by the Division of Market Regulation, pursuant to delegated authority, 17 CFR 200.30-3(a)(29).

Jonathan G. Katz,

Secretary.

[FR Doc. 94-26643 Filed 10-26-94; 8:45 am]

BILLING CODE 8010-01-M

[Release No. 34-34877; File No. SR-Amex-94-41]

### Self-Regulatory Organizations; Notice of Filing and Immediate Effectiveness of Proposed Rule Change by the American Stock Exchange, Inc. Relating to the Designation of Additional Equity Derivative Securities Pursuant to Exchange Rule 154, Commentary .04(c)

October 21, 1994.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 ("Act"), 15 U.S.C. 78s(b)(1), notice is hereby given that on October 7, 1994, the American Stock Exchange, Inc. ("Amex" or "Exchange") filed with the Securities and Exchange Commission ("Commission") the proposed rule change as described in Items I, II and III below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

<sup>3</sup> See letter from Michael L. Meyer, Schiff Hardin & Waite, Attorney for OPRA, to Scott C. Kursman, Attorney, Division of Market Regulation, Commission (August 30, 1994).

<sup>4</sup> Securities Exchange Act Release No. 34625 (September 1, 1994), 59 FR 46679 (September 9, 1994).

<sup>5</sup> Letter from Andrew McLean, Reuters, to Secretary, Commission (September 9, 1994).

### I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange is designating Standard & Poor's Depository Receipts as eligible, pursuant to Exchange Rule 154, Commentary .04(c), for stop and stop limit orders to be elected by quotation.

### II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The self-regulatory organization has prepared summaries, set forth in Sections A, B, and C below, of the most significant aspects of such statements.

#### A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

##### 1. Purpose

Exchange Rules 131 and 154 allow stop and stop limit orders<sup>1</sup> in selected derivative securities to be elected by a quotation,<sup>2</sup> provided the prior approval of a Floor Official is obtained. Absent this provision, such orders could only be elected when a transaction in the security occurred at or through the stop price, notwithstanding the fact that the quoted market had moved through the stop price as a result of trading in the underlying security.

Under Exchange Rule 154, Commentary .04(c)(v), provisions regarding the election of stop and stop limit orders are only applicable to such derivative securities as are designated by the Exchange as eligible for this treatment. Currently, only index warrants have been so designated.<sup>3</sup> The Exchange had previously designated

<sup>1</sup> Stop sell orders generally are entered in a stock whose price has increased substantially to protect the investor's profits should the stock price decline. Similarly, stop buy orders generally are entered by investors with short positions to limit losses should the stock price increase.

<sup>2</sup> A stop or stop limit order in a derivative security is elected, *i.e.*, becomes a market or limit order, respectively, when the quoted market for the derivative security reaches the appropriate stop or stop limit price. Once elected, the specialist treats the orders like any other market or limit order. The specialist must execute the market order at the next best market price, and must execute the limit order at the limit price or hold the order on his limit order book until the limit price is available.

<sup>3</sup> See Securities Exchange Act Release No. 290673 (April 10, 1991), 56 FR 15652 (April 17, 1994) (File No. SR-Amex-90-31).

Americus Trust Units, PRIMES, and SCOREs as eligible as well, but all such securities have since expired and are no longer traded.

Accordingly, the Exchange now designates, pursuant to Exchange Rule 154, Commentary .04(c), Standard & Poor's Depository Receipts<sup>4</sup> as eligible for stop and stop limit orders to be elected by quotation. These derivative equity securities can be expected to fluctuate in price based on changes in an underlying stock index, and are therefore appropriately designated as eligible for election of stop and stop limit orders by quotation.

##### 2. Statutory Basis

The proposed rule change is consistent with Section 6(b) of the Act in general and furthers the objectives of Section 6(b)(5) in particular in that it is designed to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market, and, in general, to protect investors and the public interest.

#### B. Self-Regulatory Organization's Statement on Burden on Competition

The proposed rule change will impose no burden on competition.

#### C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants or Others

No written comments were solicited or received with respect to the proposed rule change.

### III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change constitutes a stated policy, practice, or interpretation with respect to the meaning, administration, or enforcement of an existing rule of the Exchange and therefore has become effective pursuant to Section 19(b)(3)(A) of the Act and subparagraph (e) of Rule 19b-4 thereunder. At any time within 60 days of the filing of such proposed rule change, the Commission may summarily abrogate such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.

<sup>4</sup> The product, known as a "SPDR," is a Portfolio Depository Receipt ("PDR") based upon the Standard & Poor's ("S&P") 500 Stock Index. The Commission approved the listing and trading of SPDRs in Securities Exchange Act Release No. 31591 (December 11, 1992), 57 FR 60253 (December 18, 1992).

### IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing. Persons making written submissions should file six copies thereof with the Secretary, Securities and Exchange Commission, 450 Fifth Street, NW., Washington, DC 20549. 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 at the Commission's Public Reference Section, 450 Fifth Street, NW., Washington, DC 20549. Copies of such filing will also be available for inspection and copying at the principal office of the Amex. All submissions should refer to File No. SR-Amex-94-41 and should be submitted by November 17, 1994.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.

Jonathan G. Katz,  
Secretary.

[FR Doc. 94-26639 Filed 10-26-94; 8:45 am]  
BILLING CODE 8010-01-M

[Release No. 34-34869; File No. SR-Amex-94-25]

### Self-Regulatory Organizations; American Stock Exchange, Inc.; Order Granting Approval to Proposed Rule Change Relating to Increasing the Share Parameters for Orders Entered Through PER

October 20, 1994.

On June 23, 1994, the American Stock Exchange, Inc. ("Amex" or "Exchange") submitted to the Securities and Exchange Commission ("SEC" or "Commission"), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 ("Act")<sup>1</sup> and Rule 19b-4 thereunder,<sup>2</sup> a proposed rule change to increase the share parameters, from 5,099 to 30,099 shares, for orders entered through the Exchange's Post Execution Reporting (PER) system.

The proposed rule change was published for comment in Securities Exchange Act Release No. 34347 (July 11, 1994), 59 FR 36238 (July 15, 1994).

<sup>1</sup> 15 U.S.C. 78s(b)(1) (1988).

<sup>2</sup> 17 CFR 240.19b-4 (1991).

No comments were received on the proposal.

The PER system provides member firms with the means to electronically transmit equity orders up to volume limits specified by the Exchange directly to the specialist's post on the Exchange Floor. Market and marketable limit orders and reopening market orders are placed on the specialist's electronic book. Once the PER order is executed, the system transmits the execution report directly back to the member firm.

Currently, the PER system accepts (1) up to 5,099 shares for all eligible market and limit orders; (2) up to 25,000 shares for eligible market and limit orders for Unit Investment Trust securities (such as Standard & Poor's Depository Receipts);<sup>3</sup> and (3) up to 30,099 shares for market and limit round lot orders for those securities included in the S&P 500 Index.<sup>4</sup>

In the Amex Approval Order, the Commission granted partial accelerated approval for that portion of the instant filing which pertains to those Exchange-listed equity securities included in the S&P 500 Index. The Commission also stated in the Amex Approval Order that if, after three months, the Exchange wishes to extend the PER parameters to all other Exchange-listed equity securities, then it has the option to do so. During the three-month pilot the Exchange has had an opportunity to observe the level of increased utilization of PER and factor that into its assessment of how best to implement the parameter increase for the remainder of the Exchange-listed equity securities. The Exchange represents that it has not experienced any systems problems in processing the additional order flow through PER. The Exchange now requests an extension of the PER parameters to all other Exchange-listed equity securities.<sup>5</sup>

The Commission finds that the Amex's proposal to increase the PER share parameters, from 5,099 to 30,099, for orders of the remaining Exchange-listed equity securities (*i.e.*, equity securities in addition to those included

in the S&P 500 Index), is consistent with the requirements of the Act and the rules and regulations thereunder applicable to a national securities exchange. Specifically, the Commission finds that the proposed rule change is consistent with the requirements of Section 6(b)(5) of the Act<sup>6</sup> because it will facilitate transactions in securities by allowing for the timely transmission of a larger number of orders to the Amex floor. The proposal will also result in more efficient and effective market operations, consistent with Section 11A(a)(1)(B) and will further the maintenance of fair and orderly markets and the efficient execution of securities transactions consistent with Section 11A(a)(1)(C) of the Act.<sup>7</sup>

Finally, based upon representations from the Amex, the Commission is satisfied that the Exchange's PER system will have adequate computer processing capacity to accommodate the increased order size eligibility.<sup>8</sup> The Commission notes, however, that if the Exchange does not implement the expansion to all Exchange-listed equity securities within six months of the approval date of this order, then it cannot so implement without demonstrating to the Commission that the systems capacity remains adequate to facilitate the additional order flow.<sup>9</sup>

It is therefore ordered, pursuant to Section 19(b)(2) of the Act,<sup>10</sup> that the proposed rule change (SR-Amex-94-25) is approved.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.<sup>11</sup>

Jonathan G. Katz,  
Secretary.

[FR Doc. 94-26642 Filed 10-26-94; 8:45 am]

BILLING CODE 8010-01-M

[Release No. 34-34868; File No. SR-BSE-94-11]

### Self-Regulatory Organizations; Notice of Filing and Immediate Effectiveness of Proposed Rule Change by the Boston Stock Exchange, Inc. Relating to its Fee Schedules

October 20, 1994.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 ("Act"), 15 U.S.C. 78s(b)(1), notice is hereby given that on September 30,

<sup>6</sup> 15 U.S.C. 78f(b)(5) (1988).

<sup>7</sup> 15 U.S.C. 78f(b)(5) and 78k-1 (1988).

<sup>8</sup> See note 5, *infra*.

<sup>9</sup> As of the date of this order, the Exchange has indicated that it plans to expand the increased parameters for PER eligibility on November 1, 1994.

<sup>10</sup> 15 U.S.C. 78s(b)(2) (1988).

<sup>11</sup> 17 CFR 200.30-3(a)(12) (1991).

1994, the Boston Stock Exchange, Inc. ("BSE" or "Exchange") filed with the Securities and Exchange Commission ("Commission") the proposed rule change as described in Items I, II and III below, which Items have been prepared by the self-regulatory organization. On October 14, 1994, the Exchange agreed to submit the instant filing for immediate effectiveness for a period of one hundred and twenty days commencing with the date of filing.<sup>1</sup> The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

#### I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Boston Stock Exchange seeks to amend its fee schedules pertaining to transaction fees.

#### II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The self-regulatory organization has prepared summaries, set forth in Sections A, B, and C below, of the most significant aspects of such statements.

##### A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

###### 1. Purpose

The purpose of the proposed rule filing is to amend the Exchange's fee schedule in order to capitalize on the competitive niches that the Exchange currently enjoys and to improve the Exchange's competitive position. The proposal would provide a \$.25 per trade credit on all non-self-directed, electronically routed, Exchange executed, trades of any size. For purposes of the per trade credit, "non-self-directed" shall mean entered by a BEACON subscriber in stocks in which the routing firm has no affiliation with or financial interest in the specialist

<sup>1</sup> Conversation between Jack Fitzgerald, Executive Vice President, Boston Stock Exchange, and Holly Smith, Division of Market Regulation, Commission, on October 14, 1994. The proposed rule change will cease to be effective on January 30, 1995, unless the Commission approves a similar, subsequent filing by the BSE under Rule 19b-4, or disapproves the instant rule change prior to January 30, 1995.

<sup>3</sup> See Securities Exchange Act Release No. 32544 (June 29, 1993), 58 FR 36485, July 7, 1993.

<sup>4</sup> See Securities Exchange Act Release No. 34347 (July 11, 1994), 59 FR 36238 (July 15, 1994) (granting accelerated approval to that portion of the current proposed rule change as it relates to Amex securities in the S&P 500 Index) ("Amex Approval Order").

<sup>5</sup> See letter from Iovonne Nagy, Special Counsel, Amex, to Amy Bilbija, Commission, dated October 18, 1994. The letter confirms the systems capabilities and the Amex's intention, upon Commission approval, to extend the increased order size that may be routed through PER to all other Exchange-listed equity securities to take effect on November 1st.

operation registered in those stocks. The aggregate credit per firm shall be limited to the total monthly layoff transaction fees charged to that firm.<sup>2</sup>

The specific new language is as follows: *New language.*

#### Transaction Fees

### TRADE RECORDING AND COMPARISON CHARGES

• Trades up to and including 2,000 shares (all trades accumulate for volume discounts) .....	No charge.
• Trades above 2,000:	
First 2,500 trades per month .....	\$.29 per 100 shares.
Next 2,500 trades per month .....	.25 per 100 shares.
Next 2,500 trades per month .....	.15 per 100 shares.
Over 7,500 trades per month .....	.05 per 100 shares.
Maximum charge per side (non-cross) .....	50.00.
Maximum charge per side (cross) .....	25.00.
• BEACON subscriber Credits .....	.25 per trade.
<i>All non-self-directed, electronically routed trades (credit is limited to total monthly layoff transaction fees)</i>	

## 2. Statutory Basis

The statutory basis for this proposal is Section 6(b)(4) of the Act.

### B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

### C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received from Members, Participants or Others

The Exchange has neither solicited nor received comments on the proposed rule change.

## III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change establishes or changes a due, fee, or other charge imposed by the Exchange and therefore has become effective pursuant to Section 19(b)(3)(A) of the Act and subparagraph (e) of Rule 19b-4 thereunder. At any time within 60 days of the filing of such proposed rule change, the Commission may summarily abrogate such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.

## IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing. Persons making written submissions

should file six copies thereof with the Secretary, Securities and Exchange Commission, 450 Fifth Street, N.W., Washington, D.C. 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 at the Commission's Public Reference Section, 450 Fifth Street, N.W., Washington, D.C. 20549. Copies of such filing will also be available for inspection and copying at the principal office of the BSE. All submissions should refer to File No. SR-BSE-94-11 and should be submitted by November 17, 1994.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.

**Jonathan G. Katz,**

Secretary.

[FR Doc. 94-26641 Filed 10-26-94; 8:45 am]

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[Release No. 34-34867; File No. SR-NSCC-94-16]

### Self-Regulatory Organizations; National Securities Clearing Corporation; Order Granting Accelerated Approval of a Proposed Rule Change Modifying Comparison Procedures for Corporate Bond and Unit Investment Trust Transactions and Modifying the Fee Structure for Correction Fees

October 20, 1994.

On August 9, 1994, the National Securities Clearing Corporation ("NSCC") filed with the Securities and Exchange Commission ("Commission") a proposed rule change (File No. SR-NSCC-94-16) pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 ("Act").<sup>1</sup> Notice of the proposal was published in the *Federal Register* on October 4, 1994.<sup>2</sup> No comment letters were received. For the reasons discussed below, the Commission is approving the proposed rule change on an accelerated basis.

## I. Description

Since 1993, NSCC has been redesigning its bond comparison system to accelerate the processing (*i.e.*, submission and comparison) of bond transactions to achieve higher rates of trade comparison at earlier points in the comparison process.<sup>3</sup> NSCC believes accelerated processing will help to increase certainty and reduce risk in the clearance and settlement of debt transactions. The first phase of the redesign process enhanced the processing of transactions in municipal securities and was implemented by NSCC on August 13, 1993.<sup>4</sup>

<sup>1</sup> The term "layoff" refers to any trade wherein a specialist is eliminating (or decreasing) a position in a security in which he makes a market.

<sup>2</sup> 15 U.S.C. 78s(b)(1) (1988).

<sup>3</sup> Securities Exchange Act Release No. 34729 (September 27, 1994), 59 FR 50634.

<sup>4</sup> NSCC refers to this system as the Fixed Income Transaction System ("FITS").

<sup>5</sup> For a detailed description of the municipal securities phase of the bond comparison system, refer to Securities Exchange Act Release No. 32747 (August 13, 1993), 58 FR 44530 [File No. SR-NSCC-93-2] (order approving a proposed rule change establishing a program relating to

The primary purpose of the current proposed rule change is to expand the accelerated comparison system to include the processing of transactions in corporate bonds and unit investment trusts ("UITs"). The proposed rule change also permits NSCC to provide comparison services for baby bonds (*i.e.*, corporate bonds having a par value of less than \$1,000) and new issue trading. The proposed rule change also modifies the fee structure for correction fees.

Under the proposed rule change, the cutoff time for submission of original trade input for all corporate bond and UIT transactions is moved from 1:00 p.m. on the day following trade date ("T+1") to 2:00 a.m. on T+1. These trades will be reported back to members by 8:00 a.m. on T+1. Adjustments to original trade input will have to be made prior to the time specified by NSCC on T+1, which will be 6:00 p.m.

In addition, NSCC will accept trade input for trade-for-trade processing of corporate baby bonds. If transactions are submitted as a mixed lot (*i.e.*, submissions including baby bonds and round lots), the baby bond and the round lot portions of the transaction will be separated by NSCC upon input.

At the option of members, corporate bond and UIT transactions will be compared when the net buy side and sell side aggregate principal amounts can be matched for a particular security, even if the relevant principal amounts are specified in more than one buy side and/or more than one sell side submission, if the transactions would have been compared had such buy side and sell side principal amounts each been specified on a single submission.

Because correction processing occurs at the New York and American Stock Exchanges and at the National Association of Securities Dealers before the trade input is transmitted to NSCC, Add-by-Seller, Delete-by-Seller, Delete Add-by-Seller, and Delete-by-Buyer instructions will no longer be accepted under the proposed rule.<sup>5</sup> This change is being made in order to standardize correction processing.

<sup>5</sup> For a complete description of the New York Stock Exchange, American Stock Exchange, and National Association of Securities Dealers correction processing systems, refer to Securities Exchange Act Release Nos. 26773 (May 1, 1989), 54 FR 20227 [File No. SR-NYSE-89-03] (order approving the New York Stock Exchange's system for the resolution of uncomparable transactions); 28069 (May 29, 1990), 55 FR 23324 [File No. SR-AMEX-90-01] (order approving the Intra-Day Comparison System for resolving uncomparable transactions); and 28583 (November 1, 1990), 55 FR 46120 [File No. SR-NASD-89-25] (order granting accelerated approval of amendment to proposed rule change relating to the Automated Confirmation Transaction Service).

NSCC will provide comparison services for corporate bond new issue transactions on the same basic terms and conditions as it currently provided for municipal securities transactions with the exception of syndicate takedown processing.<sup>6</sup> Original trade input for new issue corporate bond transactions will be accepted until the third day prior to the initial settlement date for the issue. Original input may set forth either (1) a final settlement price and a settlement date that is either the initial settlement date or a specified number of days after the initial settlement date or (2) a dollar price. Original trade input that is submitted between three and five days prior to the initial settlement date but does not set forth a final settlement price and settlement date or does not set forth a dollar price will be treated as regular way input. Any corporate bond new issue transactions that remain uncomparable at the opening of business on the day prior to the initial settlement date will be deleted from NSCC's system.<sup>7</sup>

In addition, NSCC's fee structure relating to correction fees is being amended to reflect that correction capabilities are being accelerated in conformity with comparison capabilities. These fee changes conform all bond correction fees to the fees implemented in connection with municipal securities transaction processing in that participants will be charged for supplemental input on or after T+1.<sup>8</sup> Currently, NSCC charges participants for supplemental input relating to corporate bond and UIT transactions on or after T+2. In addition, the bond system correction fees for "don't know" and "questioned trade" input is being deleted because NSCC no longer processes such transactions. The proposed rule change also makes certain conforming changes and deletions to

<sup>6</sup> NSCC defines "new issue" transactions in this context to mean transactions which are to settle on the initial settlement date for an issue or which are to settle a specified number of days after the initial settlement date.

<sup>7</sup> This means that it may not be possible to process some new issue transactions through the entire range of available trade resolution procedures prior to being dropped. In the extreme case, new issue submissions made on the second day prior to the initial settlement date that do not compare will be dropped without any opportunity for resolution. These unresolved trades will be reported on a separate unresolved trade report, and any trade dropped without the opportunity for resolution may be resubmitted after the initial settlement date.

<sup>8</sup> For a detailed description of NSCC's correction fees for municipal securities transactions, refer to Securities Exchange Act Release No. 34193 (June 10, 1994), 59 FR 31284 [File No. SR-NSCC-94-08] (notice of filing and immediate effectiveness of a proposed rule change modifying NSCC's fee schedule for correction fees).

NSCC's Procedures in order to reflect greater uniformity in NSCC's bond comparison system and to eliminate certain language which has become obsolete.

## II. Discussion

The Commission finds that the proposed rule change is consistent with the requirements of the Act and the rules and regulations thereunder and particularly with the requirements of Section 17A(b)(3)(F).<sup>9</sup> Section 17A(b)(3)(A) requires that the rules of a clearing agency be designed to promote the prompt and accurate clearance and settlement of securities transactions. The Commission believes that the proposed changes to NSCC's comparison procedures should help achieve higher rates of trade comparison at earlier points in the comparison process and thus help increase certainty and reduce risk in the clearance and settlement of corporate bond and UIT transactions. Use of NSCC's bond comparison system should significantly improve the comparison rate for corporate bonds, baby bonds, and unit investment trusts and should facilitate moving from a five business day settlement cycle to a three business day settlement cycle.<sup>10</sup> Moreover, the Commission believes that by expanding the bond comparison system to include corporate bond, baby bond, and new issue transaction processing, NSCC is aiding in the prompt and accurate clearance and settlement of securities transactions.

NSCC's fee structure will be amended with regard to correction fees to reflect that correction capabilities will be accelerated in conformity with comparison capabilities. The Commission believes that these changes to NSCC's fee structure are appropriate and in conformity with Section 17A(b)(3)(D) of the Act which requires the rules of a clearing agency to provide for equitable allocation of reasonable fees among its participants.<sup>11</sup>

NSCC has requested that the Commission find good cause for approving the proposed rule change prior to the thirtieth day after the date of publication of notice of the filing so that NSCC can begin utilizing the new comparison procedures for trades

<sup>9</sup> 15 U.S.C. 78q-1(b)(3)(F) (1988).

<sup>10</sup> On October 6, 1993, the Commission adopted Rule 15c6-1 under the Act, which establishes three business days after the trade date instead of five business days as the standard settlement timeframe for most broker-dealer transactions. The rule becomes effective June 1, 1995. Securities Exchange Act Release No. 33023 (October 6, 1993), 58 FR 52891 (release adopting Rule 15c6-1).

<sup>11</sup> 15 U.S.C. 78q-1(b)(3)(D) (1988).

executed on October 21, 1994. The Commission finds good cause for so approving the proposed rule change because accelerated approval will allow NSCC to implement the new procedures as scheduled. Additionally, the Commission does not anticipate that it will receive any significant negative comment on the proposed rule change in view of the fact that no comments have been received to date by the Commission or NSCC.

### III. Conclusion

On the basis of the foregoing, the Commission finds that the proposal is consistent with the requirements of the Act, particularly with Sections 17A(b)(3)(F) and 17A(b)(3)(D) of the Act, and the rules and regulations thereunder.

It is therefore ordered, pursuant to Section 19(b)(2) of the Act, that the proposed rule change (File No. SR-NSCC-94-16) be, and hereby is, approved.

For the Commission by the Division of Market Regulation, pursuant to delegated authority.<sup>12</sup>

**Jonathan G. Katz,**

Secretary.

[FR Doc. 94-26579 Filed 10-26-94; 8:45 am]

BILLING CODE 8010-01-M

[Investment Company Act Release No. 20647; International Series Release No. 734/812-9242]

### The Chase Manhattan Bank, N.A.; Notice of Application

October 21, 1994.

AGENCY: Securities and Exchange Commission ("SEC").

ACTION: Notice of Application for Exemption under the Investment Company Act of 1940 ("Act").

APPLICANT: The Chase Manhattan Bank, N.A. ("Chase").

RELEVANT ACT SECTIONS: Exemption requested under section 6(c) from the provisions section 17(f) of the Act.

SUMMARY OF APPLICATION: Chase seeks an order to enable it to maintain foreign securities and other assets of United States registered investment companies for which Chase serves as custodian or subcustodian in the custody of The Chase Manhattan Bank (M) Berhad ("Chase-Malaysia").

FILING DATE: The application was filed on September 22, 1994.

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 Applicant with a copy of the request, personally or by mail. Hearing requests should be received by the SEC by 5:30 p.m. on November 14, 1994, and should be accompanied by Proof of service on Applicant, 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 reasons for the request, and the issues 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. Applicant, c/o Daniel L. Goelzer, Esq., Baker & McKenzie, 815 Connecticut Avenue, NW., Washington, DC 20006.

FOR FURTHER INFORMATION CONTACT: H.R. Hallock, Jr., at (202) 942-0564 or Barry D. Miller, Senior Special Counsel, at (202) 942-0564 (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.

### Applicant's Representations and Legal Analysis

1. Chase requests exemptive relief for itself, any management investment company registered under the Act, other than an investment company registered under section 7(d) of the Act (a "U.S. Investment Company"), and any custodian for a U.S. Investment Company from section 17(f) of the Act. The requested exemption would let Chase, such U.S. Investment Company and such custodian to maintain foreign securities, cash, and cash equivalents (collectively, "Assets") in the custody of Chase-Malaysia, an indirect subsidiary of Chase located in Malaysia. For purposes of the application, the term "foreign securities" includes (a) securities issued and sold primarily outside the United States by a foreign government, a national of any foreign country, or a corporation or other organization incorporated or organized under the laws of any foreign country, and (b) securities issued or guaranteed by the Government of the United States or by any state or any political subdivision thereof or by any agency thereof by any entity organized under the laws of the United States or of any state thereof which have been issued and sold primarily outside the United States.

2. Section 17(f) of the Act requires every registered management investment company to place and maintain its securities and similar investments in the custody of certain enumerated entities. Rules 17f-5 under the Act expands the group of entities located outside the United States that are permitted to serve as custodians for the Assets of registered management investment companies. Rule 17f-5 defines the term "Eligible Foreign Custodian" to include a majority-owned direct or indirect subsidiary of a qualified U.S. bank or bank-holding company that is incorporated or organized under the laws of a country other than the United States and that has shareholders' equity in excess of \$100,000,000 (U.S. \$ equivalent or U.S. \$) as of the close of its most recently completed fiscal year. The rule defines the term "Qualified U.S. Bank" to include a banking institution organized under the laws of the United States that has an aggregate capital, surplus and undivided profit of not less than \$500,000.

3. Chase is a national banking association and is regulated as such by the Comptroller of the Currency under the National Bank Act. At December 31, 1993, Chase had shareholders' equity in excess of \$6.4 billion. Thus, Chase is a "Qualified U.S. Bank" under the requirements of Rule 17f-5, since it is a banking institution organized under the laws of the United States, and it has aggregate capital, surplus and undivided profit substantially in excess of the \$500,000 minimum required by the rule.

4. Chase is a subsidiary of The Chase Manhattan Corporation, a Delaware company that provides financial services throughout the world. Through its Global Securities Services division ("GSS"), Chase provides custody and related services to global institutional investors, including U.S. mutual funds. GSS currently has over \$1,300 trillion in assets under custody at various locations throughout the world, including its branches and subsidiaries in approximately 50 countries.

5. Chase established a branch in Kuala Lumpur, Malaysia in 1964, and currently offers custody services in Malaysia through that branch. However, under the Malaysian Banking and Financial Institutions Act 1989, Chase must now convert its branch to a locally incorporated entity. To comply with Malaysian law, Chase proposes to transfer all the activities of the branch, as well as its personnel, to Chase-Malaysia.

6. Chase-Malaysia will be wholly-owned by Chase Manhattan Overseas Banking Corporation, a wholly-owned

<sup>12</sup> 17 CFR 200.30-3(a)(12) (1994).

direct subsidiary of Chase. Chase-Malaysia will assume the assets, liabilities, and business of the Chase Kuala Lumpur branch and will be subject to the supervision of Bank Negara Malaysia (the central bank of Malaysia). Chase-Malaysia will offer the same services as the former Chase Kuala Lumpur branch, and will become subject to the same capital and reporting requirements as other domestic banks in Malaysia.

7. Chase-Malaysia will satisfy the requirements of rule 17f-5 insofar as it will be a majority-owned indirect subsidiary of Chase and will be incorporated and organized under the laws of Malaysia. Chase-Malaysia will not, however, meet the \$100 million minimum shareholder's equity requirement of rule 17f-5. Accordingly, Chase-Malaysia will not qualify as an "Eligible Foreign Custodian" under the rule and, absent exemptive relief, could not serve as custodian for the Assets of U.S. Investment Companies.

8. Where custody services are required in Malaysia, Chase will hold the Assets of U.S. Investment Companies as custodian or subcustodian, and will deposit (or cause or permit the deposit of) the Assets with Chase-Malaysia in accordance with the arrangement described in the conditions below. Chase-Malaysia will be well-qualified to provide custody and subcustody services to Chase, U.S. Investment Companies, and custodians for U.S. Investment Companies, since Chase-Malaysia will be the successor to the business of Chase's Kuala Lumpur branch, which is experienced in providing custody services. Under the proposed foreign custody arrangements, the protection afforded the Assets of U.S. Investment Companies held by Chase-Malaysia would not be diminished from the protection afforded by rule 17f-5.

#### **Applicant's Conditions**

Chase agrees that any order of the SEC granting the requested relief may be conditioned upon the following:

1. The foreign custody arrangements proposed regarding Chase-Malaysia will satisfy the requirements of rule 17f-5 in all respects other than Chase-Malaysia's level of shareholders' equity.

2. Chase will deposit Assets with Chase-Malaysia only in accordance with the Custody Agreement and the Subcustody Agreement described in (a) and (b) below. The Custody and Subcustody Agreements will remain in effect at all times during which Chase-Malaysia fails to satisfy all the requirements of the rule.

(a) The Custody Agreement will be between Chase and the U.S. Investment Company (or its custodian). In that agreement, Chase will undertake to provide custody or subcustody services, and the U.S. Investment Company (or its custodian) will authorize Chase to delegate to Chase-Malaysia such of Chase's duties and obligations as will be necessary to permit Chase-Malaysia to hold the Assets of U.S. Investment Companies in custody in Malaysia. The Custody Agreement will further provide that the delegation by Chase to Chase-Malaysia will not relieve Chase of any responsibility to the U.S. Investment Company or its custodian for any loss due to such delegation, and that Chase will be liable for any loss or claim arising out of or in connection with the performance by Chase-Malaysia of the custody services to the same extent as if Chase had itself provided the custody services under the Custody Agreement.

(b) A Subcustody Agreement will be executed by Chase and Chase-Malaysia. Pursuant to this agreement, Chase will delegate to Chase-Malaysia such of Chase's duties and obligations as would be necessary to permit Chase-Malaysia to hold Assets in custody in Malaysia. The Subcustody Agreement will explicitly provide that (i) Chase-Malaysia is acting as a foreign custodian for Assets that belong to a U.S. Investment Company pursuant to the terms of an exemptive order issued by the SEC and (ii) the U.S. Investment Company or its custodian (as the case may be) that has entered into a Custody Agreement will be entitled to enforce the terms of the Subcustody Agreement and can seek relief directly against Chase-Malaysia. The Subcustody Agreement will provide that it will be governed by New York law.

3. Chase currently satisfies and will continue to satisfy the Qualified U.S. Bank requirement set forth in rule 17f-5(c)(3).

For the Commission, by the Division of Investment Management, under delegated authority.

Jonathan G. Katz,  
Secretary.

[FR Doc. 94-26640 Filed 10-26-94; 8:45 am]  
BILLING CODE 8010-01-M

#### **SMALL BUSINESS ADMINISTRATION**

[License # 602/02-60311]

#### **Rand SBIC, Inc.; Notice of License Surrender**

Notice is hereby given that Rand SBIC, Inc., ("RAND"), 1300 Rand Building, Buffalo, New York 14203, has

surrendered its license to operate as a small business investment company under the Small Business Investment Act of 1958, as amended ("the Act"). RAND was licensed by the Small Business Administration on May 5, 1976.

Under the authority vested by the Act and pursuant to the regulations promulgated thereunder, the surrender of the license was accepted on October 13, 1994, and accordingly, all rights, privileges, and franchises derived therefrom have been terminated.

(Catalog of Federal Domestic Assistance Program No. 59.011, Small Business Investment Companies)

Dated: October 20, 1994.

Robert D. Stillman,

Associate Administrator for Investment.

[FR Doc. 94-26610 Filed 10-26-94; 8:45 am]  
BILLING CODE 8025-01-M

[License No. 05/05-0221]

#### **River Cities Capital Fund Limited Partnership; Notice of Issuance of a Small Business Investment Company License**

On August 12, 1994, a notice was published in the Federal Register (59 FR 41549) stating that an application had been filed by River Cities Capital Fund Limited Partnership, 221 East Fourth St., Suite 2250, Cincinnati, Ohio 45202, with the Small Business Administration (SBA) pursuant to § 107.102 of the Regulations governing small business investment companies (13 CFR 107.102 (1994)) for a license to operate as a small business investment company. Interested parties were given until close of business September 12, 1994 to submit their comments to SBA. No comments were received.

Notice is hereby given that, pursuant to section 301(c) of the Small Business Investment Act of 1958, as amended, after having considered the application and all other pertinent information, SBA issued License No. 05/05-0221 on September 26, 1994, to River Cities Capital Fund Limited Partnership to operate as a small business investment company.

(Catalog of Federal Domestic Assistance Program No. 59.011, Small Business Investment Companies)

Dated: October 20, 1994.

Robert D. Stillman,

Associate Administrator for Investment.

[FR Doc. 94-26612 Filed 10-26-94; 8:45 am]  
BILLING CODE 8025-01-M

**DEPARTMENT OF STATE**

[Public Notice 2103]

**United States International Telecommunications Advisory Committee, Telecommunications Development Sector (ITAC-D) Group; Meeting**

The Department of State announces that the United States International Telecommunications Advisory Committee (ITAC), Telecommunications Development Sector (ITAC-D) Group will meet on Wednesday, November 16, 1994, in Room 1207 from 9:30 a.m. to 1:00 p.m. at the Department of State, 2201 "C" Street, NW., Washington, DC 20520.

The agenda for the ITAC-D Group meeting will include (1) a debrief of the Kyoto Plenipotentiary Conference of September 19–October 14, as it may affect the work of the ITU's Telecommunications Development Sector, with particular interest on priorities, and strategic policy and planning (–GL–)(–GL–) a debrief of the Ottawa CITEI (InterAmerican Telecommunications Commission) meetings, and (3) U.S. preparatory efforts and organization for participation and contributions to the newly formed ITU-D Study Groups 1 and 2. The discussion will concentrate on items raised in ITU-D Administrative Circular No. CA/1.

Members of the General Public may attend the meetings and join in the discussions, subject to the instructions of the chair. Admittance of public members will be limited to the seating available. In this regard, entrance to the Department of State is controlled. If you wish to attend please call 202-647-5233 no later than five (5) days before the meeting. Enter from the C Street Main Lobby. A picture ID will be required for admittance.

Dated: October 17, 1994.

**Doreen F. McGirr,***Chair, U.S. ITAC for ITU-**Telecommunications Development Sector.*

[FR Doc. 94-26620 Filed 10-26-94; 8:45 am]

BILLING CODE 4710-45-M

[Public Notice 2104]

**Overseas Security Advisory Council; Closed Meeting**

The Department of State announces a meeting of the U.S. State Department—Overseas Security Advisory Council on Wednesday and Thursday, November 16–17, 1994, at the Department of State, Washington, DC. Pursuant to Section 10(d) of the Federal Advisory

Committee Act and 5 U.S.C. 552b (c) (1) and (4); it has been determined the meeting will be closed to the public. Matters relative to classified national security information as well as privileged commercial information will be discussed. The agenda calls for the discussion of classified and corporate proprietary/security information as well as private sector physical and procedural security policies and protective programs at sensitive U.S. Government and private sector locations overseas.

For more information contact Marsha Thurman, Overseas Security Advisory Council, Department of State, Washington, DC 20522-1003, phone: 202-663-0869.

Dated: October 18, 1994.

**Mark Mulvey,***Director of the Diplomatic Security Service.*

[FR Doc. 94-26622 Filed 10-26-94; 8:45 am]

BILLING CODE 4710-24-M

[Public Notice 2102]

**Shipping Coordinating Committee; Maritime Safety Committee and International Conference; Meeting**

The Shipping Coordinating Committee (SHC) will conduct an open meeting at 9:30 A.M. on Wednesday, November 30, 1994, in room 2415, at U.S. Coast Guard Headquarters, 2100 Second Street, SW., Washington, DC. The purpose of the meeting is to finalize preparations for the 64th Session of the Maritime Safety Committee (MSC-64), and associated bodies of the International Maritime Organization (IMO), which is scheduled for December 5–9, 1994 at the IMO Headquarters in London. At the meeting, papers received and the draft U.S. positions will be discussed.

Among other things, the items of particular interest are:

a. Technical assistance subprogram in maritime safety.

b. Role of the human element in maritime casualties.

c. Prevention and abatement of marine pollution incidents.

d. Survey and Certification

e. Existing ships' safety standards

f. Reports of various subcommittees

(Stability, Load Lines and Fishing Vessel Safety; Life-Saving, Search and Rescue; Containers and Cargoes; Fire Protection; Training and Watchkeeping; Safety of Navigation; and Bulk Chemicals.)

Members of the public may attend this meeting up to the seating capacity of the room. Interested persons may seek information by writing to Mr. Gene

F. Hammel, U.S. Coast Guard (G-CI), Room 2114, 2100 Second Street SW, Washington, DC 20593-0001 or by calling (202) 267-2280.

Dated: October 18, 1994.

**Charles A. Mast,***Chairman, Shipping Coordinating Committee.*

[FR Doc. 94-26621 Filed 10-26-94; 8:45 am]

BILLING CODE 4710-07-M

[Public Notice 2101]

**Bureau of Oceans and International Environmental and Scientific Affairs; U.S. Climate Action Report (USCAR), September 1994; United Nations Framework Convention on Climate Change**

**ACTION:** Notice of availability of USCAR and public comment period.

**SUMMARY:** In June 1992, the United States signed the United Nations Framework Convention on Climate Change (UNFCCC). Pursuant to the reporting requirements under Articles 4.2 and 12 of the Convention, the United States has prepared and submitted the U.S. Climate Action Report (USCAR) in fulfillment of these requirements to the UNFCCC Secretariat. The USCAR provides a description of the current U.S. program designed to reduce emissions to 1990 levels by the year 2000. The information presented in the USCAR, together with information provided by other Annex I Parties (developed country Parties and Parties with economies in transition to market economies), will be reviewed and discussed by the Parties to the UNFCCC beginning at the first session of the Conference of the Parties in early 1995.

In keeping with international guidelines, the USCAR provides an inventory of current U.S. greenhouse gas emissions and sinks, estimates effects of current mitigation measures and policies on future emissions levels, and describes U.S. involvement in international programs including associated financial transfers and contributions. In addition, the USCAR includes a discussion of U.S. national circumstances which affect its vulnerability and responses to climate change. Information on adaptation programs and the U.S. Global Change Research Program, the largest climate change research program in the world, is also presented. While it briefly discusses the future direction of the U.S. effort, the USCAR does not seek to identify policies or measures additional to those described in the Climate Action Plan, announced by President Clinton

and Vice President Gore on October 19, 1993, that might ultimately be taken as the United States continues to move forward in addressing climate change.

**SUPPLEMENTARY INFORMATION:** In June 1992, at the United Nations Conference on Environment and Development (the "Earth Summit"), the United States signed the United Nations Framework Convention on Climate Change (UNFCCC). The ultimate objective of this Convention is to: "Achieve \* \* \* stabilization of greenhouse gas concentrations in the atmosphere at a level that would prevent dangerous anthropogenic interference with the climate system. Such a level should be achieved within a time-frame sufficient to allow ecosystems to adapt naturally to climate change, to ensure that food productions is not threatened and to enable economic development to proceed in a sustainable manner."

It has been predicted that human produced greenhouse gases (primarily carbon dioxide, methane, and nitrous oxide) will cause change in global average climate at a rate that could far exceed any natural change that has occurred in the last 10,000 years. Although there are uncertainties regarding the magnitude, timing and regional patterns of global climate change, any human-induced change that does occur is not likely to be reversed for decades—or even centuries—because of the long lifetimes of the greenhouse gases and the inertia of the climatic system.

In accordance with the UNFCCC's reporting requirements as specified in Articles 4.2 and 12, the United States has prepared the U.S. Climate Action Report (USCAR) and submitted it to the UNFCCC Secretariat. The USCAR represents the United States' first formal communication to the Secretariat under these Articles.

#### Content of the USCAR

The USCAR provides a background to the issue of global climate change and describes current U.S. efforts to reduce greenhouse gas emissions to 1990 levels by the year 2000. Following the Introduction and Overview (chapter 1), the report begins (in chapter 2) with an analysis of United States national circumstances which affect its vulnerability and responses to climate change. These circumstances include natural resources, the economy, energy production and consumption, governing institutions, and U.S. policies related to climate change.

The next chapter (chapter 3) consists of an inventory of U.S. greenhouse gas emissions, including carbon dioxide, methane, nitrous oxide, and HFC and

PFC emissions. Because the full U.S. submission includes a copy of the EPA Report "Inventory of U.S. Greenhouse Gas Emissions and Sinks for 1990–1993", the USCAR itself provides a summary of this complete inventory.

Chapter 4 deals with the specific actions being taken to reduce greenhouse gas emissions. This section is drawn from the material contained in the 1993 U.S. Climate Change Action Plan. As with the emissions inventory, a detailed supplement was also submitted to the INC Secretariat on this material. That document, "The Climate Change Action Plan: Technical Supplement," has been published separately by the Department of Energy. The 1993 Action Plan aims to limit greenhouse gas emissions while continuing to guide the U.S. economy toward environmentally sound economic growth into the next century. The Plan is comprehensive, as it targets all greenhouse gases and all sectors of the economy through a portfolio of nearly fifty different actions. It is designed for rapid implementation by building on existing technologies, programs, and voluntary efforts to deliver cost-effective results. It is a coordinated federal response, involving several government agencies working together, and was developed through an interagency process. The Plan is being actively monitored to ensure that it meets the President's goals, and will be modified to adapt to changing circumstances. Finally, the Plan lays the foundation for an international response to climate change through the United States Initiative on Joint Implementation.

The combined effect of the U.S. actions, assuming 1993 economic predictions and full funding of all mitigation measures, would reduce greenhouse gas emissions to 1,459 million metric tons of carbon equivalent (MMTCE) by the year 2000, slightly below the 1990 level of 1,462 MMTCE. Without these mitigation policies, projected net greenhouse gas emissions would rise to 1,674 MMTCE. Since these policies were first developed and their effects projected, economic growth has been more robust, and oil prices lower than predicted in the Action Plan. These differences and other effects on meeting the projected emission reductions of the Plan are now being evaluated.

Chapter 5 of the USCAR examines the potential impacts of global climate change as well as strategies to adapt to any such change. Both adverse and beneficial consequences of climate change are plausible, with the overall effect depending on the rate and

magnitude of change and the vulnerability or sensitivity of human and natural systems to such changes. Possible consequences include rising sea levels, coastal zone erosion, shifts in precipitation patterns (causing either more floods or droughts), shifts in agricultural production, and increased stress on forest ecosystems.

Chapter 6 highlights current U.S. research and public education efforts regarding climate change. The U.S. Global Change Research Program, the largest climate change research program in the world, seeks both to expand knowledge about the processes that affect climate change and to develop integrated models to predict these effects. In addition to basic science research, the U.S. is promoting research in all economic sectors—including industry, transportation, housing, and agriculture—to develop strategies to reduce emissions. The United States is coordinating its research efforts with both international organizations and on a bilateral basis with individual countries.

To ensure that the public has a solid understanding of the science of climate change and the consequences of policy options, the U.S. is also continuing to develop its efforts to coordinate general education, communication, and information programs for the public. Educational outreach programs include GLOBE (Global Learning and Observations to Benefit the Environment) for K–12 students, and Project Earthlink, a long-term effort targeting community leaders, informal educators, teachers, students, journalists, and the general public.

International activities and cooperation regarding global climate change are discussed in Chapter 7. The Climate Convention requires all Parties to communicate a national inventory of greenhouse gas emissions and sinks and describe measures taken to implement the convention. To help developing countries meet this commitment, the U.S. initiated its Country Studies program in 1992. This program is providing technical and financial support to developing countries and countries with economies in transition to help them prepare studies to address climate change. Chapter 7 also highlights other ways in which the United States is implementing its financial commitments under the Convention, including numerous U.S. bilateral mitigation projects as well as multilateral cooperation through such organizations as the Global Environment Facility, multilateral development banks, the Organization of Economic Cooperation and Development, the

International Energy Agency, and the Asia-Pacific Economic Cooperation organization.

The final chapter of the Climate Action Report addresses future actions to address climate change. In this chapter, two important issues are raised: (1) the uncertainties in projecting the effectiveness of current actions to meet the U.S. domestic commitment to return greenhouse gas emissions to their 1990 levels by the year 2000, and (2) the long-term actions that must be taken to address global warming—as greenhouse gas emissions will continue to rise beyond the turn of the millennium.

#### Preparation of the Report

The U.S. Climate Action Report was prepared in a broad interagency process, incorporating—to the greatest extent possible—data from all relevant sectors and programs. Preliminary versions of the Report were circulated to nongovernmental organizations, including environmental and business groups, for their review and comment. Where possible, suggestions received were incorporated into this text.

#### Availability of the Report

Copies of the U.S. Climate Action Report may be purchased from the Superintendent of Documents, U.S. Government Printing Office (GPO), Post Office Box 37082, Washington, DC 20013-7082; tel: (202) 512-1800. The publication number for the Report is 0-16-045214-7. In addition, GPO will provide copies to federal depository libraries.

The text of the U.S. Climate Action Report will also be available electronically through:

- The Federal Bulletin Board Service (BBS) of the U.S. Government Printing Office which can be reached at (202) 512-1387. The Report can be found in the Department of State (DOS) environment library under "global issues".

- The Internet via gopher to [summit.fiu.edu](mailto:summit.fiu.edu) under Department of State (DOS) Reports.

#### Public Comment

The Framework Convention on Climate Change requires that Parties periodically prepare additional communications on their actions to address climate change. It is the U.S. intention to collect comments received on this first submission and on the basis of those comments—and additional actions being taken within the government—to prepare additional documents for submission.

For this reason, while the timing for subsequent submissions has not been

determined, written comments on the U.S. Climate Action Report are invited. Comments should be submitted to the Department of State no later than December 30, 1994. Comments or questions should be directed to: Mr. Daniel A. Reifsnnyder, Director, Office of Global Change, Room 4329-A, Department of State, 2201 C Street, N.W., Washington, D.C. 20520-7818; telephone: (202) 647-4069; fax: (202) 647-0191.

Dated: October 12, 1994.

**Ambassador Elinor Constable,**  
*Assistant Secretary, Bureau of Oceans and International Environmental and Scientific Affairs.*

[FR Doc. 94-26628 Filed 10-26-94; 8:45 am]  
BILLING CODE 4710-09-M

## DEPARTMENT OF TRANSPORTATION

### Federal Aviation Administration

#### Executive Committee of the Aviation Rulemaking Advisory Committee; Meeting

**AGENCY:** Federal Aviation Administration (FAA), DOT.

**ACTION:** Notice of meeting.

**SUMMARY:** The FAA is issuing this notice to advise the public of a meeting of the Executive Committee of the Federal Aviation Administration Aviation Rulemaking Advisory Committee.

**DATES:** The meeting will be held on November 15, 1994, at 10 a.m. Arrange for oral presentations by November 4, 1994.

**ADDRESSES:** The meeting will be held at the General Aviation Manufacturers Association, 1400 K Street, NW., Suite 801, Washington, DC, 10 a.m.

**FOR FURTHER INFORMATION CONTACT:** Miss Jean Casciano, Federal Aviation Administration (ARM-25), 800 Independence Avenue, SW., Washington, DC 20591, telephone (202) 267-9683; fax (202) 267-5075.

**SUPPLEMENTARY INFORMATION:** Pursuant to section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92-463; 5 U.S.C. App. II), notice is hereby given of a meeting of the Executive Committee to be held on November 15, 1994, at the General Aviation Manufacturers Association, 1400 K Street, NW., Suite 801, Washington, DC, 10 a.m. The agenda will include:

- An update on the FAA Regulatory Review.
- A status report on the revision of the ARAC procedures.
- A review of the September "all hands" meeting.

- A follow-up on open action items.
- Notable comments on specific issues.
- Other business.

Attendance is open to the interested public but will be limited to the space available. The public must make arrangements by November 4, 1994, to present oral statements at the meeting. The public may present written statements to the executive committee at any time by providing 25 copies to the Executive Director, or by bringing the copies to him at the meeting. In addition, sign and oral interpretation can be made available at the meeting, as well as an assistive listening device, if requested 10 calendar days before the meeting. Arrangements may be made by contacting the person listed under the heading **FOR FURTHER INFORMATION CONTACT**.

Issued in Washington, DC, on October 21, 1994.

**Chris A. Christie,**  
*Executive Director, Aviation Rulemaking Advisory Committee.*

[FR Doc. 94-26609 Filed 10-26-94; 8:45 am]  
BILLING CODE 4910-13-M

### Federal Highway Administration

#### Environmental Impact Statement; Smith County, TX

**AGENCY:** Federal Highway Administration (FHWA), DOT.

**ACTION:** Notice of intent.

**SUMMARY:** The FHWA is issuing this notice to advise the public that an environmental impact statement (EIS) will be prepared for a proposed new location highway project in Smith County, Texas.

**FOR FURTHER INFORMATION CONTACT:** John R. Mack, P.E., Acting District Engineer, Federal Highway Administration, Room 826, Federal Building, 300 East 8th Street, Austin, Texas 78701. Rodolfo J. Rivera, P.E., Director of Transportation Planning and Development, Texas Department of Transportation, P.O. Box 2031, Tyler, Texas 75710.

**SUPPLEMENTARY INFORMATION:** The FHWA, in cooperation with the Texas Department of Transportation (TxDOT), will prepare an environmental impact statement (EIS) on a proposal to construct the southern section of Loop 49, an approximately 40 mile circumferential controlled access highway around the urbanized area of Tyler in Smith County, Texas. The southern section of the proposed Loop 49 extends from State Highway 155 to State Highway 110 in southern Smith County. The length of the project varies.

depending on the selected alternative, from approximately 15.3 kilometers (9.5 miles) to 18.5 kilometers (11.5 miles). The proposed action is intended to provide access and increased mobility to the southern Tyler/Smith County area; to alleviate traffic congestion on existing roadways in urbanized Smith County; and to provide a safer, more convenient route for traffic travelling through the Tyler area.

Alternatives to the proposed action to be discussed in the EIS consist of (1) taking no action; and (2) improving existing roadways in the urbanized areas of Smith County. The build alternatives include three alternative alignments along new location rights-of-way connecting State Highway 155 to State Highway 110.

Impacts caused by the construction and operation of Loop 49 will vary according to the alternative alignments utilized. Generally, impacts would include the following: transportation impacts (construction detours, construction traffic, and mobility improvement), air and noise impacts from construction equipment and operation of the roadway, water impacts from construction area and roadway stormwater runoff, impacts to waters of the United States including wetlands from right-of-way encroachment, and impacts to residents and businesses based on potential relocations.

Letters describing the proposed action and soliciting comments will be sent to appropriate Federal, State, and local agencies, and to private organizations and citizens who have previously expressed interest in the proposal. A Major Investment Study has been completed in compliance with the Intermodal Surface Transportation Efficiency Act. In addition, several meetings have been held by the Loop 49 Steering Committee, composed of representatives of local governments, agencies, and interested organizations and citizens. A public meeting was held on October 13, 1994, at Robert E. Lee High School in Tyler, Texas, at which public comments on the proposed action and alternatives were requested. In addition, a public hearing will be held after publication of the Draft EIS. Public notice will be given of the time and place of the hearing. The Draft EIS will be available for public and agency review and comment prior to the public hearing.

To ensure that the full range of issues related to this proposed action are addressed and all significant issues identified, comments and suggestions are invited from all interested parties. Comments or questions concerning this proposed action and the EIS should be

directed to the FHWA or TxDOT at the addresses provided above.

(Catalog of Federal Domestic Assistance Program Number 20.205, Highway Research, Planning and Construction. The regulations implementing Executive Order 12372 regarding intergovernmental consultation on Federal programs and activities apply to this program).

Issued on: October 20, 1994.

**John R. Mack,**

*Acting District Engineer.*

[FR Doc. 94-26618 Filed 10-26-94; 8:45 am]

BILLING CODE 4910-22-M

### National Highway Traffic Safety Administration

[Docket No. EA92-041; Notice 1]

#### General Motors Pickup Truck Defect Investigation; Public Proceeding Scheduled

**AGENCY:** National Highway Traffic Safety Administration (NHTSA), DOT.

**ACTION:** Notice of initial decision and public meeting.

**SUMMARY:** NHTSA will hold a public meeting beginning at 10:00 a.m. on December 6, 1994 regarding the initial decision by the Secretary of Transportation that certain pickup trucks and other vehicles manufactured by General Motors Corporation (GM) contain a defect that relates to motor vehicle safety.

**FOR FURTHER INFORMATION CONTACT:** Ellen Berlin, Director, Office of Public and Consumer Affairs, National Highway Traffic Safety Administration, 400 Seventh Street, SW, Washington, DC 20590; (202) 366-9550.

**SUPPLEMENTARY INFORMATION:** Pursuant to 49 U.S.C. 30118(a) (formerly section 152(a) of the National Traffic and Motor Vehicle Safety Act of 1966, as amended, 15 U.S.C. 1412(a)), Secretary of Transportation Federico Peña has made an initial decision that model year 1973-1991 full-sized GM pickup trucks and cab-chassis equipped with fuel tanks mounted outboard of the frame rails contain a defect that relates to motor vehicle safety.

The rationale for this initial decision is set forth in the Engineering Analysis (EA) Report for EA92-041. The entire report, as well as the complete record on which the initial decision is based, are available for inspection during working hours (9:30 a.m. to 4:00 p.m.) in NHTSA's Technical Reference Library, Room 5108, 400 Seventh Street, SW, Washington, DC 20590. That record consists of the public files for EA92-041 and Defect Petition (DP) 92-016. The

Executive Summary of the EA Report is set out below.

#### Engineering Analysis Report—Executive Summary

This Engineering Analysis was opened on December 8, 1992, as a result of granting a petition from the Center for Auto Safety (CAS) and Public Citizen to "initiate a defect investigation into and recall all Chevrolet/GMC full-sized pickups (C/K-series) with fuel tank(s) \* \* \* mounted outboard of frame rails." The objective of the investigation was to determine whether certain model year 1970-1991 Chevrolet and GMC full-sized pickup trucks contain a defect that poses an unreasonable risk to safety, related to the danger of fires following crashes, with primary focus on side-impact crashes. In the investigation, the National Highway Traffic Safety Administration's (NHTSA) Office of Defects Investigation (ODI) conducted analyses of real-world accident data and performed laboratory crash tests of the subject and peer vehicles. ODI also addressed questions related to the compliance of these trucks with Federal Motor Vehicle Safety Standard (FMVSS) No. 301, "Fuel System Integrity." Additionally, ODI examined whether the fuel tanks and related components on the trucks were unduly affected by corrosion that could make them more likely to be involved in a fire.

On April 9, 1993, ODI sent a recall request letter to General Motors Corporation (GM), recommending that GM conduct a safety recall on GM trucks with fuel tanks mounted outside the frame rails (subject vehicles). That letter was based on two principal factors:

1. Real-world accident data in the Fatal Accident Reporting System (FARS) indicate that there is an increased risk of fatality caused by fire in side-impact crashes involving the subject vehicles compared to 1973-1987 Ford full-sized pickup trucks. That increased risk led to an estimate that, in 1993, an additional 5-6 fatalities would occur in side-impact crashes involving the subject vehicles compared to what would occur if those trucks had the same side-impact fire performance as full-sized Ford pickups.

2. Laboratory crash tests corroborated the findings from the real-world accident data analysis. That is, in certain comparable side-impact crash tests, GM fuel tanks leaked and Ford tanks did not. Further, these tests used instrumented test dummies. Dummy measurements indicate that humans could have survived the crash forces at the impact speeds at which the subject

vehicles leaked. While these speeds are well in excess of the impact speed specified in FMVSS No. 301, the results indicate the increased fire risk in the GM trucks in crashes that are otherwise survivable.

GM provided an extensive amount of data and arguments in response to the recall request letter. ODI has completed an exhaustive review and analysis of the GM submissions and has conducted a variety of additional analyses associated with issues involved in this investigation. These include:

- An assessment of the effect of corrosion on fuel tank leakage and fire performance in the subject vehicles;
- An analysis of non-fatal burn injuries in side-impact crashes involving the subject vehicles;
- An in-depth review of all available police accident reports and other records of side-impact, fire-involved fatal crashes involving the subject vehicles to assess the crash conditions and severity of each;
- An update of the FARS analysis that led to the April 9, 1993 recall request letter;
- An analysis of the reasonableness of GM's decision to design the subject vehicle with side-mounted fuel-tanks, given what GM knew about the safety risks associated with that design and the availability of feasible alternative designs; and
- An analysis of the information about the risk of post-crash fuel leaks that became available to GM during the time the subject vehicles were being manufactured.

#### Principal Findings

- A review of GM submissions, as well as ODI testing, indicates that there are no data on which to conclude that the GM trucks to which FMVSS No. 301 applied, when new, did not comply with the standard.
- There are no data to indicate a relationship between fuel tank corrosion and increased fire risk in the subject vehicles, either in side impacts or in non-crash incidents.
- Apart from the basic decision to locate the fuel tanks of the subject vehicles outside of the frame rails, many of the specific features of the design of the fuel storage system and the surrounding area have increased the likelihood of post-crash fuel fires in the subject vehicles.
- Based on a review of 1979-1993 accident data reflecting the performance of full-sized pickups in side-impact fatal crashes involving fire, occupants of the subject vehicles experienced 2.8 times as many fire-related fatalities (i.e., fatalities in crashes in which a fire

occurred) per million registered vehicle-years as occupants of Ford pickups and 2.5 times as many as occupants of Dodge pickups. Where the FARS code indicated that the most harmful event (MHE) of the crash was fire, the GM-to-Ford occupant fatality per million registered vehicle-years ratio is 3.4 to 1, and the GM-to-Dodge ratio is 6.1 to 1.

- Real-world accidents data do not support GM's contention that GM and Ford pickup trucks have comparable side-impact fire performance and that differences in driver demographics and driver behavior explain the difference in the rates of fire-related and MHE-fire fatalities in side-impact crashes for the GM and Ford pickups. This is demonstrated by the tremendous reduction in the rate of MHE-fire side-impact fatalities that occurred after GM moved the fuel tanks for these pickups inside the frame rails in model year 1988.

- Contrary to GM's contentions, the MHE coding in FARS is a reliable indicator of the number of fatalities actually caused by fire.

- FARS data indicate that, if past trends continue, there would be approximately five additional fatalities due to fire in side-impact crashes in 1994 compared to what would occur if the subject vehicles had the same side-impact fire performance as Ford full-sized pickups.

- Reports of non-fatal burn injuries indicate that, if past trends continue, there would be three to four additional non-fatal burn injuries in 1994 in side-impact crashes involving the subject vehicles compared to the Ford pickups.

- Laboratory crash data indicate that, at certain impact speeds and configurations, the subject vehicles will leak fuel in side impacts, while comparable Ford pickups will not.

- While the crash severities in fatal side-impact, fire-involved crashes involving the subject vehicles are far in excess of the severity specified in FMVSS No. 301, they are generally less than the severities that result in fires in fatal side-impact crashes involving the Ford pickups.

- GM was aware at the time it designed the subject vehicles in the early 1970s that side-mounted fuel tank design presented an increased risk of post-crash fuel fed fires in side impacts, compared to the risk associated with other feasible alternative designs. Moreover, GM obtained additional information demonstrating the increased risk associated with the side-mounted tanks during the 15-year period the subject vehicles were in production.

#### Principal Conclusions

- The increased risk of death and injury from fire in side-impact crashes involving the subject vehicles is a result of the design of their fuel storage system, primarily the location of the fuel tanks outside of the frame rails, supplemented by other features of the design.

- Given the state of the art at the time and GM's awareness of the likely consequences, it was unreasonable for GM to design the subject vehicles with fuel tanks outside the frame rails.

- The increased safety risk due to post-crash fires in the subject vehicles is unreasonable.

Therefore, on the basis of the entire investigative record, I have initially decided, pursuant to 49 U.S.C. 30118(a) (formerly section 152(a) of the National Traffic and Motor Vehicle Safety Act), that the subject vehicles contain a defect that relates to motor vehicle safety.

#### [End of Executive Summary]

Pursuant to 49 CFR 554.10, a public meeting will be held beginning at 10:00 a.m., on Tuesday, December 6, 1994 in Room 2230, Department of Transportation Building, 400 Seventh Street, SW, Washington, DC, at which time GM and all other interested persons will be afforded an opportunity to present information, views, and arguments on the issue of whether the vehicles covered by this initial decision contain a safety-related defect. NHTSA's Deputy Administrator, Christopher A. Hart, will preside at that public meeting.

Interested persons are invited to participate in this proceeding through written and/or oral presentations. Persons wishing to make oral presentations are requested to notify Ms. Judy Taylor, Office of Defects Investigation, National Highway Traffic Safety Administration, Room 5326, 400 Seventh Street, SW, Washington, DC 20590 (202) 366-2850, before the close of business on November 28, 1994. Such persons should indicate the approximate amount of time their presentation is expected to take and whether they will need any audio-visual equipment. Written comments may be submitted to the same address and must be received not later than the beginning of the meeting on December 6, 1994.

Authority: 49 U.S.C. 30118(a).

Issued on: October 21, 1994.

Federico Peña,

Secretary of Transportation.

[FR Doc. 94-26650 Filed 10-26-94; 8:45 am]

BILLING CODE 4910-59-M

**DEPARTMENT OF THE TREASURY****Internal Revenue Service**

[Delegation Order No. 205 (Rev. 7)]

**Delegation of Authority****AGENCY:** Internal Revenue Service (IRS), Treasury.**SUMMARY:** Authority to approve the interception of verbal wire and non-wire communications in Criminal Investigation.**EFFECTIVE DATE:** September 23, 1994.**FOR FURTHER INFORMATION CONTACT:** Pat Allen, CP:Cl:R, Room 7030, 1111 Constitution Ave., NW, Washington, DC 20224, telephone 202-622-5688 (not a toll-free call).

Pursuant to the Authority vested in the Commissioner of Internal Revenue by Department of the Treasury Order 150-10 and in accordance with a Memorandum from the Attorney General to the Heads and Inspectors General of Executive Department and Agencies (dated November 7, 1983), the authority to approve the interception of verbal wire and non-wire communications with the consent of at least one party to the communication is hereby delegated as follows:

1. The Deputy Chief Inspector; the Assistant Chief Inspector (Internal Security); and the Director and Deputy Director, National Operations Division (Criminal Investigation) are authorized to approve the interception of non-telephone conversations in all criminal investigations conducted by the Internal Revenue Service pursuant to the requirements set out in the Attorney General's November 7, 1983, memorandum.

2. Regional Inspectors may approve interception of non-telephone conversations when exigent circumstances preclude obtaining prior written approval from an otherwise designated official.

3. The Director, Office of Investigations (Internal Security); Assistant Regional Inspectors (Internal Security); Division Chiefs, Criminal Investigation; and the Director and Deputy Director, National Operations Division (Criminal Investigation) are authorized to approve the interception of telephone conversations in all criminal investigations conducted by the Internal Revenue Service.

4. Criminal Investigators (GS-1811 series) of the Internal Security or Criminal Investigation functions, or persons acting under the direction of Criminal Investigators, are authorized to use monitoring equipment to intercept verbal wire and non-wire

communications when approved by delegated officials in this Delegation Order.

5. This authority may not be redelegated.

6. Delegation Order No. 205 (Rev. 6), effective January 19, 1994, is superseded.

Dated: October 13, 1994.

James McGovern,

Acting Chief Compliance Officer.

[FR Doc. 94-26570 Filed 10-26-94; 8:45 am]

BILLING CODE 4830-01-U

**UNITED STATES INFORMATION AGENCY****Freedom Support Act—NIS Secondary School Initiative for School Linkages****ACTION:** Notice—Request for proposals.

**SUMMARY:** The Office of Citizen Exchanges, Division of the NIS Secondary School Initiative, of the United States Information Agency's Bureau of Educational and Cultural Affairs announces an open competition for an assistance award to conduct exchanges through the multiple secondary school linkage program with select countries of the NIS. The countries are Russia, Belarus, Ukraine, Kazakhstan, and Uzbekistan. Public or private non-profit organizations meeting the provisions described in IRS regulation 501(c)(3) may apply either to enhance/expand existing linkages or to develop new school linkage programs. Both models are described in the guidelines section of this solicitation. Applicants may submit a proposal for only one of the two models. All submissions must contain an Educator (teacher and/or administrator) exchange component AND a Student exchange component. Approximately one third of the grants awarded will be to promote the development of new linkages. Organizations asking for USIA funding for previously established linkages must demonstrate the value of the linkages to the NIS Secondary School Initiative program as well as show evidence that the linkage is designed to outlast USIA funding.

Overall funding and grant making authority for this program is contained in the Freedom Support Act (Pub. L. 102-391). These exchanges represent part of the activities for the NIS Secondary School Initiative and are subject to the availability of funding for the Fiscal Year 1995 program. Proposals for programs and projects must conform with Agency requirements and guidelines outlined in the Solicitation Package.

**ANNOUNCEMENT NAME AND NUMBER:** All communications with USIA concerning this announcement should refer to the above title and reference number E/P-95-25. This is a request for proposals for reciprocal exchanges based on multiple school linkages. Requests for proposals in support of other programs under the aegis of the NIS Secondary School Initiative are published separately.

**DATES:** Deadline for proposals: All copies must be received at the U.S. Information Agency by 5 p.m. Washington, D.C. time on Wednesday, December 21, 1994. Faxed documents will not be accepted, nor will documents postmarked on Wednesday, December 21, 1994 but received at a later date. It is the responsibility of each applicant to ensure that proposals are received by the above deadline. Subject to the availability of funding, grants will be awarded April 1, 1995 for exchanges to begin after August 1, 1995.

**FOR FURTHER INFORMATION CONTACT:** NIS Secondary School Division, E/PY, Room 314, U.S. Information Agency, 301 4th Street, S.W., Washington, D.C. 20547, telephone: (202) 619-6299; Fax: (202) 619-5311; e-mail irome@usia.gov to request a Solicitation Package, which includes more detailed award criteria, all application forms, and guidelines for preparing proposals, including specific criteria for preparation of the proposal budget. For specific questions or concerns regarding the solicitation, contact USIA Program Officer Diana Aronson. Interested applicants should read the complete Federal Register announcement before addressing inquiries to the USIA or submitting their proposals. Once the RFP deadline has passed, representatives of the USIA and the Division of NIS Secondary School Initiative may not discuss this competition in any way with applicants until after the Bureau proposal review process has been completed.

**ADDRESSES:** Applicants must follow all instructions given in the Solicitation Package and send only complete applications to: U.S. Information Agency Ref.: E/P-95-25, Office of Grants Management, E/XE, Room 336, 301 4th Street, S.W., Washington, D.C. 20547.

**SUPPLEMENTARY INFORMATION:** Pursuant to the Bureau's authorizing legislation, programs must maintain a non-political character and should be balanced and representative of the diversity of American political, social, and cultural life. "Diversity" should be interpreted in the broadest sense and encompass differences including but not limited to race, gender, ethnicity, religion,

geographic location, socio-economic status, and physical challenges. Applicants are strongly encouraged to adhere to the advancement of this principle.

**Overview:** The purpose of this program is to link a network of U.S. secondary schools with a network of schools in one or more NIS countries to serve as the basis for exchanges of Educators and Students during the academic year. The USIA's main objective is to foster interaction between American and foreign participants. Proposals should demonstrate how participants will interact in a way which encourages the exchange of ideas and promotes mutual understanding in both the short- and long-term. The linkages between networks of secondary schools in the U.S. with networks of schools in the NIS must occur through at least three main program components: (1) the Exchange of secondary school educators between the U.S. and participating NIS countries; (2) the exchange of secondary school students, and 14 to 17 years of age, between the U.S. and participating NIS countries; and, (3) the establishment of institution-building ties between the schools in the networks.

**Guidelines:** This solicitation is for two separate models of multiple secondary school linkages between networks of schools. Applicants must submit a proposal for only one of the two models. The proposal should state clearly which model is being used. In both models, each network, one in the U.S. and one in the NIS, should consist of a minimum of three schools.

**Model A** is designed to enhance and expand existing linkages between a network of U.S. secondary schools and a network of secondary schools in one or more of the countries listed above. USIA funding may not be used to supplant existing private sector funding. Applicants must indicate how activities have been funded in the past and how the activities will be expanded with assistance from USIA. The U.S. recipient of the grant is responsible for recruiting/selecting/organizing a minimum of three U.S. secondary schools to form the U.S. network, strengthening an existing working relationship with an organization or agency of government in the NIS responsible for a network of schools there, and linking the two networks through three main components of the program: Educator exchange, Student exchange, and Institution-building links.

**Model B** is designed to encourage the development of new links whereby the U.S. network that does not have existing

links to secondary schools in the NIS will be matched with an NIS network chosen by USIA. Proposals must rank-order participating NIS countries where the applicant would like to establish linkages. The U.S. recipient of the grant is responsible for recruiting/selecting/organizing a network composed of a minimum of three U.S. secondary schools, agreeing to form partnership with a NIS network selected by USIA, and linking the two networks through three main components of the program: Educator exchange, Student exchange, and Institution-building links.

In some special cases, applicants who are involved in existing linkage activity may request that USIA select new schools and networks in the NIS for a proposed expanded linkage. In this case, the applicant should rank-order the preferred countries to be considered for linkage. Depending on availability of suitable matches, USIA will select the NIS network or school and inform applicant of the match.

For both Model A and Model B, the U.S. recipient of the grant will: Design the overall plan which integrates the three components of the linkage, manage all travel arrangements, logistics, passports, visas, etc., provide competent and informed escorts for student groups, and distribute and account for grant funds.

Proposals must address other essential operations of the program including the incorporation of a feasible plan to establish communication (through computer linkages and other forms of correspondence) and the formation of a solid working relationship between the partner schools before the student groups arrive in the host country.

Recipients of the assistance award are responsible for ensuring the selection of exchange participants who are suitable for the program. Participants (both Educators and Students) from the U.S. and the NIS countries should represent a broad array of backgrounds to give greater understanding to the culture and society as a whole. Selection of individual participants from the U.S. and the NIS in the exchange components of the program must be merit based; the proposal should describe the mechanisms used for participant selection.

Partnerships should have an existence beyond the scope of this initiative; that is, there should be an inherent reason for their linkage apart from the availability of grant funds. Competitive proposals demonstrate this linkage and the types of activities (follow-on) that will continue after the grant has expired.

Applicants should be familiar with the "General Provisions" of J-1 visa regulations. The Agency will process the IAP-66 forms for travel to the U.S. Applicant must arrange for basic health and accident insurance coverage of exchange participants while they are on exchange.

Please refer to the Program Objectives, Goals, and Implementation section of the Solicitation Package for greater detail regarding the design of the component parts as well as other program information.

**Proposed budget:** Applicants must submit a comprehensive budget for the entire program. There must be a summary budget as well as a breakdown reflecting both the administrative budget and the program budget. All program costs should clearly indicate whether they cover U.S. or NIS participants.

Grants awarded to eligible organizations with less than four years of experience in conducting international exchange programs will be limited to \$60,000.

Please refer to the POGI and Proposal Submission Instructions sections of the Solicitation Package for complete budget guidelines and format instructions.

#### Review Process

USIA will acknowledge receipt of all proposals and will review them for technical eligibility. Proposals will be deemed ineligible if they do not fully adhere to the guidelines stated herein and in the Solicitation Package. Eligible proposals will be forwarded to panels of USIA officers for advisory review. All eligible proposals also will be reviewed by the Agency contracts office, as well as the pertinent USIA area office and the USIA post overseas, where appropriate. Proposals may be reviewed by the Office of the General Counsel or by other Agency elements. Funding decisions are at the discretion of the USIA Associate Director for Educational and Cultural Affairs. Final technical authority for grant awards resides with the USIA grants officer.

#### Review Criteria

Technically eligible applications will be competitively reviewed according to the criteria stated below. These criteria are not rank ordered and all carry equal weight in the proposal evaluation:

1. **Quality of the program idea:** Proposals should exhibit originality, substance (particularly in academic/educational aspects), precision, and relevance to Agency mission.
2. **Program planning:** Detailed agenda and relevant work plan should

demonstrate substantive undertakings and logistical capacity. Agenda and plan should adhere to the program overview and guidelines described above.

**3. Ability to achieve program objectives:** Objectives should be reasonable, feasible, and flexible. Proposals should clearly demonstrate how the institution will meet the program's objectives and plan.

**4. Multiplier effect/impact:** Proposed programs should strengthen long-term mutual understanding, including maximum sharing of information and establishment of long-term individual and institutional linkages.

**5. Support of diversity:** Proposals should demonstrate the recipient's commitment to promoting the awareness and understanding of diversity.

**6. Institutional capacity:** Proposed personnel and institutional resources should be adequate and appropriate to achieve the program or project's goals.

**7. Institution's record/ability:** Proposals should demonstrate an institutional record of successful exchange programs, including responsible fiscal management and full compliance with all reporting requirements for past Agency grants as determined by USIA's Office of Contracts. The Agency will consider the past performance of prior recipients and the demonstrated potential of new applicants.

**8. Follow-on activities:** Proposals should provide a plan for continued

follow-on activity (without USIA support) which ensures that USIA supported programs are not isolated events. Proposal should demonstrate how activity will contribute to institution-building in the NIS.

**9. Project evaluation:** Proposals should include a plan to evaluate the program, both as the activities unfold and at the end. USIA recommends that the proposal include a draft survey questionnaire or other technique plus description of a methodology for use in linking outcomes to original project objectives. Award-receiving organizations/institutions will be expected to submit intermediate reports after each project component is concluded or quarterly, whichever is less frequent.

**10. Cost-effectiveness:** The overhead and administrative components of the proposal, including salaries and honoraria, should be kept as low as possible. All other items should be necessary and appropriate.

**11. Cost-sharing:** Proposals should maximize cost-sharing through other private sector support as well as institutional direct funding contributions.

**12. Value to U.S.-partner country relations:** Proposed projects will be reviewed by USIA's geographic area desk officer and overseas officers to assess the relevance to program need, potential impact, and significance in the partner country(ies).

**13. Selection process:** Proposals should provide a specific plan to ensure a selection based on merit and should include detailed criteria for selection of U.S. and NIS teacher and administrator as well as U.S. and NIS student participants.

#### Notice

The terms and conditions published in this RFP are binding and may not be modified by any USIA representative. Explanatory information provided by the Agency that contradicts published language will not be binding. Issuance of the RFP does not constitute an award commitment on the part of the Government. The needs of the program may require the award to be reduced, revised, or increased. Final awards cannot be made until funds have been appropriated by Congress, allocated and committed through internal USIA procedures.

#### Notification

All applicants will be notified of the results of the review process on or about February 15, 1995. Awards made will be subject to periodic reporting and evaluation requirements.

Dated: October 19, 1994.

**John P. Loiello,**

*Associate Director, Educational and Cultural Affairs.*

[FR Doc. 94-26456 Filed 10-26-94; 8:45 am]

BILLING CODE 8230-01-M

# Sunshine Act Meetings

Federal Register

Vol. 59, No. 207

Thursday, October 27, 1994

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).

## FARM CREDIT ADMINISTRATION

Farm Credit Administration Board;  
Amendment to Sunshine Act Meeting

**SUMMARY:** Pursuant to the Government in the Sunshine Act (5 U.S.C. 552b(e)(3)), the Farm Credit Administration gave notice on October 12, 1994 (59 FR 51668) of the regular meeting of the Farm Credit Administration Board (Board) scheduled for October 13, 1994. This notice is to amend the agenda by removing an item from the closed session of that meeting.

**FOR FURTHER INFORMATION CONTACT:** Curtis M. Anderson, Secretary to the Farm Credit Administration Board, (703) 883-4003, TDD (703) 883-4444.

**ADDRESS:** Farm Credit Administration, 1501 Farm Credit Drive, McLean, Virginia 22102-5090.

**SUPPLEMENTARY INFORMATION:** Parts of this meeting of the Board were open to the public (limited space available), and parts of this meeting were closed to the public. The closed session of the agenda for October 13, 1994, is amended as follows:

### Closed Session \*

#### A. New Business

#### 2. Other

##### a. Proposed FY 1996 Budget

Dated: October 21, 1994.

Floyd Fithian,

Acting Secretary, Farm Credit Administration Board.

\* Session closed—Exempt pursuant to 5 U.S.C. 552b(c)(9).

[FR Doc. 94-26738 Filed 10-25-94; 11:47 am]

BILLING CODE 6705-01-P

## FEDERAL ELECTION COMMISSION

"FEDERAL REGISTER" NUMBER: 94-26206.

**PREVIOUSLY ANNOUNCED DATE AND TIME:** Thursday, October 27, 1994, at 10:00 a.m., meeting open to the public.

**THE FOLLOWING ITEM WAS ADDED TO THE AGENDA:** Advisory Opinion 1994-30: Edward D. Feigenbaum on behalf of Conservation Concepts, Inc. (continued from meeting of October 20, 1994).

**DATE AND TIME:** Tuesday, November 1, 1994 at 10:00 a.m.

**PLACE:** 999 E Street, N.W., Washington, D.C.

**STATUS:** This meeting will be closed to the public.

### ITEMS TO BE DISCUSSED:

Compliance matters pursuant to 2 U.S.C. § 437g.

Audits conducted pursuant to 2 U.S.C. § 437g, § 438(b), and Title 26, U.S.C.

Matters concerning participation in civil actions or proceedings and arbitration.

Internal personnel rules and procedures or matters affecting a particular employee.

**DATE AND TIME:** Thursday, November 3, 1994 at 10:00 a.m.

**PLACE:** 999 E Street, N.W., Washington, D.C. (Ninth Floor).

**STATUS:** This meeting will be open to the public.

### ITEMS TO BE DISCUSSED:

Correction and Approval of Minutes.

Final Approval of the National Voter Registration Form.

Regulation:

MCFL Rulemaking: Summary of Comments and Draft Final Rules:

Candidate Debates (11 CFR 110.13, 114.4(f))

Candidate Appearances on Educational Institution Premises (11 CFR 114.4(c)(7))

Voting Records (11 CFR 114.4(c)(4))

Voter Guides (11 CFR 114.14(c)(5))

Voter Drives (11 CFR 114.4(d) and

114.3(c)(4))

Voter Communications (11 CFR 114.4(c)(2), (3))

Administrative Matters.

### PERSON TO CONTACT FOR INFORMATION:

Ron Harris, Press Officer, Telephone: (202) 219-4155.

Delores Hardy,

Administrative Assistant.

[FR Doc. 94-26788 Filed 10-25-94; 3:09 pm]

BILLING CODE 6715-01-M

## SECURITIES AND EXCHANGE COMMISSION

Notice is hereby given, pursuant to the provisions of the Government in the Sunshine Act, Pub. L. 94-409, that the Securities and Exchange Commission will hold the following meetings during the week of October 31, 1994.

An open meeting will be held on Tuesday, November 1, 1994, at 10:00 a.m., in Room 1C30. A closed meeting will be held on Wednesday, November 2, 1994, at 10:00 a.m.

Commissioners, Counsel of the Commissioners, the Secretary to the

Commission, and recording secretaries will attend the closed meeting. Certain staff members who have an interest in the matters may also be present.

The General Counsel of the Commission, or his designee, has certified that, in his opinion, one or more of the exemptions set forth in 5 U.S.C. 552b(c) (4), (8), (9)(A) and (10) and 17 CFR 200.402(a) (4), (8), (9)(i) and (10), permit consideration of the scheduled matters at a closed meeting.

Commissioner Roberts, as duty officer, voted to consider the items listed for the closed meeting in a closed session.

The subject matter of the open meeting scheduled for Tuesday, November 1, 1994, at 10:00 a.m., will be:

1. Consideration of whether to adopt Rule 3a12-11 under the Securities Exchange Act of 1934 ("Exchange Act") exempting debt securities listed on a national securities exchange from the restrictions on borrowing of Section 8(a) and most of the proxy, shareholder communications, and information statement rules of Sections 14(a), 14(b), and 14(c) of the Exchange Act. In addition, consideration of whether to adopt amendments providing for the automatic effectiveness of Form 8-A registration statements for listed debt securities and the elimination of the filing fee associated with Form 8-A registration statements for listed debt. For further information, please contact Beth Stekler at (202) 942-0190; with regard to issues relating to the proxy rules or Form 8-A, contact Joseph P. Babits at (202) 942-2910.

2. Consideration of whether to propose amendments that would: (1) Expand the categories of legal proceedings involving directors, executive officers, controlling persons, significant shareholders and specified others, required to be disclosed in various filed documents; (2) extend the reporting period for such disclosure from the current five years to 10 years; (3) conform provisions of forms and schedules that currently require disclosure of legal proceedings; and (4) add legal proceedings disclosure provisions to registration statement forms used by registered investment companies. For further information, please contact Jim Budge at (202) 942-2846.

3. Consideration of whether to issue a concept release requesting comments on modernization of the regulation of public-utility holding companies. The concept release relates to the Commission's thorough reevaluation of the Public Utility Holding Company Act of 1935 as a result of developments in recent years. For further information, please contact Joanne C. Rutkowski at (202) 942-0545.

The subject matter of the closed meeting scheduled for Wednesday, November 2, 1994, at 10:00 a.m., will be:

- Institution of administrative proceedings of an enforcement nature.
- Institution of injunctive actions.
- Settlement of administrative proceedings of an enforcement nature.
- Settlement of injunctive action.
- Opinions.

At times, changes in Commission priorities require alterations in the scheduling of meeting items. For further information and to ascertain what, if any, matters have been added, deleted or postponed, please contact: The Office of the Secretary (202) 942-7070.

Dated: October 24, 1994.

**Jonathan G. Katz,**

*Secretary.*

[FR Doc. 94-26696 Filed 10-24-94; 4:25 pm]

BILLING CODE 8010-01-M

# Corrections

Federal Register

Vol. 59, No. 207

Thursday, October 27, 1994

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.

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## DEPARTMENT OF ENERGY

### Federal Energy Regulatory Commission

[Docket No. ER94-1673-000, et al.]

#### PECO Energy Company, et al.; Electric Rate and Corporate Regulation Filings

##### Correction

In notice document 94-24964 beginning on page 51425 in the issue of Tuesday, October 11, 1994 make the following correction:

On page 51426, in the first column, under entry 5., the Docket No. should read "[Docket No. ER94-1677-000]".

BILLING CODE 1505-01-D

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## DEPARTMENT OF ENERGY

### Federal Energy Regulatory Commission

[Docket No. RP94-420-000]

#### Proposed Changes in FERC Gas Tariff; Boundary Gas, Inc.

##### Correction

In notice document 94-24969 appearing on page 51431 in the issue of Tuesday, October 11, 1994 the Docket No. was omitted and should read as set forth above.

BILLING CODE 1505-01-D

## SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-34729; File No. SR-NSCC-94-16]

### Self Regulatory Organizations; National Securities Clearing Corporation; Notice of Filing of Proposed Rule Change Modifying Comparison Procedures for Corporate Bond and Unit Investment Trust Transactions and Modifying the Fee Structure for Correction Fees

##### Correction

In notice document 94-24517 beginning on page 50634 in the issue of Tuesday, October 4, 1994 make the following correction:

On page 50636, in the first column, above the FR Doc. line, the signature was omitted and should read as set forth below.

Margaret H. McFarland,  
Deputy Secretary.

BILLING CODE 1505-01-D

# Federal Register

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Thursday  
October 27, 1994

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Part II

Department of  
Health and Human  
Services

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Food and Drug Administration

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21 CFR Part 600  
Adverse Experience Reporting  
Requirements For Licensed Biological  
Products; Final Rule

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

**21 CFR Part 600**

[Docket No. 85N-0506]

RIN 0905-AB53

**Adverse Experience Reporting Requirements for Licensed Biological Products**

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

**SUMMARY:** The Food and Drug Administration (FDA) is amending the regulations to require manufacturers of licensed biological products (hereinafter referred to as licensed manufacturers) to report to FDA within 15 working days all adverse experiences associated with the use of a biological product that are both serious and unexpected; any significant increase in the frequency of a serious, but expected adverse experience; periodically, all other adverse experiences; and product distribution and disposition data. FDA is taking this action to provide a mechanism under which licensed manufacturers would inform the agency, on a timely basis, of any unanticipated safety problems with marketed biological products.

**EFFECTIVE DATE:** This regulation is effective December 27, 1994.

**ADDRESSES:** Copies of Form FDA-3500A may be obtained from the Center for Biologics Evaluation and Research (HFM-210), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852-1448. Additional copies of the form may be obtained from the Consolidated Forms and Publications Distribution Center, 3222 Hubbard Rd., Landover, MD 20785. Copies of the VAERS form may be obtained from the Vaccine Adverse Event Reporting System (VAERS) by calling 1-800-822-7967.

All reports required by this regulation pertaining to nonvaccine biological products should be sent to the Center for Biologics Evaluation and Research (address above). All reports required by this regulation pertaining to vaccines should be sent to VAERS, P.O. Box 1100, Rockville, MD 20849-1100.

**FOR FURTHER INFORMATION CONTACT:** Paula S. McKeever, Center for Biologics Evaluation and Research (HFM-635), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1448, 301-594-3074.

**SUPPLEMENTARY INFORMATION:**

**I. Introduction**

In the *Federal Register* of April 24, 1979 (44 FR 24233), FDA made available for public comment a draft proposed regulation that would require the maintenance of records and submission of reports of adverse experiences involving licensed biological products. After evaluating the comments received and analyzing other information, FDA issued a proposed regulation (hereinafter referred to as the 1990 proposal) and notice of availability of a draft guideline in the *Federal Register* of March 29, 1990 (55 FR 11611 and 11655, respectively). The 1990 proposal was to require all manufacturers of licensed biological products to submit the following reports to FDA: (1) Alert reports within 15 working days of receipt of adverse experiences associated with the use of a licensed biological product that are both "serious and unexpected," and of any "significant increase in frequency" of an adverse experience that is both "serious and unexpected;" and (2) periodic reports of all adverse experiences, including both serious and nonserious adverse experiences, that are not included in a 15-day Alert report. The statutory authority for promulgating these regulations was described in detail in the preamble to the 1990 proposal (55 FR 11611 at 11613). The agency provided 60 days for interested persons to submit written comments on the 1990 proposal.

Prior to promulgation of this final rule, only adverse experiences associated with certain childhood vaccines (see 53 FR 10565, April 1, 1988) and fatalities resulting from blood collection or transfusion (§ 606.170 (21 CFR 606.170)) were required to be reported to FDA for biological products. Although many manufacturers of other types of biological products voluntarily submit adverse experience reports to FDA, there has not necessarily been consistent or complete reporting from all licensed manufacturers.

In the *Federal Register* of June 3, 1993 (58 FR 31596), FDA issued a notice announcing the availability of a new form for reporting adverse events and product problems with human drug products, biologic products, medical devices, special nutritional products, and other products regulated by FDA. One version of the form (FDA Form 3500) was made available for use by health professionals for voluntary reporting; the other version of the form (FDA Form 3500A) was made available for use by user facilities, distributors, and manufacturers for reporting that is required by statute or by FDA

regulation. The new form is part of an FDA MEDWATCH program which is intended to consolidate and simplify reporting of adverse events and product problems for all FDA-regulated products.

Many of the comments received in response to the 1990 proposal, while having merit, if implemented would require changes to the regulations governing the reporting of adverse experiences for biologic products which would cause these requirements to diverge significantly from the requirements and reporting program for drugs as provided in §§ 310.305 and 314.80 (21 CFR 310.305 and 314.80). Such a divergence would be contrary to the MEDWATCH program which is intended, in part, to enhance consistency in the reporting and collection of information on adverse experiences related to FDA-regulated products. Rather than making such significant changes in this final rule, FDA is issuing a notice of proposed rulemaking elsewhere in this issue of the *Federal Register* which would appropriately amend the requirements in §§ 310.305, 312.32 (21 CFR 312.32), and 314.80 for reporting of adverse experiences related to human drugs and the requirements in this final rule (§§ 600.80 and 600.81) for reporting adverse experiences related to biological products. Later in this preamble, in response to a number of public comments which request significant changes to the regulations, FDA refers to the proposed rule which provides a more substantial discussion of the issues involved.

Elsewhere in this issue of the *Federal Register*, FDA is also announcing the availability of a guideline entitled "The Guideline for Adverse Experience Reporting for Licensed Biological Products" (referred to as "guideline" in this final rule). The guideline discusses in detail the reports required by this rule, and provides guidance concerning some appropriate means of meeting the reporting requirements.

**II. Highlights of the Final Rule**

This final rule establishes procedures under §§ 600.80 and 600.81 for licensed manufacturers to inform FDA about adverse experiences that are associated with the use of a licensed biological product and about biological product distribution. These procedures are intended to support the agency's efforts to protect the public safety by providing the agency with the information necessary for effective postmarket surveillance of biological products. This final rule requires licensed manufacturers of biological products to

submit various reports to the agency and specifies the timeframes for submission of these reports. The reports are: (1) Fifteen-day Alert reports, (2) increased frequency alert reports, (3) periodic adverse experience reports and (4) distribution reports. The timeframes and contents of these adverse experience reports were the subject of numerous comments, which are discussed below. In addition to the reporting requirements, the final rule specifies record-keeping requirements, provides for exemptions of two categories of biological products, provides a disclaimer regarding causality, and provides for license revocation if licensed manufacturers fail to establish and maintain records and submit the required reports. In addition, this final rule provides procedures, under § 600.90, for applying for waivers from any of the reporting requirements.

The requirements in this final rule are consistent with existing requirements in §§ 314.80 and 314.81 (21 CFR 314.81) regarding approved new drug products, except when differences are necessary to accommodate laws, terminology, procedures, and characteristics unique for biological products.

#### A. Scope

The new procedures apply to all licensed manufacturers of biological products and any person, other than the licensed manufacturer of a biological product, whose name appears on the label of a licensed biological product as a manufacturer, packer, distributor, shared manufacturer, joint manufacturer, or a participant in divided manufacturing.

#### B. Format

The format of § 600.80 has been revised from what was proposed to be consistent with § 314.80. FDA believes that the revised format will reduce the burden for manufacturers following the regulations for both drug and biological products.

### III. Comments on the Proposed Rule and FDA Responses

FDA received 15 letters of comment on the proposed rule. Most letters contained numerous comments on various areas of the proposed rule. Four of these comments supported codification of the reporting requirements for adverse experiences associated with biological products. Other comments either addressed particular paragraphs in the proposed regulation or dealt with the effect of the regulation on a particular type of biological product. In addition to the amendments discussed below, editorial

changes were made throughout the rule. A summary of these comments and the agency's responses follow:

#### A. General Comments

##### 1. Consistency With Section 314.80

Two comments on § 600.80 recognized the reporting issues unique to biological products and were supportive of both the 1990 proposal and the draft guideline for recognizing the differences between drugs and biological products. In contrast, four comments requested that FDA not deviate from the rules and guidelines applicable to drugs and requested that the regulations for reporting adverse experiences for biological products mirror the regulations for drugs.

FDA intends these rules to be consistent with other agency initiatives and requirements regarding adverse experience reporting for drugs and medical devices wherever practical. This is demonstrated by the new adverse experience reporting Form FDA-3500A, which, with the exception of adverse experience reports associated with vaccines, is to be used for reporting of adverse events associated with drugs, biologics, and certain other products regulated by FDA. The final rule contains requirements unique to biological products only when necessary to accommodate the laws applicable only to biological products, such as vaccines, or to accommodate special characteristics of biological products.

##### 2. Agency Review of Adverse Experience Reports

One comment requested that the unit of FDA responsible for receiving adverse experience reports for drugs continue to be responsible for the adverse experiences for biologics to assure consistency of interpretation of the regulations and dissemination of information within FDA.

The agency intends to maintain consistency between the Center for Biologics Evaluation and Research (CBER) and the Center for Drugs Evaluation and Research (CDER) in the interpretation of the regulations, especially with respect to terminology. A separate unit was created with the responsibilities related to postmarketing surveillance of licensed biological products because the agency recognizes that these products can present different safety concerns due to inherent differences in the products. In addition, the National Childhood Vaccine Injury Act of 1986 (NCVIA) mandated specific reporting requirements for manufacturers of certain vaccines and

for health care providers administering those vaccines. VAERS was established to receive these required reports, as well as reports on other vaccines. The VAERS program is administered jointly by FDA and by the Centers for Disease Control and Prevention (CDC) and replaces previous vaccine reporting systems within both agencies. Section 600.80(c) has been amended in the final rule to reflect the change of address for submitting reports due to the reorganization and relocation of CBER.

##### 3. Clarification of Overlap Between the Vaccine Adverse Event Reporting System and § 600.80

Comments were received requesting clarification of overlap between the requirements of NCVIA and the regulations.

NCVIA created a new Title XXI of the Public Health Service Act (the PHS Act). Section 2125 of the PHS Act (42 U.S.C. 300aa-25) requires health care providers who administer certain vaccines and manufacturers of the vaccines to report specified adverse experiences, occurring within specified time intervals after administration of the vaccines. These adverse experience reports are submitted to VAERS, which is jointly managed by FDA and CDC and became operational on November 1, 1990. A form VAERS-1 was developed for these reports. When the requirements set forth in both § 600.80 and NCVIA necessitate reporting of an adverse event, licensed manufacturers of vaccines are not required to submit duplicate reports to VAERS and FDA. Submission of the report to VAERS is sufficient. However, licensed manufacturers of vaccines must comply with the regulations in § 600.80. Therefore, any requirements in these regulations that are in addition to those specified in the NCVIA must be satisfied. For example, although NCVIA does not specify the time periods for submission of adverse experience reports, the time periods set forth in § 600.80 apply to reports being submitted to VAERS.

##### 4. Requests for Waivers

Six comments requested waivers from the reporting requirements for specific types of adverse experiences or for certain categories of biological products. These requests for waivers were with respect to parts or all of the requirements of proposed § 600.80. In addition, one comment requested that the final rule specify the provisions for requesting a waiver.

The agency agrees that the provisions for a waiver should be specified in the final rule and has added a new § 600.90 describing the procedures for requesting

a waiver. Section 600.90 is similar to § 314.90 (21 CFR 314.90), the provision for waivers for drugs or antibiotics. Manufacturers and other interested persons should submit requests for waivers as provided in § 600.90 of the final rule.

#### 5. Economic Assessment

One comment requested clarification of FDA's estimate of the cost of complying with the reporting requirements of the proposed rule of approximately \$255,490. The company estimates that its cost in labor and overhead would be approximately \$40,000. In contrast, another comment stated that the company did not anticipate that this reporting requirement would significantly alter the manner in which companies would share their postmarketing information with FDA.

The agency's assessment of cost was made over 4 years ago when both the number of approved biological products was fewer and costs somewhat less. In addition, the agency's figures did not take into account overhead and other costs associated with basic manufacturing practices. Every responsible manufacturer and distributor, regardless of the type of product manufactured, implements a means to receive inquiries about the quality and adverse effects of its products as good manufacturing practices and as an accepted part of doing business. Therefore, this cost has not been included in assessing the cost of this regulation. The costs assessed for this regulation only related to the specific costs incurred by the requirements in the regulation which are in addition to customary business practice. The costs of the regulation are for preparation of the specific reports and analyses required by the regulation and do not include the normal operating and overhead costs of doing business. The revised economic assessment is discussed at the end of this preamble.

#### B. Definitions Section 600.80(a)

##### 1. Adverse Experience

Four comments requested clarification of the definition of "adverse experience" in proposed § 600.80(a), particularly the phrase "significant failure of expected pharmacologic action \* \* \* whether or not considered product related." One comment stated that the word "significant" has one meaning in the definition of "adverse experience" and another statistical meaning in the usage of the term "increased frequency" in proposed § 600.80(c)(1)(ii) and

requested that the word be used consistently with the same meaning throughout the regulation. Another comment requested a definition of "significant failure" as used in the definition of adverse experience. One comment requested that the definition be amended to require reporting of changes in failure rates instead of any significant failure. One comment gave the following examples of incidents that would be considered an adverse experience with any significant failure: a patient who dies of acute myocardial infarction in spite of thrombolytic therapy; or a patient who dies of congestive heart failure despite diuretic therapy, i.e., deaths from progression of the indicated disease. One comment stated that it concurs with the agency's definition of "adverse experience" because it does not include "loss of response" as an adverse experience. The comment goes on to state that loss of immunity over time from a vaccine is not logically an adverse event.

The agency agrees that the word "significant" when used in this context is a source of confusion and ambiguity. To eliminate this source of confusion and to encourage the reporting of all adverse experiences, FDA revised § 314.80 to delete the word "significant" from the definition of "adverse experience" in the reporting requirements for drugs (see 57 FR 17950, April 28, 1992) and is revising the definition of "adverse experience" in this final rule by deleting the word "significant."

The agency is retaining the proposed language in the definition of "adverse experience" instead of adopting the suggestion to require reporting only of changes in failure rate because a "change in failure rate" can only be determined retrospectively. A change in failure rate is to be reported in an increased frequency report; however, a failure of expected pharmacologic action that causes a serious and unexpected adverse experience in humans should be reported within 15 days regardless of the rate of such reports.

The agency believes that the examples given may or may not indicate a "failure of expected pharmacologic action." For example, patients with congestive heart failure often have irreparable kidney damage which even the most potent diuretics cannot overcome. In such a situation congestive heart failure would not be a failure of expected pharmacologic action. However, the extent of pre-existing kidney damage and the degree to which kidney failure may be expected would be demonstrable through kidney function

tests prior to medication. Therefore, FDA is not amending the definition of adverse experience as requested.

The agency agrees partially with the comment regarding "loss of response." If loss of immunity over time is the expected pharmacologic action of the vaccine, then it is not an adverse experience. If loss of immunity is due to a patient's compromised immune system, this also would not be considered an adverse experience. However, loss of immunity due to an unexpected failure of the pharmacologic action of the vaccine, thereby leaving recipients susceptible to a communicable disease, is an adverse experience and should be reported. The guideline points out that for purposes of adverse events reporting, "lack of effect" is generally synonymous with "failure to produce the expected pharmacologic action." Certain products are indicated for immunization through a recommended course of several doses to achieve a specified level of antibody titer to provide seroprotection. In this case, "lack of effect" is synonymous with "failure to produce the expected pharmacologic action" only when adequate seroconversion is not achieved following the final dose.

##### 2. Blood Components

One comment noted that the language in the proposed § 600.80(l)(1) and preamble refers to blood components yet the section of the CFR upon which the exemption is predicated (§ 606.170) refers to blood products. The comment specifically asked whether albumin and immunoglobulin are exempt from the rule and requested clarification of the meaning of blood component in § 600.80(a).

FDA is clarifying the regulations by adding in § 600.80(a) of the final rule a reference to 21 CFR 606.3(c), which defines a "Blood Component" as "that part of a single-donor unit of blood separated by physical or mechanical means." The exemption in § 600.80(l), for reporting adverse experiences associated with blood components, does not include products derived from pooled blood such as albumin or immunoglobulin. Therefore, albumin and immunoglobulin are biological products subject to this rule.

In a future issue of the Federal Register FDA intends to propose revisions to § 606.170, concerning reports related to blood collection or transfusion.

##### 3. Disability

Two comments requested that a definition for "disability" be included in § 600.80(a) as the phrase

"permanently disabling" is used in the definition of "serious."

The agency agrees that the term "disability" should be defined and is proposing a definition in the notice of proposed rulemaking found elsewhere in this issue of the **Federal Register**.

#### 4. Increased Frequency

Four comments on proposed § 600.80(a) requested clarification of the definition for "increased frequency." Two comments stated that the proposed definition of "increased frequency," as an increase in the rate of occurrence, is misleading inasmuch as the rate of occurrence cannot be determined by a spontaneous reporting system. Two comments requested that the definition of increased frequency take into account an adjustment for product exposure.

The agency agrees with these comments and is revising the definition in § 600.80(a) as follows: "Increased frequency means an increase in the rate of occurrence of a particular adverse biological product experience, after appropriate adjustment for exposure to the biological product."

#### 5. Life Threatening

One comment requested that a definition for "life threatening" be included, similar to that found in 21 CFR 312.32.

The agency agrees and is proposing a definition of "life threatening" in the notice of proposed rulemaking found elsewhere in this issue of the **Federal Register**.

#### 6. Serious

Three comments noted discrepancies between the preamble, § 600.80(a) of the proposed rule, reporting form FDA-1639, and the draft guideline regarding the meaning of the term "serious." The discrepancies consisted of differences in scope regarding the reportability of overdose, prolonged hospitalization, and severe disability.

To clarify the discrepancies concerning "overdose," the agency reevaluated the definition of "serious" to determine whether all overdoses should be included in the definition and determined that not all overdoses are serious.

In resolving the discrepancies in the definition of "serious" regarding inpatient hospitalization, the agency determined that prolonged inpatient hospitalization should be included as a serious adverse event. FDA is proposing a revision of the definition of "serious" to exclude the term "overdose" and to include "requires or prolongs inpatient hospitalization" in the notice of

proposed rulemaking found elsewhere in this issue of the **Federal Register**.

The term "disability" is discussed in section III.B.3 of this preamble.

#### 7. Significant

One comment requested that a definition for the word "significant" which compensates for changes in use patterns be included in § 600.80(a). The comment is in reference to the use of the term "significant" in the increased frequency alert reports.

The agency agrees in part with this comment. The agency considers "significant" in this context to mean a noticeable or measurable increase in frequency after adjustment for documented changes in use patterns. However, the agency is not codifying this definition in § 600.80(a) because "significant" may have a different meaning in a different context within adverse experience reporting. The guideline provides clarifying examples utilizing a formula and table to determine if there is a significant increase in frequency of an adverse experience.

#### 8. Clarification Between Product Defects and Adverse Experiences

One comment requested clarification regarding the definitions in § 600.80(a) for adverse experiences and the reporting of product defects.

The definition of "adverse experience" in § 600.80(a) specifies that the adverse experience must be "associated with the use of a biological product in humans \* \* \*." Therefore, product defects either discovered in the manufacturing process or not associated with an adverse experience in humans are not subject to this regulation. These defects may be reportable under good manufacturing practice regulations covered in 21 CFR 600.14. However, product defects which result in an adverse experience in a human are subject to reporting under § 600.80.

#### C. Review of Adverse Experiences Section 600.8(b)

##### 1. Reported by Scientific Papers or Competitors

One comment on proposed § 600.80(b) stated that to place responsibility on the licensed manufacturer for review of all adverse experience information pertaining to its product from any source, including published and unpublished scientific papers, is both time consuming and possibly open to abuse by competitors. The comment went on to state that if an unsubstantiated mailing from a competitor alleged "adverse or

unexpected experiences," the licensed manufacturer becomes subject to the entire 15-day alert procedures, including the need to conduct, if not actually report to FDA, the followup investigation. One comment asked the agency to specify the degree of vigor that licensed manufacturers should use to pursue reports of adverse experiences in the scientific literature.

Section 600.80(b) is not intended to require licensed manufacturers to discover every published and unpublished report on its product. However, once a report of an adverse experience is made known to the licensed manufacturer, it is the licensed manufacturer's responsibility to comply with the requirements in § 600.80 regardless of the source of the adverse experience report. It is acceptable for the licensed manufacturer to come to the conclusion that the mailing or publication alleging an adverse experience is false or misleading and report this conclusion to the agency. In some cases the agency may take appropriate regulatory action against persons preparing a false or misleading report of an adverse experience.

#### 2. Lack of Response Reports

One comment on proposed § 600.80(b) stated that "lack of response" complaints from consumers do not have sufficient validity to aid in decisionmaking and therefore should not be submitted to FDA. Another comment requested that "lack of response" should not be submitted for single patient incidents but limited to studies.

The agency believes that all reports of "lack of response" for single patient incidents should be reviewed and submitted by the licensed manufacturer. Complaints from consumers should be verified with the patient's health-care provider, if possible, prior to being submitted to FDA.

#### D. Clarification of Reporting Requirements Section 600.80(c)

##### 1. Terminology

Two comments on proposed § 600.80(c) requested clarification of terminology between the term "applicant" used in § 314.80 and the term "manufacturer" used in proposed § 600.80. One comment preferred the term "licensee" for this regulation regarding biological products.

The agency uses the term "licensed manufacturer" in these rules because it presents a more accurate representation of those required to comply with these regulations. These rules are being promulgated for the purpose of

gathering postmarketing surveillance information, which will occur after product licensing.

## 2. Responsibilities

Two comments requested clarification of responsibilities for joint manufacturers, shared manufacturers, divided manufacturers, and contractual manufacturers so that duplicate adverse experience reports are not submitted. One comment requested that, in order to avoid duplicate reporting or failures to report adverse experiences, the agency should add language similar to § 314.80(c)(1)(iii). Another comment requested that the agency specify the reporting requirements of a nonapplicant.

FDA recognizes that manufacturing of a biological product can be shared or divided among a number of business establishments. In the *Federal Register* of November 25, 1992 (57 FR 55544), FDA published a notice that discussed cooperative manufacturing arrangements for licensed biological products. In addition, 21 CFR 600.12(e) requires that "each participating manufacturer shall furnish to the manufacturer who prepares the product in final form for sale, barter or exchange, a copy of all records relating to the manufacturing operations performed by such participating manufacturer insofar as they concern the safety, purity and potency of the lots of the product involved, \* \* \*." Other requirements regarding divided manufacturing are contained in 21 CFR 610.63, which requires that "If two or more establishments participate in the manufacture of a product, the name, address, and license number of each must appear on the package label, and on the label of the container if capable of bearing a full label."

The agency is clarifying the reporting requirements in § 600.80(c)(1)(iii) by substituting the term "licensed manufacturer" for the term "manufacturer." The agency intends that the manufacturer licensed to prepare the final product for commercial distribution has the primary responsibility for reporting adverse experiences to FDA. To prevent duplicate reports, language has been added to § 600.80(c)(1)(iii) in this final rule to clearly delineate the responsibilities of the licensed manufacturer of the final product and other persons whose names may appear on the product label.

## E. Reporting Requirements Section 600.80(c)

### 1. Failure of Pharmacologic Action

One comment on proposed § 600.80(c) requested that FDA not require single patient adverse experience forms for each failure of expected pharmacological action. The comment suggested that increased frequency analyses should not be performed on spontaneous lack of response reports because it is not possible for an appropriate baseline to be constructed using either domestic or foreign spontaneous reports in this setting.

FDA believes that the use of single patient adverse experience reporting forms provides the agency with information that may be helpful in assessing whether there is a need for further investigation of the reported lack of response. The agency also believes that increased frequency analyses and reports are useful to serve as an indicator that an investigation is needed to explore the issue further.

### 2. Followup Reports to 15-day Alerts

Two comments regarding proposed § 600.80(c)(1)(i) questioned the need for a report that briefly describes the steps taken to seek additional information about an adverse event and the reasons why such information could not be obtained. The comments stated that the proposed language placed an additional burden on licensed manufacturers by requesting not only that they make every effort to obtain such information but also that they write a report describing such efforts.

Under § 600.80(c) licensed manufacturers will be required to seek additional information and document the steps taken to comply with the rule in a manner consistent with § 314.80(c). The agency is not, at this time, specifying the format for this documentation. The agency must be able to verify the licensed manufacturer's efforts and advise licensed manufacturers of additional steps that should be pursued to retrieve the necessary information when appropriate. The proposed rule stated that this report should not be submitted to the agency unless so requested but should be maintained in the licensed manufacturer's files. This requirement differs from § 314.80(c)(1)(i). The agency believes it would reduce the burden for manufacturers who produce both biologics and drugs if § 600.80(c)(1)(i) is consistent with § 314.80(c)(1)(i). Therefore, the sentence in proposed § 600.80(c)(1)(i), "This report should be retained by the manufacturer in its files but not submitted as a followup to FDA

unless so requested" has been deleted. Further discussion of changing the final disposition of these reports is included in the notice of proposed rulemaking found elsewhere in this issue of the *Federal Register*.

### 3. Increased Frequency Analysis

Two comments on proposed § 600.80(c)(1)(ii) requested information regarding the utility of increased frequency analysis. These comments suggest that the analysis is not of the increased frequency of adverse experiences but rather the analysis is of the increased frequency of reports of adverse experiences. One comment requested that the agency develop improved methods for determining increased frequency that would account for fluctuations in reporting.

FDA agrees that increased frequency of adverse experience reports does not necessarily correlate with an increase in adverse experiences. Case reports are used to alert the agency about areas which may need further investigation. FDA takes into account the fact that reporting rates vary over time in postmarketing surveillance when analyzing the reporting rate for an individual biologic. FDA does not assume that an increase in incidence of adverse experiences will automatically trigger an increase in reports of adverse experience. Nor does the agency assume that an increase in the number of reports of adverse experiences necessarily indicates an increase in incidence of adverse experiences. The agency believes that an increase in reporting rates, when taken into account with other relevant information, may indicate that an epidemiologic investigation is needed to explore the situation further.

### 4. Periodic Reports

Three comments on proposed § 600.80(c)(2) noted a discrepancy on when the reporting period begins. One comment requested that the interval for periodic reporting be extended to annually rather than quarterly. One comment requested that the agency extend the time for submitting periodic reports from 30 to 60 days after the end of the reporting period.

FDA believes that the reports need to be submitted in a timely manner because the public is continuing to be exposed to the products. Accordingly, FDA is retaining the proposed time schedule for submitting periodic reports in this final rule. In the notice of proposed rulemaking published elsewhere in this issue of the *Federal Register*, FDA is proposing to amend the regulations regarding when the reporting period begins and to amend

the schedule for submitting periodic reports.

#### 5. Schedule for Submitting Reports

Four comments on proposed § 600.80(c)(2)(i) requested that the agency limit reporting requirements (other than 15-day alerts) to the first 3 or 10 years of marketing. These comments stated that the initial postmarketing period would provide the most benefit and that after an initial period these reports would offer little benefit and would be a burden to the agency and the licensed manufacturer.

FDA believes that there is a need for licensed manufacturers to continually monitor adverse experiences. The length of time a product is marketed does not guarantee that it will not be implicated in latent adverse experiences that were not recognized previously. Novel adverse experiences can occur when a biological product is used concomitantly with another drug or biological product. In addition, a product that has been on the market for many years can be implicated in adverse experiences that were either previously undetected or unknown in the scientific community. For these reasons, this requirement for periodic review and submission of reports of adverse experiences is necessary for the public safety. However, the licensed manufacturer can request a waiver under § 600.90 in order to decrease or eliminate the periodic reporting requirements for older products with a proven safety record.

Under § 600.80(c)(2)(i) the agency may also require more frequent reports for products if appropriate; for example, products with special safety or efficacy concerns. Similarly the agency may require less frequent reports or no reports for products with a history of continual safety.

#### 6. Effect of Significant Change in Manufacturing on Reporting Requirements

One comment on proposed § 600.80(c)(2)(i) expressed concern that significant changes in the manufacturing process, as provided in the Product License Application (PLA), may lead FDA to require that the frequency of the periodic reports be maintained as quarterly reports. The example given in the comment was for influenza virus vaccine. The comments questioned whether this product would be considered a new product annually due to its inherent strain changes.

Influenza vaccine is an example of a product for which more frequent reports may be appropriate. The agency considers the influenza vaccine to be a

new product annually because variations in influenza strains make it necessary to reformulate the influenza vaccine each year.

In the past, there have been many reports of adverse experiences associated with the influenza vaccine, including reports of Guillain-Barre Syndrome and false positive test results for other viral markers. In situations such as this, the agency may require more frequent reporting which will help it assess the magnitude and accuracy of reports of adverse experiences. In § 600.80(c)(2)(i) FDA may upon written notice extend or reestablish the requirement that a licensed manufacturer submit quarterly reports, or require that the license manufacturer submit reports under this section at different times than those stated. Prompt reporting of these adverse experiences will make it easier to either recall a problem lot or discredit a false rumor.

#### 7. Requirement for Negative Periodic Reports

Two comments on proposed § 600.80(c)(2) requested that the agency clarify the discrepancy between the proposed rule and the draft guideline regarding periodic reports for products that had no adverse experiences reported. The proposed rule did not require periodic reports for products that had no adverse experiences reported. The guideline asked that a letter be sent stating that no adverse experiences were reported. These comments also stated that the negative report is an "undue burden."

The guideline has been changed to be consistent with the final rule in not requiring negative reporting at this time. However, the agency believes that the negative reports are appropriate for the agency to determine that the licensed manufacturer is focusing attention on whether there have been adverse experiences reported to FDA. Therefore, requirements regarding submission of negative reports are included in the notice of proposed rulemaking found elsewhere in this issue of the Federal Register.

#### 8. Tabular Line Listing in Periodic Reports

Three comments on proposed § 600.80(c)(2)(ii)(C) regarding the tabular listing of adverse experiences required in the periodic reports stated that the requirements to list the patient's identification number, age, sex, and adverse experience terms in the tabular listing were viewed as unnecessary and excessive. Also noted were discrepancies regarding the tabular

listing requirements between the guideline and the proposed rule.

The agency agrees that the age and sex are not necessary in the tabular listing. However, the agency believes that the adverse experience terms should be included in such a listing. The tabular line listing is intended to provide a synopsis of individual case histories previously submitted, to assist FDA in identifying potential issues and individual case histories for further review. The agency is amending § 600.80(c)(2) to require only the licensed manufacturer's patient identification number and adverse experience terms in the tabular listing.

#### 9. Submission of Labeling

Two comments on proposed § 600.80(c)(2)(ii)(E) requested that the agency not require licensed manufacturers to submit with periodic reports a copy of the most current labeling, including container labels, carton labels, package inserts, and other materials distributed with the product. In addition, the comments stated that the current labeling is reviewed by FDA before use and licensed manufacturers should not be required to repeatedly submit this information with periodic reports. One comment stated that the only labeling useful for evaluating adverse experience reports is the package insert, unless the product is sold over-the-counter, then submission of directions for consumers on the container label may be justified.

The agency agrees with the comments and is amending § 600.80(c)(2)(ii)(C) of the final rule to require "a history of actions taken since the last report because of adverse experiences (for example, labeling changes or studies initiated)." This ensures that the review of the adverse experiences is conducted in the context of the latest information available.

#### 10. Submission of Distribution Data

Ten comments related to various aspects of the requirements in proposed § 600.80(c)(2)(iv) for submission of distribution data for licensed biological products. Two comments stated that the request for foreign distribution data is a heavy burden. Three comments stated that the requirement to report dose distribution data is difficult and inappropriate for certain types of products and that this information is not required in § 314.80 for drugs. Two comments disagreed with a statement in the preamble that the quantity of a product distributed enables FDA to estimate more accurately the incidence of a product's adverse effects. The comments reasoned that distribution

data do not determine how much product is actually used. One comment questioned FDA's ability to keep the distribution information confidential. One comment stated that the proposed schedule for distribution reports places a hardship on manufacturers as it required quarterly reports for new biological products, annual reports for biological products licensed more than 3 years, and annual reports for drugs. Another comment requested guidance on the preferred format for distribution data. The agency agrees that foreign distribution data should not be required for biological products. Although the agency agrees that distribution data do not accurately estimate the incidence of a product's adverse effects, it is information needed to help FDA determine whether further study is needed. FDA, on its own initiative, is amending the final rule to parallel the drug regulations format by moving the requirements to submit distribution data to § 600.81. The agency has revised the schedule for submitting distribution reports in § 600.81 of the final rule. The reports will now be due on the semiannual and annual anniversary of the licensing of the product. Licensed manufacturers that believe that the requirements for submission of distribution data are inappropriate for certain types of products may request a waiver under § 600.90, as discussed elsewhere in this preamble. Until a waiver is granted the provisions specified in the final rule are applicable.

#### F. Review of Scientific Literature

One comment on § 600.80(d) requested that submission of reports from scientific literature be limited to those articles where the author believes the product is associated with the experience; i.e., "reasonable causation" by the author should be used in determining what adverse experiences from the literature need to be reported to FDA.

The agency believes that reports of adverse experiences in the literature where the author clearly states that the licensed manufacturer's product is not the cause do not need to be reported. Reports in the scientific literature where no conclusion is reached regarding causality should be further investigated by the licensed manufacturer and reported to FDA if the adverse experience is associated or remains possibly associated with the licensed biological product. The licensed manufacturer should document the information that determines the cause to be other than product related and retain this documentation.

#### G. Reporting Form FDA-1639

Five comments on proposed § 600.80(f) concerned the use of Form FDA-1639 for reporting adverse experiences. One comment stated that the form is inappropriate for their biological products, one comment asked that the form be updated, one comment requested that Form FDA-1639 be retained for VAERS reporting as well as for adverse experience reporting for drugs and biological products. Two comments questioned whether an approved alternate form for reporting adverse experiences for drugs must be resubmitted to CBER for approval. One comment requested that the agency not allow implementation of an alternative reporting form as it will cause a hardship in computerization of adverse experience data across the biological and pharmaceutical product lines. This comment requested that the same form (Form FDA-1639) be used for all adverse experience reports regardless of the nature of the product.

FDA has designed a new adverse experience reporting form (Form FDA-3500A) which, with the exception of reporting adverse experiences associated with vaccines, is ordinarily to be used to report under §§ 310.305, 312.32, 314.80, 600.80, and parts 803 and 807 regarding drugs, biological products, and devices, respectively. The new form will simplify and consolidate the reporting of adverse events and product problems and will enhance agency-wide consistency in the collection of postmarketing data. Any computer-generated forms will have to be submitted to MEDWATCH, 5600 Fishers Lane, Rockville, MD 20852-9787, for approval to use in complying with this final rule. As one comment suggested, alternative formats will make computerization of adverse experience data across product lines difficult. Therefore, a licensed manufacturer should submit adequate justification for an alternative format.

Form FDA-3500A is referenced in § 600.80(f) of the final rule. The term "form designated by FDA" is used throughout the remainder of the final rule to accommodate any future changes in the form itself. For vaccines the designated form for reporting adverse experiences is Form VAERS-1. The form for VAERS is discussed in a published report in *Morbidity and Mortality Weekly Report* (see MMWR, 39:730-733, 1990).

#### H. Reporter Identification

One comment on proposed § 600.80(h) requested that if the reporter is the patient (or relative) that his or her

name not be listed on the adverse experience form.

The agency concurs with this request for adverse experience reporting for licensed biological products other than vaccine-associated experiences being reported in accordance with NCVIA. Under NCVIA it would be appropriate to include the patient's name in the report because copies of this report may be made available to the vaccinee or legal representative of the vaccinee. For adverse experience reporting of licensed biological products other than vaccines being reported under NCVIA, the report should not include the name of the patient, but should assign a unique code number to each report. For adverse experience reporting of biological products, patient identifiers are not releasable to the public under FDA's public information regulations (21 CFR part 20). Section 600.80(h) is amended to reflect that VAERS reports are subject to the CDC Privacy Act System.

#### I. Unique Code Number

One comment concerning proposed § 600.80(h) requested that the agency increase the number of characters in the unique code number assigned to each report from eight characters in length to nine characters.

The agency encourages consistency by designating in the final rule a number of characters to be used, to simplify preparing and processing the reports. To allow some flexibility, note that § 600.80(h) in the final rule recommends but does not require use of a code number of eight characters or less.

#### J. Recordkeeping

Two comments on proposed § 600.80(i) related to the length of time a licensed manufacturer is required to keep adverse experience records. One comment requested clarification regarding whether form letters sent by the licensed manufacturer to the adverse experience reporter must be retained 10 years; another comment requested that the recordkeeping be limited to 1 year past the involved product's expiration date.

FDA believes that 10 years is a reasonable time to maintain such records. This requirement corresponds with existing regulations for drug products. If a form letter to the reporter is the documentation that the licensed manufacturer sought additional information about an adverse experience, then the form letter must be maintained in the file for 10 years. Any letters which are part of the correspondence regarding an adverse experience reporting must be maintained in the file for 10 years.

**K. Exemptions**

FDA has determined that § 600.80(l) should be amended to clarify that licensed manufacturers of in vitro diagnostic products, including assay systems for the detection of antibodies or antigens to retroviruses, report adverse experiences under the device reporting regulations. The best way to monitor product defects with these licensed biological devices is for them to be reported under the Medical Devices: Medical Device User Facility, Distributor, and Manufacturer Reporting, Certification, and Registration Regulations (see 56 FR 60024, November 26, 1991). To eliminate any confusion over how to report product defects with these products, the final rule is amended to state specifically that in vitro diagnostics, including assays to detect antibodies or antigens to retroviruses (such as HIV-1 and HIV-2), are exempt from this rule but are subject to the device reporting regulations.

**IV. Analysis of Impacts**

FDA has examined the impacts of the proposed rule under Executive Order 12866 and the Regulatory Flexibility Act (Pub. L. 96-354). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The agency believes that this final rule is consistent with the regulatory philosophy and principles identified in the Executive Order. In addition, the final rule is not

a significant regulatory action as defined by the Executive Order and so is not subject to review under the Executive Order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. The final rule codifies adverse experience reporting for biological products currently being practiced by licensed manufacturers on a voluntary basis. FDA believes that the information collection resulting from postmarket surveillance required by this final rule will be of benefit to the public health. FDA has prepared a Threshold Assessment to estimate the cost to comply with the final rule by the regulated industry. The estimation by FDA for the total annual cost to industry is \$3,937,164. The agency certifies that the final rule will not have a significant economic impact on a substantial number of small entities. Therefore, under the Regulatory Flexibility Act, no further analysis is required.

**V. 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.

**VI. Paperwork Reduction Act of 1980**

Sections 600.80 and 600.81 of this final rule contain information collection requirements which are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1980. The title, description, and respondent description

of the information collection are shown below with an estimate of the annual reporting and recordkeeping burden. Included in the estimate is the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

**Title: Adverse Experience Reporting Requirements for Licensed Biological Products.**

**Description:** FDA is charged with the responsibility for determining that a biological product meets the statutory standards for safety, purity, and potency for initial and continued licensure. To carry out this mandate, the agency needs to be informed whenever a manufacturer of a licensed biological product receives or otherwise becomes aware of information about adverse experiences associated with the use of its product. Only if FDA is provided with such information will it be able to evaluate the risk, if any, associated with a biological product and take whatever action is necessary to reduce or eliminate the public's exposure. FDA is taking this action to provide a mechanism under which manufacturers would inform the agency, on a timely basis, of any unanticipated safety problems with marketed biological products. This action is similar to initiatives taken by FDA regarding new drugs and medical devices.

**Description of Respondents:** Businesses or other for-profit and small businesses or organizations.

As required by the Paperwork Reduction Act, FDA has submitted a copy of this rule to OMB with a request that it approve these information collection requirements.

**ESTIMATED TOTAL ANNUAL REPORTING BURDEN**

Section	Number of Respondents	Number of Respondents per Respondent	Total Annual Responses	Hours Per Response	Total Hours
600.81	63	175.12698	11,033	1.0	11,033

**ESTIMATED TOTAL ANNUAL RECORDKEEPING BURDEN**

Section	No. of Recordkeepers	Annual Hours Per Recordkeeper	Total Recordkeeping Hours
600.80(i)	63	0.5	31.5

This final rule also contains information collection requirements contained in § 600.80(c) that have been approved by OMB under OMB No. 0910-0291 with a total of 11,033 hours. It is estimated that the information requirements for this section under this

final rule will add 11,064.5 hours to the burden estimate.

**List of Subjects in 21 CFR Part 600**

Biologics, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act, the Public Health Service Act, and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 600 is amended as follows:

**PART 600—BIOLOGICAL PRODUCTS:  
GENERAL**

1. The authority citation for 21 CFR part 600 is revised to read as follows:

**Authority:** Secs. 201, 501, 502, 503, 505, 510, 519, 701, 704 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 351, 352, 353, 355, 360, 360i, 371, 374); secs. 215, 351, 352, 353, 361, 2125 of the Public Health Service Act (42 U.S.C. 216, 262, 263, 263a, 264, 300aa-25).

2. A new subpart D consisting of §§ 600.80, 600.81, and 600.90 is added to read as follows:

**Subpart D—Reporting of Adverse Experiences**

Sec.

- 600.80 Postmarketing reporting of adverse experiences.  
600.81 Distribution reports.  
600.90 Waivers.

**Subpart D—Reporting of Adverse Experiences****§ 600.80 Postmarketing reporting of adverse experiences.**

(a) *Definitions.* The following definitions of terms apply to this section:

*Adverse experience* means any adverse event associated with the use of a biological product in humans, whether or not considered product related, including the following: an adverse event occurring in the course of the use of a biological product in professional practice; an adverse event occurring from overdose of the product, whether accidental or intentional; an adverse event occurring from abuse of the product; an adverse event occurring from withdrawal of the product; and any failure of expected pharmacological action.

*Blood Component* for this purpose has the same meaning as defined in § 606.3(c) of this chapter.

*Increased frequency* means an increase in the rate of occurrence of a particular adverse biological product experience, e.g., an increased number of reports of a particular adverse biological product experience after appropriate adjustment for biological product exposure.

*Serious* means an adverse experience associated with the use of a biological product that is fatal or life-threatening, is permanently disabling, requires inpatient hospitalization, or is a congenital anomaly, cancer, or overdose.

*Unexpected* means an adverse biological product experience that is not listed in the current labeling for the product and includes an event that may be symptomatically and

pathophysiologically related to an event listed in the labeling, but differs from the event because of greater severity or specificity. For example, under this definition, hepatic necrosis would be unexpected (by virtue of greater severity) if the labeling only referred to elevated hepatic enzymes or hepatitis. Similarly, cerebral thromboembolism and cerebral vasculitis would be unexpected (by virtue of greater specificity) if the labeling only listed cerebral vascular accidents.

(b) *Review of adverse experiences.* Any person having a product license under § 601.20 of this chapter shall promptly review all adverse experience information pertaining to its product obtained or otherwise received by the licensed manufacturer from any source, foreign or domestic, including information derived from commercial marketing experience, postmarketing clinical investigations, postmarketing epidemiological/surveillance studies, reports in the scientific literature, and unpublished scientific papers.

(c) *Reporting requirements.* The licensed manufacturer shall report to FDA adverse experience information, as described in this section. The licensed manufacturer shall submit two copies of each report described in this section for nonvaccine biological products, to the Center for Biologics Evaluation and Research (HFM-210), Food and Drug Administration, 1401 Rockville Pike, suite 200 N., Rockville, MD 20852-1448. Submit all vaccine adverse experience reports to: Vaccine Adverse Event Reporting System (VAERS), P.O. Box 1100, Rockville, MD 20849-1100. FDA may waive the requirement for the second copy in appropriate instances.

(1) *Fifteen-day Alert reports.* (i) The licensed manufacturer shall report each adverse experience that is both serious and unexpected, regardless of source, as soon as possible but in any case within 15 working days of initial receipt of the information. These reports are required to be submitted, for nonvaccine biological products, on a form designated by FDA or a suitable format containing all of the data elements in the FDA designated reporting form, and, for vaccines on a VAERS form. The licensed manufacturer shall promptly investigate all adverse experiences that are the subject of these 15-day Alert reports and shall submit followup reports within 15 working days of receipt of new information or as requested by FDA. If additional information is not obtainable, a followup report may be required that describes briefly the steps taken to seek additional information and the reasons why it could not be obtained. These 15-

day Alert reports and followups to them are required to be submitted under separate cover and may not be included, except for summary or tabular purposes, in a periodic report.

(ii) The licensed manufacturer shall review periodically (at least as often as the periodic reporting cycle) the frequency of reports of adverse biological product experiences that are both serious and expected and reports of therapeutic failure (lack of effect), regardless of source, and report any significant increase in frequency as soon as possible but in any case within 15 working days of determining that a significant increase in frequency exists. Upon written notice, FDA may require that licensed manufacturers review the frequency of reports of serious, expected adverse biological product experiences at intervals different than the periodic reporting cycle. Reports of a significant increase in frequency are required to be submitted in narrative form (including the time period on which the increased frequency is based, the method of analysis, and the interpretation of the results), rather than using the form designated by FDA. Fifteen-day Alert reports based on increased frequency are required to be submitted under separate cover and may not be included, except for summary purposes, in a periodic report.

(iii) The requirements of paragraphs (c)(1)(i) and (c)(1)(ii) of this section, concerning the submission of Fifteen-day Alert reports, shall also apply to any person other than the licensed manufacturer of the final product whose name appears on the label of a licensed biological product as a manufacturer, packer, distributor, shared manufacturer, joint manufacturer, or any other participant involved in divided manufacturing. In order to avoid unnecessary duplication in the initial and followup submission of reports to FDA, the obligations of a manufacturer other than the licensed manufacturer, may be met by submitting all reports to the licensed manufacturer of the final product. If a manufacturer other than the licensed manufacturer elects to submit reports to the licensed manufacturer rather than to FDA, it shall submit each report to the licensed manufacturer within 3 working days of its receipt, and the licensed manufacturer shall then comply with the requirements of this section. Under this circumstance, the manufacturer shall maintain a record of this action which shall include:

(A) A copy of all adverse biological product experience reports submitted to the licensed manufacturer,

(B) Date the report was received by the manufacturer.

(C) Date the report was submitted to the licensed manufacturer.

(D) Name and address of the licensed manufacturer.

(iv) Each report submitted under this paragraph shall bear prominent identification as to its contents, i.e., "15-day Alert report" or "15-day Alert report-followup."

(2) *Periodic adverse experience reports.* (i) The licensed manufacturer shall report each adverse experience not reported under paragraph (c)(1)(i) of this section at quarterly intervals, for 3 years from the date of issuance of the product license, and then at annual intervals. The licensed manufacturer shall submit each quarterly report within 30 days of the close of the quarter (the first quarter beginning on the date of issuance of the product license) and each annual report within 60 days of the anniversary date of the issuance of the product license. Upon written notice, FDA may extend or reestablish the requirement that a licensed manufacturer submit quarterly reports, or require that the licensed manufacturer submit reports under this section at different times than those stated. Followup information to adverse experiences submitted in a periodic report may be submitted in the next periodic report.

(ii) Each periodic report shall contain:

(A) A narrative summary and analysis of the information in the report and an analysis of the 15-day Alert reports submitted during the reporting interval (all 15-day Alert reports being appropriately referenced by the licensed manufacturer's patient identification number, adverse reaction term(s), and date of submission to FDA);

(B) A form designated for Adverse Experience Reporting by FDA for each adverse experience not reported under paragraph (c)(1)(i) of this section (with an index consisting of a line listing of the licensed manufacturer's patient identification number and adverse reaction term(s)); and

(C) A history of actions taken since the last report because of adverse experiences (for example, labeling changes or studies initiated).

(iii) Periodic reporting, except for information regarding 15-day Alert reports, does not apply to adverse experience information obtained from postmarketing studies (whether or not conducted under an investigational new drug application), from reports in the scientific literature, and from foreign marketing experience.

(d) *Scientific literature.* (1) A 15-day Alert report based on information from the scientific literature shall be

accompanied by a copy of the published article. The 15-day Alert reporting requirements in paragraph (c)(1)(i) of this section (i.e., serious, unexpected adverse experiences) apply only to reports found in scientific and medical journals either as case reports or as the result of a formal clinical trial. The 15-day Alert reporting requirements in paragraph (c)(1)(ii) of this section (i.e., a significant increase in frequency of a serious, expected adverse experience or of a therapeutic failure) apply only to reports found in scientific and medical journals either as the result of a formal clinical trial, or from epidemiologic studies or analyses of experience in a monitored series of patients.

(2) As with all reports submitted under paragraph (c)(1)(i) of this section, reports based on the scientific literature shall be submitted on the reporting form designated by FDA or comparable format as prescribed by paragraph (f) of this section. In cases where the licensed manufacturer believes that preparing the form designated by FDA constitutes an undue hardship, the licensed manufacturer may arrange with the Division of Biostatistics and Epidemiology (HFM-210) for an acceptable alternative reporting format.

(e) *Postmarketing studies.* (1) Licensed manufacturers are not required to submit a 15-day Alert report under paragraph (c) of this section for an adverse experience obtained from a postmarketing clinical study (whether or not conducted under a biological investigational new drug application) unless the licensed manufacturer concludes that there is a reasonable possibility that the product caused the adverse experience.

(2) The licensed manufacturer shall separate and clearly mark reports of adverse experiences that occur during a postmarketing study as being distinct from those experiences that are being reported spontaneously to the licensed manufacturer.

(f) *Reporting forms.* (1) Except as provided in paragraphs (c)(1)(ii), and (f)(3) of this section, the licensed manufacturer shall complete the reporting form designated by FDA (FDA-3500A, or, for vaccines, a VAERS form) for each report of an adverse experience.

(2) Each completed form should refer only to an individual patient or single attached publication.

(3) Instead of using a designated reporting form, a licensed manufacturer may use a computer-generated form or other alternative format (e.g., a computer-generated tape or tabular listing) provided that:

(i) The content of the alternative format is equivalent in all elements of information to those specified in the form designated by FDA; and

(ii) the format is approved in advance by MEDWATCH: The FDA Medical Products Reporting Program; or, for alternatives to the VAERS Form, by the Division of Biostatistics and Epidemiology.

(4) Copies of the reporting form designated by FDA (FDA-3500A) for nonvaccine biological products may be obtained from the Center for Biologics Evaluation and Research (address above). Additional supplies of the form may be obtained from the Consolidated Forms and Publications Distribution Center, 3222 Hubbard Rd., Landover, MD 20785. Supplies of the VAERS form may be obtained from VAERS by calling 1-800-822-7967.

(g) *Multiple reports.* A licensed manufacturer should not include in reports under this section any adverse experiences that occurred in clinical trials if they were previously submitted in the product license application. If a report refers to more than one biological product marketed by a licensed manufacturer, the licensed manufacturer should submit the report to the license for the product listed first in the report.

(h) *Patient privacy.* For nonvaccine biological products, a licensed manufacturer should not include in reports under this section the names and addresses of individual patients; instead, the licensed manufacturer should assign a unique code number to each report, preferably not more than eight characters in length. The licensed manufacturer should include the name of the reporter from whom the information was received. The names of patients, health care professionals, hospitals, and geographical identifiers in adverse experience reports are not releasable to the public under FDA's public information regulations in part 20 of this chapter. For vaccine adverse experience reports, these data will become part of the CDC Privacy Act System 09-20-0136, "Epidemiologic Studies and Surveillance of Disease Problems." Information identifying the person who received the vaccine or that person's legal representative will not be made available to the public, but may be available to the vaccinee or legal representative.

(i) *Recordkeeping.* The licensed manufacturer shall maintain for a period of 10 years records of all adverse experiences known to the licensed manufacturer, including raw data and any correspondence relating to the adverse experiences.

(j) *Guideline.* FDA has prepared a guideline for the submission of reports of adverse experiences and suggested followup investigation of reports.

(k) *Revocation of license.* If a licensed manufacturer fails to establish and maintain records and make reports required under this section with respect to a licensed biological product, FDA may revoke the product license for such a product in accordance with the procedures of § 601.5 of this chapter.

(l) *Exemptions.* Manufacturers of the following listed products are not required to submit adverse experience reports under this section:

- (1) Whole blood or components of whole blood.
- (2) In vitro diagnostic products, including assay systems for the detection of antibodies or antigens to retroviruses. These products are subject to the reporting requirements for devices.

(m) *Disclaimer.* A report or information submitted by a licensed manufacturer under this section (and any release by FDA of that report or information) does not necessarily reflect a conclusion by the licensed manufacturer or FDA that the report or information constitutes an admission that the biological product caused or contributed to an adverse effect. A licensed manufacturer need not admit, and may deny, that the report or information submitted under this section constitutes an admission that the biological product caused or contributed to an adverse effect. For

purposes of this provision, this paragraph also includes any person reporting under paragraph (c)(1)(iii) of this section.

#### § 600.81 Distribution reports.

The licensed manufacturer shall submit information about the quantity of the product distributed under the product license, including the quantity distributed to distributors. The interval between distribution reports shall be 6 months. Upon written notice, FDA may require that the licensed manufacturer submit distribution reports under this section at times other than every 6 months. The distribution report shall consist of the bulk lot number (from which the final container was filled), the fill lot numbers for the total number of dosage units of each strength or potency distributed (e.g., fifty thousand per 10-milliliter vials), the label lot number (if different from fill lot number), labeled date of expiration, number of doses in fill lot/label lot, date of release of fill lot/label lot for distribution at that time. If any significant amount of a fill lot/label lot is returned, include this information. Disclosure of financial or pricing data is not required. As needed, FDA may require submission of more detailed product distribution information. Upon written notice, FDA may require that the licensed manufacturer submit reports under this section at times other than those stated. Requests by a licensed manufacturer to submit reports at times

other than those stated should be made as a request for a waiver under § 600.90.

#### § 600.90 Waivers.

(a) A licensed manufacturer may ask the Food and Drug Administration to waive under this section any requirement that applies to the licensed manufacturer under §§ 600.80 and 600.81. A waiver request under this section is required to be submitted with supporting documentation. The waiver request is required to contain one of the following:

(1) An explanation why the licensed manufacturer's compliance with the requirement is unnecessary or cannot be achieved,

(2) A description of an alternative submission that satisfies the purpose of the requirement, or

(3) Other information justifying a waiver.

(b) FDA may grant a waiver if it finds one of the following:

(1) The licensed manufacturer's compliance with the requirement is unnecessary or cannot be achieved,

(2) The licensed manufacturer's alternative submission satisfies the requirement, or

(3) The licensed manufacturer's submission otherwise justifies a waiver.

Dated: October 13, 1994.

**William K. Hubbard,**

*Interim Deputy Commissioner for Policy.*

[FR Doc. 94-26482 Filed 10-26-94; 8:45 am]

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# Federal Register

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Thursday  
October 27, 1994

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## Part III

### Department of Health and Human Services

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Food and Drug Administration

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21 CFR Part 20, et al.  
Adverse Experience Reporting  
Requirements for Human Drug and  
Licensed Biological Products; Proposed  
Rule

**DEPARTMENT OF HEALTH AND HUMAN SERVICES****Food and Drug Administration****21 CFR Parts 20, 310, 312, 314, and 600****[Docket No. 93N-0181]****Adverse Experience Reporting Requirements for Human Drug and Licensed Biological Products****AGENCY:** Food and Drug Administration, HHS.**ACTION:** Proposed rule.

**SUMMARY:** The Food and Drug Administration (FDA) is proposing to amend its current adverse experience reporting regulations for human drug products and for licensed biological products to provide consistency with the elements of FDA Form 3500A and require the use of this new reporting form; revise certain definitions and reporting periods and formats as recommended by the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) and the World Health Organization's Council for International Organizations of Medical Sciences (CIOMS); require applicants or manufacturers, packers, and distributors to develop written procedures for monitoring and reporting adverse experiences; state that reports of adverse experiences that are forwarded by FDA to the applicant or manufacturer, packer, and distributor should not be resubmitted to the agency; and make other revisions to the regulations to provide uniformity in adverse experience reporting for human drug products and licensed biological products. These changes would simplify and facilitate the reporting of adverse experiences and would enhance agencywide consistency in the collection of postmarketing adverse experience data. In addition, FDA is proposing to amend the requirements for clinical study design and conduct and the sponsor reporting requirements in the investigational new drug application (IND) regulations. These amendments are intended to provide more complete and accurate information that would enable sponsors, investigators, and FDA to determine serious toxicities of investigational drugs more expeditiously during clinical studies.

**DATES:** Submit written comments by January 25, 1995. The agency proposes that any final rule that may issue based on this proposal become effective 30 days after its date of publication in the *Federal Register*.

**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:**

Concerning human drug products: Howard P. Muller, Center for Drug Evaluation and Research (HFD-362), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-594-1049.

Concerning licensed biological products: Paula S. McKeever, Center for Biologics Evaluation and Research (HFM-635), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852-1448, 301-594-3074.

**SUPPLEMENTARY INFORMATION:****I. Background**

In the *Federal Register* of June 3, 1993 (58 FR 31596), FDA announced the availability of a new form for reporting adverse events and product problems with medications, devices, and other FDA-regulated medical products. This form is available in two versions. One version of the form (FDA Form 3500) is to be used by health professionals for voluntary reporting; the other version of the form (FDA Form 3500A) is to be used by applicants or manufacturers (including licensed manufacturers of licensed biological products), and other persons subject to mandatory reporting requirements under FDA regulations. Under existing regulations, drug manufacturers, packers, and distributors and applicants for new drug products and generic drug products must report adverse events under §§ 310.305 and 314.80 (21 CFR 310.305 and 314.80). Elsewhere in this issue of the *Federal Register*, FDA is issuing a final rule establishing new § 600.80. This section makes licensed manufacturers of biological products subject to certain reporting requirements.

The new form is part of FDA's Medical Products Reporting Program (MedWatch) and is designed to encourage and facilitate the reporting of adverse events and product problems for most FDA-regulated human medical products by the entire health care community, including manufacturers, distributors, user facilities, and health professionals. FDA issued the new form to simplify and consolidate the reporting of suspected adverse events and product problems with human drug products, biologics, and medical devices, as well as the reporting of adverse events with other FDA-

regulated medical products, such as dietary supplements. FDA has found that, under the current system, there is some confusion about what to report to the agency and that the existing assortment of reporting forms and systems can interfere with the efficient reporting of suspected problems. FDA has attempted to clarify and simplify adverse event reporting with the new form by eliminating redundant or nonessential elements and by clarifying those areas that have caused confusion.

FDA Form 3500A replaces current Form FDA-1639, as well as most other adverse event and product problem reporting forms currently required by the agency. Adverse events associated with vaccines will continue to be reported through the FDA and Centers for Disease Control and Prevention Vaccine Adverse Event Reporting System (VAERS). FDA is proposing to amend the adverse experience reporting requirements for human drug products and for licensed biological products to be consistent with the elements of FDA Form 3500A.

In developing FDA Forms 3500 and 3500A, the agency considered several recommendations from ICH and CIOMS. These organizations were formed to facilitate international consideration of issues, particularly safety issues, concerning the use of both foreign and domestic data in the development and use of drugs and biological products. ICH has worked to promote the harmonization of technical requirements for the registration of pharmaceutical products among three regions: The European Union, Japan, and the United States. ICH has prepared a draft guideline specific to parts of this issue entitled: "Clinical Safety Data Management: Definitions and Standards for Expedited Reporting." In the *Federal Register* of July 9, 1993 (58 FR 37408), FDA published this draft guideline for public comment. Several CIOMS working groups have worked to coordinate and standardize the international reporting of postmarketing adverse drug reactions by pharmaceutical manufacturers to regulatory authorities. CIOMS Working Group II has proposed an international system of standardized time intervals, formats, and inclusion criteria in order to lessen confusion and reduce preparation time among manufacturers and to enable them to report postmarketing adverse experiences more rapidly, efficiently, and effectively (Refs. 1 and 2). FDA believes that many changes recommended by CIOMS and ICH would result in more effective reporting of serious adverse experiences to regulatory authorities worldwide.

FDA is proposing to amend the adverse experience reporting requirements for human drug products and licensed biological products in part to be consistent with certain standardized definitions, procedures, and formats proposed by these international organizations.

FDA is also proposing to amend the requirements for clinical study design and conduct and the sponsor reporting requirements in the IND regulations. These amendments are intended to provide more complete and accurate information that would enable sponsors, investigators, and FDA to determine serious toxicities of investigational drugs more expeditiously during clinical studies. A clinical study of fialuridine (FIAU) resulted in several instances of severe liver and pancreatic injury and five deaths, beginning in June 1993. This incident prompted FDA to establish a task force to see whether the data available before the study gave any suggestion of the serious toxicity that emerged, and whether some differences in process or behavior by investigators and sponsors might have made it possible or more likely for them to have anticipated the toxicity in the 1993 study. The proposed IND amendments contained in this document are largely the result of recommendations by this task force.

## II. Description of the Proposed Rule

### A. Replacement of Form FDA-1639 and How to Obtain Copies of FDA Form 3500A

FDA's existing regulations at 21 CFR 20.112, 310.305, and 314.80 refer to Form FDA-1639. The agency is proposing to amend these regulations to replace references to Form FDA-1639 with new FDA Form 3500A. This change is necessary because new FDA Form 3500A replaces Form FDA-1639 (58 FR 31596).

The existing regulations at §§ 310.305(d)(4) and 314.80(f)(4) also provide an address where a person may obtain copies of Form FDA-1639. FDA is proposing to amend these regulations to state where a person can obtain copies of FDA Form 3500A. Ten or fewer copies of FDA Form 3500A and a copy of the instructions for completing the form can be obtained from the Division of Epidemiology and Surveillance (HFD-730), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Large numbers of copies (greater than 10 copies) may be obtained by writing to the Consolidated Forms and Publications Distribution Center,

Washington Commerce Center, 3222 Hubbard Rd., Landover, MD 20785.

### B. Definitions of "Data Lock-Point" and "International Birth Date"

FDA is proposing to amend §§ 314.80(a) and 600.80(a) to define the terms "data lock-point" and "international birth date." The "data lock-point" is the end of the reporting period (cutoff date) for data to be incorporated into a specific postmarketing adverse experience periodic report. On this date, the data available to the reporter are held for review and evaluation by the applicant or licensed manufacturer prior to being submitted to FDA. The international birth date is the date that the first regulatory authority in the world approved the human drug or biological product for marketing. As explained further in section II.E. of this document, each 6-month anniversary of the international birth date is the data lock-point for data to be incorporated into a specific postmarketing adverse experience periodic report.

The proposed rule would define these terms because they describe the standardized international reporting period developed by CIOMS for submitting postmarketing adverse experience reports. CIOMS developed this standardized reporting period to lessen confusion and to enable applicants and licensed manufacturers to prepare and submit similar reports of adverse experiences to regulatory authorities. It would also reduce preparation time among applicants and licensed manufacturers because it eliminates varying due dates presently required for submitting postmarketing adverse experience reports to regulatory authorities worldwide. FDA believes the CIOMS reporting schedule, which decreases reporting rates currently required by FDA for drug and licensed biological products for the first 3 years of marketing from every 3 months to every 6 months and increases it thereafter from every 12 months to every 6 months, permits adequate time for reporters to make periodic submissions to regulatory authorities. In addition, the agency believes that the proposed reporting frequency is sufficient to notify FDA of potential postmarketing safety problems that do not require expedited reporting.

### C. Definition of "Serious"

FDA's existing adverse experience reporting regulations (21 CFR 310.305(b)(4), 312.32(a), 314.80(a), and 600.80(a)) define a serious adverse experience as one that is "fatal or life-threatening, is permanently disabling,

requires inpatient hospitalization, or is a congenital anomaly, cancer, or overdose." Consistent with new FDA Form 3500A and with recommendations by the ICH and CIOMS, the proposed rule would amend this definition to read as follows:

*Serious* means an adverse drug experience occurring at any dose that is fatal or life-threatening, results in persistent or significant disability/incapacity, requires or prolongs inpatient hospitalization, necessitates medical or surgical intervention to preclude permanent impairment of a body function or permanent damage to a body structure, or is a congenital anomaly.

The agency is proposing to remove "cancer" from the definition because cancer would most often be reported under the other broader elements in the definition. For example, cancer may be reported as life-threatening or requiring inpatient hospitalization. Other diseases or conditions that may be life-threatening or require hospitalization, such as heart disease or myocardial infarction, have not been identified as separate elements in previous definitions, and the agency believes it is not necessary to single out cancer.

The proposed amendment would also remove "overdose" from the definition of serious. Reports of overdoses that had serious outcomes would still be reported under the other broader elements in the definition. Reports of overdoses that did not lead to outcomes defined as serious would provide the agency with less critical safety information.

By adding the phrase "occurring at any dose" after "adverse drug experience" in the definition, the agency will ensure that a serious adverse experience at any dose, whether it is the labeled dose or a different dose, including an overdose or an underdose, should be reported.

FDA is also proposing to clarify the phrase "is permanently disabling" by substituting "results in persistent or significant disability/incapacity." This change is intended to clarify that a disability need not be permanent to be considered a serious adverse experience.

The proposed amendments would also modify the phrase "requires inpatient hospitalization" to read "requires or prolongs inpatient hospitalization." This change is intended to cover those situations where a serious adverse experience occurs while the patient is already hospitalized, and the adverse experience prolongs the patient's hospital stay.

FDA is also proposing to add the phrase "necessitates medical or surgical intervention to preclude permanent

impairment of a body function or permanent damage to a body structure." The agency believes such events should be considered serious adverse experiences and should be reported. This change is also consistent with ICH's proposed definition of a serious adverse event. FDA notes that a serious adverse experience would not include the discontinuation of therapy, changes in dosage, or routine treatment with a prescription medication.

#### D. Definitions of "Disability" and "Life-Threatening"

The proposed rule would amend §§ 310.305(b), 314.80(a), and 600.80(a) to define the terms "disability" and "life-threatening." These terms further explain what constitutes a serious adverse experience. "Disability" means a substantial disruption of one's ability to carry out normal life functions. "Life-threatening" means that the patient was, in the view of the initial reporter, at immediate risk of death from the adverse experience as it occurred. It does not include an adverse experience that, had it occurred in a more serious form, might have caused death. For example, product-induced hepatitis that resolved without evidence of hepatic failure would not be considered life-threatening even though hepatitis of a more severe nature can be fatal. Similarly, an allergic reaction resulting in angioedema of the face would not be life-threatening, even though angioedema of the larynx, allergic bronchospasm, or anaphylaxis can be fatal. FDA believes these definitions will help enable reporters to determine when a serious adverse experience occurs.

#### E. Periodic Adverse Experience Reports

Current regulations (§§ 314.80(c)(2)(i) and 600.80(c)(2)(i)) require the submission of periodic postmarketing reports at quarterly intervals for 3 years from the date of approval of the application, and then annually. Quarterly reports must be submitted within 30 days of the close of the quarter (the first quarter beginning on the date of U.S. approval of the application); each annual report must be submitted within 60 days of the date of U.S. approval of the application.

FDA is proposing to revise this schedule by requiring the submission of periodic postmarketing adverse reaction reports every 6 months. The first 6-month anniversary of the international birth date after the application is approved in the United States is the data lock-point for the first periodic reporting term. Each subsequent 6-month anniversary of the international

birth date is the data lock-point for subsequent periodic reporting terms for that particular product. The proposed rule would require periodic reports to be submitted to FDA within 45 days after the data lock-point. For example, a product approved by FDA, or licensed, if a biological product, on June 15, with an international birth date of April 1, would have its first data lock-point on October 1, which is less than 6 months after FDA approval, but which is the 6-month anniversary of the international birth date. Therefore, the first periodic report would be for the period of June 15 to October 1 and would be due at FDA by November 14. The second periodic report would cover October 2 to April 1 and would be due to the agency no later than May 15.

The proposed rule would create the same reporting schedule based on the international birth date and data lock-point for licensed biological product distribution reports under § 600.80(c)(3).

This new reporting schedule is consistent with the standardized international reporting period proposed by the CIOMS II Working Group. This working group has recommended that all international regulatory authorities accept the same reporting schedule in order to lessen confusion and reduce preparation time by manufacturers, rather than the current system of varying due dates. FDA believes the CIOMS reporting schedule, which decreases reporting rates currently required by FDA for drug and licensed biological products for the first 3 years of marketing from every 3 months to every 6 months and increases reporting rates thereafter from every 12 months to every 6 months, permits adequate time for reporters to make nonexpedited submissions to regulatory authorities. In addition, FDA believes that the proposed reporting frequency is sufficient to alert the agency to potential postmarketing safety problems that are not within the categories requiring 15-day "Alert reports."

Applicants and licensed manufacturers who wish to submit periodic postmarketing adverse experience reports at different intervals could, under proposed §§ 314.80(c)(2)(i) and 600.80(c)(2)(i), submit a request for a waiver under 21 CFR 314.90 or 600.90 to alter the reporting intervals for these periodic reports.

Proposed §§ 314.80(c)(2)(i) and 600.80(c)(2)(i) would also amend the reporting requirements for periodic postmarketing adverse experience reports to state that, in cases where the applicant or licensed manufacturer has received no reports of adverse experiences during a reporting period,

the applicant or licensed manufacturer should submit a copy of the current approved labeling and a letter to the agency in place of a periodic postmarketing adverse experience report. The letter should identify the product, the application number, and the reporting period, and state that no adverse experience reports were received during that reporting period.

Sections 314.80(c)(2)(ii) and 600.80(c)(2)(ii) set forth the contents currently required for a periodic report: (1) A narrative summary and analysis of the information in the report and an analysis of the 15-day postmarketing Alert reports submitted during the reporting interval; (2) a report describing each adverse experience not previously reported; and (3) a history of actions taken since the last periodic report. FDA is proposing to amend these regulations to provide a more extensive list of contents for a periodic postmarketing adverse experience report, as follows:

#### 1. Title Page, Table of Contents, and Introduction

This section would provide a summary of the periodic report with page references to detailed data and information.

#### 2. Applicant's Core Safety Data Sheet

The applicant's core safety data sheet would be a document prepared by the applicant that contains all relevant safety information, including adverse drug experiences, which the applicant believes should be listed for the drug in all countries where the drug is marketed. It may be used by the applicant as the reference document by which an adverse drug experience is judged to be expected or unexpected for purposes of this postmarketing periodic report. For all other determinations of whether an adverse drug experience is expected or unexpected, the definition in §§ 314.80(a) or 600.80(a) would apply.

FDA recognizes that the postmarketing periodic report may be submitted by the applicant to multiple countries and the product may have different approved labels in the different countries. The use of the applicant's core safety data sheet as the reference document for determining whether an adverse drug experience is expected or not may result in some overreporting of unexpected adverse events that actually are expected by the U.S. approved product label. This is because the approved label for the United States may have more safety information included in it than the manufacturer's core safety data sheet.

An applicant may also use the approved U.S. label as the reference by which expected and unexpected adverse drug experiences are determined for the postmarketing periodic report. If an applicant chooses to use the approved U.S. label for this purpose, it must clearly be stated in this section of the report. In all instances, if an adverse event is not listed in the U.S. label, but is in the manufacturer's core safety data sheet, this shall be clearly noted in the "Overall safety evaluation" (see section II.E.8. of this document).

This section would also highlight clearly any changes and the reasons for the changes in the applicant's core safety data sheet since the previous postmarketing periodic report.

### 3. The Product's Marketing Status

This section would contain, in tabular form, a chronological history of the marketing status of the product worldwide (all regulatory and marketing decisions affecting the product) from the date it was first approved through its current status. Approvals or applications voluntarily withdrawn for safety reasons would have to be included. The product would be listed by chemical (U.S. Adopted Names, international nonproprietary names, or proper name in accordance with "Chemical Abstracts Nomenclature Standards") and brand name(s).

### 4. Regulatory Actions for Safety Reasons

This section would identify in narrative form the reasons for significant regulatory authority or manufacturer-initiated actions taken anywhere in the world, or to be taken imminently, for safety reasons during the reporting period. This would include, for example, application withdrawal or license suspension or failure to renew, distribution restrictions, clinical trial suspension, labeling changes due to significant safety concerns, dosage modifications, or pharmaceutical changes.

### 5. Patient Exposure

This section would include the product's domestic and foreign marketing distribution data during the reporting period. This information would be used to calculate the extent of patient exposure. The method used by the manufacturer to estimate patient exposure would always be described and would include the total number of dosage units of each dosage form and strength or potency (e.g., 100,000/5-milligram tablets, 50,000/10-milliliter vials).

### 6. Individual Case Histories

These reports would be presented in line listing format with the following 10 columns: country, source, age, gender, dose, duration of treatment (prior to event), time to onset, description of reaction (as reported), outcome (e.g., fatal, resolved), other comments (e.g., manufacturer's report number). This format is consistent with that suggested by CIOMS. In addition, a tabular summary of the number of adverse events by body system may be included. The individual case reports would consist of adverse drug experiences that are: (a) Serious, unexpected reports from published or unpublished clinical studies where it has been concluded that there is a reasonable possibility that the drug or licensed biological product caused the adverse experience; (b) serious, expected or unexpected spontaneous adverse drug experience reports and nonserious, unexpected spontaneous adverse experience reports received directly by the applicant or licensed manufacturer from the initial reporter or received by the applicant or licensed manufacturer from a drug regulatory authority, both U.S. or foreign; and (c) serious, expected or unexpected individual published case histories and nonserious, unexpected individual published case histories. This section would end with an analysis by the reporter, in narrative form, of the cases submitted. The applicant or licensed manufacturer would also attach to the end of the postmarketing periodic report a completed FDA Form 3500A for all U.S. spontaneous reports of adverse experiences except those not to be included in the periodic report as specified in proposed §§ 314.80(c)(1)(i) and (c)(1)(ii) and 600.80(c)(1)(i) and (c)(1)(ii), or those sent by FDA to the applicant or licensed manufacturer.

### 7. Safety Studies

This section would analyze and discuss fully and critically all toxicological, clinical, and epidemiological studies containing important safety information.

### 8. Overall Safety Evaluation

This section would provide critical analysis of the safety information provided in the periodic report as it pertains to serious unexpected reactions, increased frequencies of known toxicity, reactions listed in the manufacturer's core safety data sheet but not included in the U.S. label, drug or licensed biological product interactions, overdose, drug or licensed biological product abuse, experiences during pregnancy or lactation, chronic

treatment, pediatric or geriatric treatment, and new safety issues. For each of these areas, any absence of significant information would be reported. The evaluation would indicate whether the safety profile of the product remains consistent with cumulative experience to date and with the previous manufacturer's core safety data sheet. The evaluation would specify any action recommended and the reasons for such recommendations.

### 9. Other Information

This section would consist of important information received after the data lock-point. It may include significant new cases or followup data that affect the interpretation or evaluation of existing reports.

### 10. FDA Form 3500A

This section would consist of a completed FDA Form 3500A for each spontaneous U.S. adverse drug experience not reported under paragraphs (c)(1)(i) and (c)(1)(ii) in §§ 314.80 and 600.80.

### 11. Location of Adverse Experience Records

This section would identify the current address(es), including street, city, State, and zip code, where all adverse experience reports and records are maintained.

This revised list of contents for periodic postmarketing adverse experience reports is generally consistent with the international system of standardized postmarketing periodic reporting procedures and formats proposed by the CIOMS II Working Group. This standardization would allow applicants and licensed manufacturers to prepare a single postmarketing periodic report of adverse experiences for regulatory authorities worldwide. The agency also believes that the proposed rule would improve reporting and would enhance FDA's ability to monitor potential postmarketing safety problems.

As a result of this proposed revised list of contents for periodic postmarketing adverse experience reports, FDA is proposing to remove §§ 314.80(c)(2)(iii) and 600.80(c)(2)(iii). These sections state that periodic reporting does not apply to information obtained from postmarketing studies, reports in the scientific literature, and foreign marketing experience. The proposed revised list of contents would include such information.

### F. IND Amendments

FDA regulations governing the use of investigational drugs in clinical

investigations are contained in part 312 (21 CFR part 312). In order to conduct a clinical investigation using an investigational drug, a sponsor must first submit an IND, described in § 312.23, which contains, among other things, a description of the drug, the results of preclinical studies intended to show that the drug can be introduced into humans with reasonable safety, and a proposed protocol for the investigation. This protocol provides a description of all aspects of the study, including the identity and qualifications of the investigators conducting the study, procedures and criteria for selecting subjects, the amount of the drug to be administered, the duration of use, the observations to be made to assess the effects of the drug, and the clinical procedures, laboratory tests, and other measures carried out to minimize risk to the patient. After the IND becomes effective and the investigational drug is being administered to human subjects, the sponsor is required under § 312.32 to make both telephone and written safety reports on serious and unexpected adverse experiences associated with the administration of the drug, as well as written reports only, on other serious adverse events associated with administration of the drug. Under current § 312.33, the sponsor is also required to submit an annual report containing significant safety and other information. If FDA concludes that a study would place subjects at unreasonable and significant risk, FDA may place a study on clinical hold. This means that the drug may not be administered to subjects until the hold is lifted (see § 312.42). FDA may also terminate the study under § 312.44 based on such safety concerns.

FDA is concerned that these IND reporting requirements may not be adequate to protect against some unexpected adverse events. For example, there is a potential for such events to be disguised by patient conditions that might lead the investigator to conclude that the experimental drug was not implicated in those events. The agency believes that certain modifications in the way clinical investigations are conducted and reported may help to ensure that drug toxicity is detected as early as possible. A recent internal task force that examined an incident that involved a fatal drug toxicity that was not detected in early trials has recommended improvements in IND reporting that the agency is incorporating into this proposal for public consideration. These

improvements, as explained below, are intended to provide more frequent and more complete evaluations of potentially serious adverse effects so that drug-related events can be detected earlier by sponsors, investigators, and FDA.

A clinical study of a nucleoside analog, FIAU, resulted in several instances of severe liver injury and five deaths, beginning in June 1993. The study involved 15 subjects with chronic hepatitis B virus infection. FIAU had been considered a highly promising agent without recognized serious toxicity. This incident prompted FDA to establish a task force to see whether the data available prior to the study gave any suggestion of the serious toxicity that emerged. The task force examined data from the 1993 FIAU study as well as data from previous studies on FIAU and a closely related drug conducted by another sponsor. The data from these previous studies was, or should have been, available to the sponsor of the 1993 FIAU study. The task force was also to determine whether some differences in process or behavior by investigators and sponsors might have made it possible or more likely to have anticipated the toxicity. The proposed IND amendments contained in this document are largely the result of recommendations by the task force (Ref. 3).

Focusing on hepatic and pancreatic adverse events, the task force reviewed the data and data analyses that were available to investigators, sponsors, and FDA at the start of the study to determine whether improvements in the rules governing design, analysis, and reporting of data from clinical studies were warranted. The task force found a number of observations and events that suggested an association between FIAU and hepatic and/or pancreatic abnormalities. However, none of these events was attributed by the sponsors or investigators to FIAU. Rather, each event, even when recognized as temporally related to a study, was attributed by investigators and sponsors to other factors, such as concomitant drug administration and/or concurrent illness. The task force found that an overview of the data, in which deaths and serious adverse experiences were analyzed cumulatively, and, with the hypothesis that the events were drug related, was not produced and thus was not available for use by the sponsors, the principal investigators, or FDA reviewers. Rather, the analyses performed focused on each individual event and determined a plausible explanation, other than drug toxicity, for each occurrence. The task force

recommended that, to detect similar patterns of events reflecting toxicity in future studies, sponsors should conduct cumulative analyses with a systematic consideration of the possibility that the adverse events are caused by the investigational drug.

The proposed IND amendments would apply to all investigational studies conducted under part 312. However, FDA invites comments from the public and industry on whether any or all of the proposed requirements should apply only to certain IND's, whose selection could be determined by application of criteria that could be included in these regulations, or only to certain phases of drug testing.

### 1. Clinical Study Design

FDA is proposing to amend the requirements governing IND format and content in § 312.23. Under current § 312.23(a)(6), an IND must contain the protocols for each planned study, including information such as a statement of the study's objectives and purpose, the criteria for patient selection and exclusion, a description of the study design, the method for determining the dose(s) to be administered and the duration of individual patient exposure to the drug, and a description of clinical procedures, laboratory tests, or other measures to be taken to monitor the effects of the drug in human subjects and to minimize risk.

In several instances, FDA's FIAU task force found that deaths and serious hepatic and pancreatic injuries that appear in retrospect to have been related to FIAU were attributed by investigators and sponsors to the subjects' underlying disease or to other drugs the subjects were taking for their conditions. The task force made several recommendations intended to improve the likelihood that clinical studies will identify, early in drug development, drug toxicity that mimics the underlying disease or the toxicity of concomitant medications. These recommendations include: (1) Choosing study designs and safety endpoints that increase a study's ability to distinguish drug toxicity from underlying disease or other drug toxicity; (2) prospectively identifying observations that will trigger certain actions by investigators; and (3) summarizing safety data at regular intervals with systematic considerations of the possibility that adverse events are drug related. The proposed rule would create new § 312.23(a)(6)(iii)(h) to require that the protocols describe any adverse clinical or laboratory outcomes in the study that are to be immediately reported to the sponsor. These reportable events might include death.

any life-threatening event, or any other serious event that might reflect potential drug toxicity, as suggested by preclinical data, and include abnormal laboratory results falling outside of a specified range. The identified events and abnormal laboratory values are to include those that focus attention on toxicity that may target the same organs and body systems as the underlying disease or concomitant medications. Under the proposal, these events would be reported to the sponsor even if they are potentially attributable to the patient's underlying disease or concomitant medications. Proposed § 312.23(a)(6)(iii)(h) would also require instructions for investigators, such as reporting requirements, remeasurement or challenge procedures, or discontinuation of the drug in response to identified events.

The task force also recommended that sponsors consider the use of a control group (for example, placebo, active control, or historical control) in studies that focus on safety when the underlying disease process is likely to produce adverse events that might be confused with drug toxicity. The task force concluded that such controls would help detect some adverse events. Consequently, proposed § 312.23(a)(6)(iii)(i) states that sponsors should consider the use of a formal control group when the underlying disease is likely to produce adverse events that might be confused with drug toxicity.

The task force also recommended that sponsors attempt to estimate the expected incidence of death and serious adverse events in the study population that arise from the underlying disease or concomitant medications used to treat the disease. This recommendation is reflected in proposed new § 312.23(a)(6)(iii)(j) that would require sponsors to provide such estimates. Under the proposal, any deaths or adverse events that exceed the estimates would create the presumption that the events are associated with use of the investigational drug, and the sponsor would be required to submit a written safety report to FDA.

The task force found that the followup periods in some of the FIAU and related studies were too short to detect some of the adverse events that occurred because significant adverse events sometimes occurred weeks to months after dosing with FIAU ended. The task force recommended that all protocols contained in the IND include an explicit description of the length and type of followup to be performed so that the agency may review the followup procedures (task force report at 57).

Accordingly, FDA is proposing to add new § 312.23(a)(6)(iii)(k) to require that the protocol section of an IND specify and justify the length and type of followup for subjects after the conclusion of dosing. The justification may be brief; for example, a reference to a study of a similar drug with the same followup period. The followup period would ensure that clinical studies are adequately designed to detect drug toxicity that occurs after the conclusion of drug dosing. The sponsor would propose an appropriate followup period based on preclinical data, experience with other members of the drug class, the drug's mechanism of action, and prior human experience. The intensity of the followup may change with time; e.g., a full evaluation might be scheduled for 2 weeks postdosing, with a telephone followup for possible serious events at a later time. Ordinarily, in Phase 1 and 2 studies, telephone followup should occur at 3 months after the dosing is completed, but alternative timeframes and procedures can be proposed by the sponsor. For some drugs, like FIAU, a review of available data may suggest that the minimum followup period should be longer than 3 months.

Current regulations in § 312.56 require sponsors to review and evaluate the evidence relating to a drug's safety and effectiveness as it is obtained from investigators. The regulations also require sponsors to report safety information to FDA. The task force observed that in the FIAU study sponsors may not have had available adequate resources to evaluate safety data reported by investigators. The proposed rule would amend § 312.56(c) to require sponsors, in addition to reviewing and evaluating safety and effectiveness information, to develop a safety monitoring and evaluation program before starting clinical trials. This provision is intended to ensure that sponsors have or will develop adequate resources to evaluate safety data reported by investigators and is consistent with the task force's recommendations (see task force report at 57). Consistent with this proposed requirement, FDA is also proposing in new § 312.23(a)(3)(v) that an IND contain a description of any safety monitoring and evaluation program. This description would be in addition to the introductory statement and general investigational plan that are required under current regulations.

## 2. Safety Reports

FDA is proposing several amendments to the requirements for IND safety reports in § 312.32. FDA is

proposing to alter the period for submitting written safety reports, under § 312.32(c)(1)(i) and (d)(3), from 10 working days to 15 calendar days, and for submitting safety reports by telephone, under § 312.32(c)(2), from 3 working days to 7 calendar days. FDA is also proposing to allow telephone safety reports to be made by facsimile transmission as well as orally by telephone. These changes will give sponsors additional time to gather appropriate data to help interpret the reports before submitting these reports. FDA believes the extended time period would be sufficient to alert the agency to potential safety problems, especially because of the new investigational reporting requirements the agency is proposing.

Proposed § 312.32(c) would also permit sponsors to submit IND safety reports to the agency by using FDA Form 3500A. If FDA determined that insufficient data were submitted on FDA Form 3500A, the agency could require additional narrative data to be submitted. As explained elsewhere in this proposal, this amendment is consistent with the proposal to use this form for postmarketing reporting of human drug and licensed biological product adverse experiences.

FDA is also proposing to amend the disclaimer contained in § 312.32(e) to emphasize that safety information submitted to FDA are not to be considered admissions of causation or liability. The proposal would substitute the word "part" for "section" so that the revised disclaimer would clearly apply to all safety information submitted under part 312. Summaries of such safety information would not constitute a statement or admission that there was a causal link between the administration of the drug and the subsequent adverse event.

## 3. Semiannual Reports

FDA is proposing to amend the periodic reporting requirements in § 312.33 by adding, in addition to the annual report, a semiannual death and serious adverse experiences report. This change is intended to ensure that reports of deaths and other serious adverse experiences in all clinical studies are collected and reviewed in a timely and comprehensive manner, and that the possibility of drug relatedness is always considered.

Under current regulations, sponsors must report deaths and serious and unexpected adverse experiences within 3 or 10 working days only if the events are associated with the use of the drug. "Associated with the use of the drug" is defined to mean that there is a

reasonable possibility that the experience may have been caused by the drug (see § 312.32(a)). Deaths and a summary of serious adverse experiences that occur in a clinical trial that the sponsor concludes are not associated with use of the drug must be reported only in an IND annual report. The task force found that many adverse experiences occurring during the FIAU study that appear, in retrospect, to have been drug related were not reported in safety reports, although, at times, they were reported in the annual report as attributable to causes other than FIAU.

The proposed rule, therefore, would create a new "semiannual report" to require, among other things, the submission of reports of all deaths, serious adverse experiences, and study discontinuations resulting from an adverse experience, whether expected or unexpected and whether or not there was thought to be a possibility that the death or adverse experience was caused by the drug. In these twice yearly reports, sponsors would also report all deaths and serious adverse experiences that occurred during the trial or within the prescribed followup period. The report would include data not only from studies conducted under the IND, but also data from all premarketing studies of the drug conducted worldwide, with an analysis of all unexpected deaths, serious adverse experiences, and study discontinuations thought to be related to the study drug from foreign postmarketing clinical trials and from foreign postmarketing spontaneous or required reporting systems. Serious adverse events should include laboratory changes that result in discontinuation or that are identified in the study protocol as reportable events. Sponsors would present these data both for the 6-month reporting interval and cumulatively, and submit an analysis of the data. The agency would expect the analysis to conform generally to the evaluation of deaths, serious adverse experiences, and discontinuations in the section entitled "Integrated Summary of Safety Information" in FDA's "Guideline for the Format and Content of the Clinical and Statistical Sections of New Drug Applications." FDA also recommends that the sponsor employ, in preparing the analysis, at least one individual who had no involvement in conducting the clinical study. The proposal would also require a sponsor to conduct a "worst-case" analysis of the safety data, presuming that observed adverse events were the result of toxicity from the investigational drug, and then attempt to refute this presumption, with appropriate data and

evaluations (task force report at 59). The analysis should include estimates of the rate of an analyzed event occurring spontaneously in the population and specific analyses of cases.

The sponsor would submit the semiannual report for the 6-month period following the day the IND goes into effect, and for each 6-month period thereafter, until the end of the followup period specified in the protocol. The report would be due within 60 days of the end of the reporting period. The semiannual safety report that is due during the same period as the annual report would be submitted with the annual report.

The task force recommended (task force report at 59) that FDA require the submission of all available autopsy reports and medical reports concerning all deaths reported in these semiannual reports, because, in at least one instance during the FIAU study, the cause of death originally reported was not fully consistent with the autopsy and terminal medical reports later obtained for that subject. Proposed § 312.33(b)(2) would require the submission of these reports and would require the sponsor to clarify any inconsistencies between these reports and the cause of death reported to FDA by the sponsor. FDA is proposing this requirement to help ensure that reports covering deaths submitted to the agency are complete and accurate.

Under proposed § 312.33(b)(3), at the request of the sponsor, or on its own initiative, FDA may modify certain semiannual reporting requirements where, for example, the clinical study endpoint is mortality or where the study is blinded and full compliance with the reporting requirement would require breaking the blind. FDA is proposing this provision because studies vary concerning the nature and seriousness of the disease to be treated, the number of subjects exposed to the drug, and the general pace at which the drug's development proceeds.

#### 4. Special Safety Summary

In new § 312.37(a), FDA also proposes an additional mechanism to allow the agency to obtain safety data on investigational drugs and summaries of these data not otherwise obtained through other reporting requirements if, and when, these data are necessary. Most investigational drugs do not present unusual safety concerns, so that the safety data contained in the 6-month and annual reports, as well as the IND safety reports submitted under § 312.32, would provide adequate information to allow FDA to observe drug safety. Some drugs, however, may raise significant

safety concerns either anticipated or unanticipated, so that more comprehensive data on events that do not meet the definition of a serious adverse reaction as well as those that do are needed. Events that might trigger this heightened scrutiny include agency experience with similar drugs, animal toxicity study results, and information derived from IND safety, annual, or semiannual reports. As recommended by the task force (task force report at 59 and 60), the proposed regulation is drafted in general language to allow the agency, in consultation with the sponsor, flexibility in determining when a report should be required and what information it should contain. This flexibility is considered necessary because the specifics of the safety summary may vary from study to study. FDA anticipates that the safety summary will generally not only contain the results of the cumulative analysis of deaths and serious adverse experiences contained in the 6-month report, but also an analysis of related events of lesser seriousness.

Although the task force recommended that FDA require safety summaries unless an exemption had been granted to the sponsor, FDA is proposing to require safety summaries only for those studies or products where the agency has determined that a specific need for them exists. FDA would generally expect safety summaries to be submitted within 30 days after they are requested; however, the agency recognizes that in cases where large amounts of data are required to be summarized and those data are not readily available or easily summarized, a longer period of time may be necessary to prepare the summary.

#### 5. Final Clinical Study Report

Information about FIAU risks and benefits that the sponsor might have derived from the process of collecting and analyzing study results was delayed or never developed because final reports were not required for the earlier clinical studies of FIAU and FIAC (a closely related nucleoside analog). Thus, FDA is proposing in § 312.37(b) to require sponsors to submit, when required by FDA, a final report or study summary of a clinical study. FDA anticipates that final reports usually will not be necessary. Instituting requirements for semiannual reporting of deaths, serious adverse experiences, and discontinuations, and for summarization of all safety data will largely fulfill the need for more careful monitoring and analysis of potential drug toxicity during drug testing. In some cases, however, it may still be

valuable to have available an analysis of the results of particular trials; e.g., to provide data on the likely effectiveness of a drug for purposes of weighing risks against likely benefits to study subjects. The proposal would require final clinical study reports to be submitted within 90 days of a request from FDA, but provides for exceptions under extraordinary circumstances.

#### 6. Clinical Holds

Section 312.42 currently allows FDA to delay a proposed clinical investigation or to suspend an ongoing investigation under certain circumstances. Under the proposal, FDA would amend § 312.42 to allow the agency to place an investigation on clinical hold if the sponsor fails to submit a special safety summary or final clinical study report. If the same or a closely related drug is the subject of a concurrent investigation, conducted by the same sponsor, proposed § 312.42(b)(1)(v) would require safety summaries from all investigations or the agency could place any of the investigations on clinical hold. FDA believes this is appropriate because data from all studies involving the drug or closely related drugs may help FDA evaluate the safety of each study.

#### 7. Termination

FDA is also proposing in § 312.44(b)(1)(viii) to amend the regulations regarding termination so that failure to submit a semiannual report would be grounds for terminating an IND. Failure to submit an annual report is already grounds for terminating an IND, and FDA is aware of no reason why semiannual and annual reports should be treated differently in this matter.

FDA considers that failure to implement an adequate safety monitoring and evaluation program, as described in proposed 21 CFR 312.56(c), would be grounds for either a clinical hold under § 312.42 or a termination of the IND under § 312.44, since failure to have a program in place would mean that "[h]uman subjects are or would be exposed to an unreasonable and significant risk of illness or injury," which is currently grounds for either a clinical hold or termination.

#### 8. Review of Ongoing Investigations

FDA is also proposing to amend § 312.64(b) to require investigators to submit safety data to sponsors necessary to allow sponsors to comply with the other proposed safety reporting requirements, such as the proposed semiannual report. The proposed amendment would require the

investigator to comply with safety reporting requirements established in the protocol for the study. Current § 312.64(b) requires investigators to report adverse effects if they may reasonably be regarded as caused by, or probably caused by, the drug. If the adverse effects are alarming, they are to be reported to the sponsor immediately. These provisions are being retained as minimal requirements which must be met, even if the protocol does not require the events to be reported.

#### G. Written Procedures for Monitoring Adverse Experiences

FDA is also proposing to amend §§ 310.305(a) and 314.80(b) for marketed human drug products and § 600.80(b) for licensed biological products to require applicants or manufacturers, packers, and distributors to develop written procedures for the surveillance, receipt, evaluation, and reporting of adverse experiences to FDA. This requirement would improve postmarketing surveillance by applicants or manufacturers and would enhance an applicant's or manufacturer's ability to evaluate and report adverse experiences to the agency. FDA believes that this provision would not impose a new burden on applicants and manufacturers, because it codifies a practice that is already customary and usual in the pharmaceutical industry for handling adverse experiences. Based on field inspections, FDA is aware that many manufacturers already have written procedures for the receipt, evaluation, and reporting of adverse experiences to FDA. The agency also notes that the current good manufacturing practice (CGMP) regulations for finished pharmaceuticals, which apply to manufacturers of all marketed human drug and biological products, require written procedures describing the handling of all written and oral complaints regarding a drug product (21 CFR 211.198).

Furthermore, the agency's "Guideline For Postmarketing Reporting of Adverse Drug Experiences" (Ref. 4), which provides guidance on adverse drug experiences reported under §§ 310.305 and 314.80, states (at page 17) that:

Each applicant should develop standardized, formal procedures for the surveillance, receipt, evaluation, and reporting of ADE's to FDA. \* \* \* All applicants should develop procedures that allow expedited adverse experience report handling, and the applicant should keep on file documentation of due diligence.

Elsewhere in this issue of the *Federal Register* FDA is announcing the availability of a guideline entitled "Guideline for Adverse Experience

Reporting for Licensed Biological Products." This guideline discusses the reports required by § 600.80 and provides guidance concerning appropriate means of meeting the reporting requirements.

#### H. Resubmission of Reports Received From FDA

Under the MedWatch program, FDA will transmit reports of spontaneously reported serious adverse experiences received by the agency to the applicant, manufacturer, packer, or distributor (as appropriate) on an expedited basis. Consequently, FDA is proposing to revise §§ 310.305(c), 314.80(b), and 600.80(b) to state that applicants or manufacturers, packers, and distributors should not resubmit to the agency reports of adverse experiences that the agency has forwarded to them. In addition, FDA is proposing to revise §§ 314.80(c)(1)(i) and 600.80(c)(1)(i) to remove the phrase "regardless of source" from the description of which adverse experiences are reported to FDA. These revisions are intended to reduce duplicate reporting of adverse experiences to the agency, consistent with the reporting instructions in new FDA Form 3500A. FDA notes, however, that applicants or manufacturers, packers, and distributors receiving reports forwarded to them by FDA are required to handle these reports as they would any others and that followup, if obtained, is to be sent to the agency as specified in the regulation. These followup reports should be included, where appropriate, in the postmarketing adverse experience periodic report.

FDA is also proposing that applicants and licensed manufacturers incorporate into any safety analysis (i.e., periodic reports, increased frequency reports) the expedited reports received from FDA, whether or not additional followup information was obtained, and any information received through Freedom of Information requests.

#### I. Other Revisions to the Reporting Requirements

FDA is proposing to remove §§ 314.80(c)(2)(iii) and 600.80(c)(2)(iii). These paragraphs state that periodic reporting for non-15-day Alert reports does not apply to adverse drug experience information obtained from postmarketing studies and reports in the scientific literature and from foreign marketing experience. FDA is proposing to remove these paragraphs because this information would now be required under the proposed revisions to the contents of a periodic report.

Current regulations, at § 314.80(c)(1)(ii), require applicants and,

at § 600.80(c)(1)(iii), licensed manufacturers to "review periodically (at least as often as the periodic reporting cycle)" the frequency of reports of adverse experiences and report any significant increase in frequency to FDA. Similarly, current § 310.305(c)(4) requires manufacturers, packers, and distributors to "review periodically (at least once each year)" the frequency of reports of adverse experiences and report any significant increase in frequency to FDA. In order to provide consistency with the proposed semiannual reporting requirements for periodic adverse experience reports under §§ 314.80 and 600.80, FDA is proposing to amend § 310.305(c)(4) to require manufacturers, packers, and distributors to review periodically, at least twice each year, the frequency of adverse experience reports for the purposes of making increased frequency reports to FDA.

FDA is also proposing to amend §§ 310.305(c) and 314.80(c) by reorganizing, renumbering, and retitling the paragraphs in these sections to distinguish between postmarketing 15-day Alert reports, followups to postmarketing 15-day Alert reports, and increased frequency reports. The proposed amendments would also distinguish between the reporting intervals for postmarketing 15-day Alert reports and the revised intervals proposed for postmarketing periodic reports.

FDA is also proposing to amend §§ 310.305(c)(1) through (c)(4) and 314.80(c)(1)(i), through (c)(1)(iv) to alter the period for submitting postmarketing "15-day" Alert reports from 15 working days to 15 calendar days. This change should decrease misunderstandings with the reporting requirements as all timeframes would now be stated in terms of calendar days. In addition, this change would increase consistency between the premarketing and postmarketing reporting requirements.

FDA is also proposing to amend §§ 310.305(c)(2), 314.80(c)(1)(ii), and 600.80(c)(1)(ii) to require applicants or manufacturers, packers, and distributors who have been unable to obtain additional information about adverse experiences that are the subject of postmarketing 15-day Alert reports to maintain records of their attempts to seek additional information. These proposed revisions will help ensure that applicants or manufacturers are making good faith efforts to investigate adverse experiences that are the subject of postmarketing 15-day Alert reports.

Finally, FDA is proposing to amend §§ 310.305(d)(3)(ii) and 314.80(f)(3)(ii) to instruct applicants or manufacturers,

packers, and distributors that, before using an alternative reporting form instead of FDA Form 3500A, they must obtain approval from MedWatch: The FDA Medical Products Reporting Program, 5600 Fishers Lane, Rockville, MD 20852-9787. Current regulations require prior approval from the Division of Epidemiology and Surveillance for human drug products.

#### J. Distribution Reports

As stated earlier, the proposed rule would change the reporting interval for licensed biological product distribution reports to be consistent with the suggested CIOMS standardized reporting period for postmarketing adverse drug experience periodic reports. Licensed biological product distribution reports would be based on the international birth date and data lock-point. The proposal would also remove § 600.81 and move the regulatory requirements for licensed biological product distribution reports to § 600.80(c)(3).

#### K. Multiple Reports

FDA is proposing to amend § 600.80(g) concerning multiple reports by adding information pertaining to a licensed biological product for which a licensed manufacturer holds more than one biological product license. This revision would be consistent with the requirements in § 314.80(g).

#### L. Guidelines

FDA is proposing to amend §§ 314.80(j) and 600.80(j) to indicate where guidelines for the submission of adverse experience reports may be obtained. In addition, FDA is adding this information in § 310.305(g) for the submission of adverse experience reports for prescription drugs without an approved application. For human drug products, the guidelines may be obtained from the CDER Executive Secretariat Staff (HFD-8), Center for Drug Evaluation and Research, Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, and for licensed biological products from the Congressional and Consumer Affairs Branch (HFM-12), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852-1448.

#### M. Proposed Implementation Scheme

FDA proposes that any final rule that may issue based on this proposal become effective 30 days after its date of publication in the Federal Register. All applications for human drug or licensed biological products approved

on or after the effective date of any final regulation would be subject to the periodic reporting time periods based on the international birth date. All human drug and licensed biological product applications approved before the effective date of any final regulation would use the U.S. approval date as the international birth date.

#### III. Request for Comments

Interested persons may, on or before January 25, 1995, 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. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the 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.

#### V. Analysis of Impacts

FDA has examined the impacts of the proposed rule under Executive Order 12866 and the Regulatory Flexibility Act (Pub. L. 96-354). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety and other advantages; distributive impacts; and equity). The agency believes that this proposed rule is consistent with the regulatory philosophy and principles identified in the Executive Order. In addition, the proposed rule is not a significant regulatory action as defined by the Executive Order and so is not subject to review under the Executive Order.

The economic costs imposed on the industry as a result of this proposed rule are the costs associated with reporting deaths, serious adverse experiences, or clinical study discontinuations. Reporting burdens on the industry resulting from FDA regulations are analyzed under the Paperwork Reduction Act of 1980. Based on an estimated total of 480,602 annual burden hours, FDA has estimated that

the total annual reporting cost to the industry as a result of this proposed rule would be \$ 24,030,100 (the estimated per hour cost to the industry is \$ 50). In addition, the rule may increase certain nonpaperwork activities. For example, added costs may result if the formal control groups suggested in § 312.23(a)(6)(iii)(i) prompts additional clinical trial control arms, or if the implementation of the followup plan required in § 312.23(a)(6)(iii)(k) provokes more elaborate monitoring procedures. At this time, FDA cannot predict the extent of these actions, but welcomes public comment on issues regarding the scope or cost of these activities.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. The agency certifies that the proposed rule will not have a significant economic impact on a substantial number of small entities. Therefore, under the Regulatory Flexibility Act, no further analysis is required.

#### VI. Paperwork Reduction Act of 1980

This proposed rule contains information collection requirements which are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1980. The title, description, and respondents of the information collection requirements are shown below.

**Title:** Adverse Experience Reporting Requirements For Human Drug and Licensed Biological Products.

**Description:** FDA is proposing to amend its current adverse experience reporting requirements to replace current Form FDA-1639 with new FDA Form 3500A; to revise certain definitions and reporting periods and formats; to require applicants or manufacturers, packers, and distributors to develop written procedures for monitoring and reporting adverse experiences; and to make other revisions to provide uniformity to the reporting regulations. These changes would simplify and facilitate the reporting of adverse events and product problems under a single form and help harmonize international adverse event reporting requirements. In addition, FDA is proposing to amend the sponsor reporting requirements in part 312.

**Description of Respondents:** Businesses or other for profit and small businesses or organizations.

The burden hours for §§ 310.305 and 314.80 are approved under OMB information collection number 0910-0230. The burden hours for § 600.80 have been submitted to OMB for approval and can be found elsewhere in this issue of the **Federal Register**. FDA estimates no change in the burden hours that have already been approved. OMB has approved use of the new form, under OMB information collection number 0910-0291, through December 1994. The new recordkeeping

requirements under § 310.305(c)(2), 314.80(c)(1)(ii), and 600.80(c)(1)(ii), that applicants or manufacturers, packers, and distributors maintain records of unsuccessful attempts to obtain additional followup information on 15-day "Alert reports," would be negligible and would result in no change in the burden hours that have already been approved.

The new requirements under §§ 310.305(a), 314.80(b), and 600.80(b), that applicants or manufacturers, packers, and distributors develop written procedures for the surveillance, receipt, evaluation, and reporting of adverse experiences, would not impose a new burden because they codify a practice that is already customary and usual in the pharmaceutical industry for handling adverse experiences.

The more extensive list of contents for the periodic postmarketing adverse experience report, in proposed §§ 314.80(c)(2)(ii) and 600.80(c)(2)(ii), would result in an increased reporting burden on the industry. As indicated in the accompanying chart, the proposed periodic reporting requirements would require, on an average, 19 additional hours for respondents to prepare.

The proposal would also increase the reporting requirements for sponsors under part 312. As indicated in the accompanying chart, the proposed amendments to part 312 would result in an increase of 167,900 burden hours on the industry.

#### ESTIMATED TOTAL ANNUAL REPORTING BURDEN

Section	Number of respondents	Responses per respondent	Total annual responses	Hours per response	Total hours
312.23(a)(3) and (a)(6) .....	1,623	1	1,623	4	6,492
312.33(b) .....	1,517	2.6	3,944	40	157,760
312.37(a) .....	152	1	152	16	2,432
312.37(b) .....	152	1	152	8	1,216
314.80(c)(2) .....	528	30.50	16,106	19	306,014
600.80(c)(2) .....	63	5.58	352	19	6,688
Total .....					480,602

As required by section 3504(h) of the Paperwork Reduction Act of 1980, FDA has submitted a copy of this proposed rule to OMB for its review of these information collection requirements. Other organizations and individuals desiring to submit comments regarding the burden estimate or any aspects of these information collection requirements, including suggestions for reducing the burden, should direct them to FDA's Dockets Management Branch (address above) and to the Office of Information and Regulatory Affairs,

OMB, rm. 3208, New Executive Office Bldg., Washington, DC 20503, Attn: Desk Officer for FDA.

#### VII. 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. to 4 p.m., Monday through Friday.

1. "International Reporting of Adverse Drug Reactions," Final Report of the CIOMS Working Group, 1990.

2. "International Reporting of Periodic Drug Safety Update Summaries," Final Report of the CIOMS Working Group II, 1992.

3. "Fialuridine: Hepatic and Pancreatic Toxicity," FDA Task Force Report, November 12, 1993.

4. "Guideline for Postmarketing Reporting of Adverse Drug Experiences," FDA, Center for Drug Evaluation and Research, March 1992.

**List of Subjects****21 CFR Part 20**

Confidential business information, Courts, Freedom of information, Government employees.

**21 CFR Part 310**

Administrative practice and procedure, Drugs, Labeling, Medical devices, Reporting and recordkeeping requirements.

**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 600**

Biologics, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act, the Public Health Service Act, and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR parts 20, 310, 312, 314, and 600 be amended as follows:

**PART 20—PUBLIC INFORMATION**

1. The authority citation for 21 CFR part 20 continues to read as follows:

**Authority:** Secs. 201–903 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321–393); secs. 301, 302, 303, 307, 310, 311, 351, 352, 354–360F, 361, 362, 1701–1706, 2101 of the Public Health Service Act (42 U.S.C. 241, 242, 242a, 242l, 242n, 243, 262, 263, 263b–263n, 264, 265, 300u–300u–5, 300aa–1); 5 U.S.C. 552; 18 U.S.C. 1905.

**§ 20.112 [Amended]**

2. Section 20.112 *Voluntary drug experience reports submitted by physicians and hospitals* is amended in paragraph (a) by removing the words "Form FDA-1639" and adding in their place "FDA Form 3500".

**PART 310—NEW DRUGS**

3. The authority citation for 21 CFR part 310 continues to read as follows:

**Authority:** Secs. 201, 301, 501, 502, 503, 505, 506, 507, 512–516, 520, 601(a), 701, 704, 705, 721 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 351, 352, 353, 355, 356, 357, 360b–360f, 360j, 361(a), 371, 374, 375, 379e); secs. 215, 301, 302(a), 351, 354–360F of the Public Health Service Act (42 U.S.C. 216, 241, 242(a), 262, 263b–263n).

4. Section 310.305 is amended by adding a new sentence at the end of the concluding text of paragraph (a); by revising paragraphs (b), (c), (d)(3)(ii), and (d)(4); by removing in paragraph (d)(1) the words "Form FDA-1639 (Adverse Reaction Report)" and adding in their place "FDA Form 3500A"; by removing in paragraph (d)(2), the introductory text of paragraph (d)(3), and paragraph (d)(3)(i) the words "Form FDA-1639" and adding in their place "FDA Form 3500A"; by removing in paragraph (f)(1) the words "paragraph (c)(5)" and adding in their place the words "paragraph (c)(4)"; and by redesignating paragraph (g) as paragraph (h) and by adding new paragraph (g) to read as follows:

**§ 310.305 Records and reports concerning adverse drug experiences on marketed prescription drugs for human use without approved new drug applications.**

(a) \* \* \* Manufacturers, packers, and distributors shall also develop written procedures for the surveillance, receipt, evaluation, and reporting of adverse drug experiences to FDA.

(b) *Definitions.* The following definitions of terms apply to this section:

(1) *FDA* means the Food and Drug Administration.

(2) *Adverse drug experience* means any adverse event associated with the use of a drug in humans, whether or not considered drug related, including the following: An adverse event occurring in the course of the use of a drug product in professional practice; an adverse event occurring from drug overdose; an adverse event occurring from drug withdrawal; and any failure of expected pharmacological action.

(3) *Disability* means a substantial disruption of a person's ability to carry out normal life functions.

(4) *Increased frequency* means an increase in the rate of occurrence of a particular adverse drug experience, e.g., an increased number of reports of particular adverse drug experience after appropriate adjustment for drug exposure.

(5) *Life-threatening* means that the patient was, in the view of the initial reporter, at immediate risk of death from the adverse drug experience as it occurred. It does not include an adverse drug experience that, had it occurred in a more serious form, might have caused death. For example, product-induced hepatitis that resolved without evidence of hepatic failure would not be considered life-threatening even though hepatitis of a more severe nature can be fatal. Similarly, an allergic reaction resulting in angioedema of the face

would not be life-threatening, although angioedema of the larynx, allergic bronchospasm, or anaphylaxis can be fatal.

(6) *Serious* means an adverse drug experience occurring at any dose that is fatal or life-threatening, results in persistent or significant disability/incapacity, requires or prolongs inpatient hospitalization, necessitates medical or surgical intervention to preclude permanent impairment of a body function or permanent damage to a body structure, or is a congenital anomaly.

(7) *Unexpected* means an adverse drug experience that is not listed in the current labeling for the drug product and includes an event that may be symptomatically and pathophysiologically related to an event listed in the labeling, but differs from the event because of greater severity or specificity. For example, under this definition, hepatic necrosis would be unexpected (by virtue of greater severity) if the labeling only referred to elevated hepatic enzymes or hepatitis. Similarly, cerebral thromboembolism and cerebral vasculitis would be unexpected (by virtue of greater specificity) if the labeling only listed cerebral vascular accidents.

(c) *Reporting requirements.* Each person identified in paragraph (c)(1) of this section shall report to FDA adverse drug experience information as described in this section and shall submit one copy of each report to the Division of Epidemiology and Surveillance (HFD-730), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857.

(1) *Postmarketing 15-Day "Alert reports"*. (i) Any person whose name appears on the label of a marketed prescription drug product as its manufacturer, packer, or distributor shall report to FDA each adverse drug experience received or otherwise obtained that is both serious and unexpected as soon as possible, but in any case, within 15 calendar days of initial receipt of the information. Each report shall be accompanied by a copy of the current labeling for the drug product.

(ii) A person identified in paragraph (c)(1)(i) of this section is not required to submit a 15-day "Alert report" for an adverse drug experience obtained from a postmarketing study (whether or not conducted under an investigational new drug application) unless the applicant concludes that there is a reasonable possibility that the drug caused the adverse experience.

(2) *Postmarketing 15-Day "Alert reports"—followup.* Each person identified in paragraph (c)(1)(i) of this section shall promptly investigate all serious, unexpected adverse drug experiences that are the subject of these 15-day postmarketing Alert reports and shall submit followup reports within 15 calendar days of receipt of new information or as requested by FDA. If additional information is not obtainable, records should be maintained of the unsuccessful steps taken to seek additional information.

(3) *Increased frequency report.* Each person identified in paragraph (c)(1)(i) of this section shall review periodically (at least twice each year) the frequency of reports of adverse drug experiences that are both serious and expected and reports of therapeutic failure (lack of effect), received or otherwise obtained, and report any significant increase in frequency as soon as possible, but in any case within 15 calendar days of determining that a significant increase in frequency exists. Reports of a significant increase in frequency are required to be submitted in narrative form (including the time period on which the increased frequency is based, the method of analysis, and the interpretation of the results) rather than using FDA Form 3500A.

(4) *Submission of reports.* In order to avoid unnecessary duplication in the submission of, and followup to, reports required in this section, including reports required by paragraph (c)(3) of this section, a packer's or distributor's obligations may be met by submission of all reports of serious adverse drug experiences to the manufacturer of the drug product. If a packer or distributor elects to submit these adverse drug experience reports to the manufacturer rather than to FDA, it shall submit each report to the manufacturer within 3 calendar days of its receipt by the packer or distributor, and the manufacturer shall then comply with the requirements of this section even if its name does not appear on the label of the drug product. Under this circumstance, the packer or distributor shall maintain a record of this action which shall include:

- (i) A copy of each drug experience report.
- (ii) Date the report was received by the packer or distributor.
- (iii) Date the report was submitted to the manufacturer.
- (iv) Name and address of the manufacturer.

(5) Each report submitted to FDA under this section shall bear prominent identification as to its contents, i.e., "15-day Alert report," "15-day Alert

report—followup," or "Increased frequency report."

(6) A person identified in paragraph (c)(1)(i) of this section should not resubmit to FDA reports forwarded to that person by FDA; however, all followup information must be submitted to FDA.

(d) \* \* \*

(3) \* \* \*

(ii) The format is agreed to in advance by MedWatch: The FDA Medical Products Reporting Program.

(4) Ten copies or fewer of FDA Form 3500A and/or a copy of the instructions for completing the form may be obtained from the Division of Epidemiology and Surveillance (HFD-730), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. More than 10 copies of the form may be obtained by writing to the Consolidated Forms and Publications Distribution Center, Washington Commerce Center, 3222 Hubbard Rd., Landover, MD 20785.

\* \* \* \* \*

(g) *Guideline.* FDA has prepared under § 10.90(b) of this chapter a guideline for the submission of reports of adverse drug experiences and suggested followup investigation of reports. Copies of this guideline may be obtained from the CDER Executive Secretariat Staff (HFD-8), Center for Drug Evaluation and Research, Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855.

\* \* \* \* \*

#### PART 312—INVESTIGATIONAL NEW DRUG APPLICATION

5. 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).

6. Section 312.23 is amended by adding new paragraph (a)(3)(v) and paragraphs (a)(6)(iii)(h) through (a)(6)(iii)(k) to read as follows:

#### § 312.23 IND content and format.

(a) \* \* \*

(3) \* \* \*

(v) A description of the safety monitoring and evaluation program developed by the sponsor in order to evaluate safety data reported by investigators.

\* \* \* \* \*

(6) \* \* \*

(iii) \* \* \*

(h) A description of any adverse clinical or laboratory outcomes in the

study that are to be reported by the investigators to the sponsor immediately. This would ordinarily include any death, any life-threatening event, any serious event that might reflect potential toxicity, as suggested by preclinical data, laboratory values that exceed specified limits, or any markedly abnormal laboratory value. The identified events and abnormal laboratory values are to include those that focus attention on toxicity that may target the same organs and body systems as the underlying disease or concomitant medications for the disease. The events are to be reported to the sponsor even if they are potentially attributable to the patient's underlying disease or to other medications the patient may have received. This section of the protocol shall include instructions for the investigator encountering such an event, such as reporting requirements, a remeasurement or challenge procedure, or discontinuation of the study drug.

(i) Sponsors should consider use of a formal control group (for example, placebo, active, documented historical) in studies that focus on safety when the underlying disease is likely to produce serious adverse events that might be confused with drug toxicity.

(j) The sponsor shall estimate the expected incidence of deaths and serious adverse experiences in the study population that may arise from the underlying disease or from medications used to treat the underlying disease. Deaths or serious adverse experiences that exceed these estimates would create a presumption that the events are associated with the use of the investigational drug.

(k) The sponsor shall determine and include in each protocol an appropriate followup period and appropriate followup procedures based on preclinical data, experience with other members of the drug class, the drug's mechanism of action, and prior human experience. The sponsor shall include a brief description of the rationale used in selecting the followup period and procedures. The intensity of the followup may change with time; e.g., a full evaluation might be scheduled for 2 weeks after the end of drug dosing, with a telephone followup at a later time. Ordinarily, in Phase 1 and 2 studies, there should be at least telephone followup for 3 months after drug dosing is completed, but alternative timeframes and procedures can be proposed by the sponsor. In some cases, available information may dictate followup periods longer than 3 months.

\* \* \* \* \*

7. Section 312.32 is amended in paragraph (a) by revising the second sentence in the definition for "Serious adverse experience," paragraph (c)(1)(i), the first sentence in paragraph (c)(2), paragraph (d)(3), and in paragraph (e) by removing the word "section" and replacing it with the word "part" to read as follows:

**§ 312.32 IND safety reports.**

(a) \* \* \*  
*Serious adverse experience* \* \* \* A serious adverse drug experience means an experience occurring at any dose that is fatal or life-threatening, results in permanent or significant disability/incapacity, requires or prolongs inpatient hospitalization, necessitates medical or surgical intervention to preclude permanent impairment of a body function or permanent damage to a body structure, or is a congenital anomaly. \* \* \*

(c) *IND safety reports*—(1) *Written reports.* (i) The sponsor shall notify FDA and all participating investigators in a written IND safety report of any adverse experience associated with use of the drug that is both serious and unexpected. This includes notification of any death or other serious adverse experience that exceeds the estimate of the expected incidence of deaths and serious adverse experiences required under § 312.23(a)(6)(iii)(f). Such notification shall be made as soon as possible and in no event later than 15 calendar days after the sponsor's initial receipt of the information. Each written notification may be submitted on FDA Form 3500A or in a narrative form and shall bear prominent identification of its contents, i.e., "IND Safety Report." Each written notification to FDA shall be transmitted to the FDA division of the Center for Drug Evaluation and Research or the Center for Biologics Evaluation and Research that has responsibility for review of the IND. If FDA determines that insufficient data were submitted on FDA Form 3500A, the agency may require further narrative data to be submitted.

(2) *Telephone safety reports.* The sponsor shall also notify FDA by telephone, either orally or by facsimile transmission, of any unexpected fatal or life-threatening experience associated with the use of the drug no later than 7 calendar days after the sponsor's initial receipt of the information. \* \* \*

(d) \* \* \*  
 (3) If the results of a sponsor's investigation show that an adverse

experience not initially determined to be reportable under paragraph (c) of this section is so reportable, the sponsor shall report such experience in a written safety report as soon as possible after the determination is made, but in no event longer than 15 calendar days.

8. Section 312.33 is revised to read as follows:

**§ 312.33 Annual and semiannual reports.**

(a) *Annual reports.* A sponsor shall within 60 days of the anniversary date that the IND went into effect, submit a brief report of the progress of the investigation that includes:

(1) *Individual study information.* A brief summary of the status of each study in progress and each study completed during the previous year. The summary is required to include the following information for each study:

(i) The title of the study (with any appropriate study identifiers such as protocol number), its purpose, a brief statement identifying the patient population, and a statement as to whether the study is completed.

(ii) The total number of subjects initially planned for inclusion in the study, the number entered into the study to date, the number whose participation in the study was completed as planned, and the number who dropped out of the study for any reason.

(iii) If the study has been completed, or if interim results are known, a brief description of any available study results.

(2) *Summary information.* Information obtained during the previous year's clinical and nonclinical investigations, including:

(i) A narrative or tabular summary showing the most frequent and most serious adverse experiences by body system.

(ii) A summary of all IND safety reports submitted during the past year.

(iii) A list of subjects who died during participation in the investigation, with the cause of death for each subject.

(iv) A list of subjects who dropped out during the course of the investigation in association with any adverse experience, whether or not thought to be drug related.

(v) A brief description of what, if anything, was obtained that is pertinent to an understanding of the drug's actions, including, for example, information from controlled trials, and information about bioavailability.

(vi) A list of the preclinical studies (including animal studies) completed or in progress during the past year and a

summary of the major preclinical findings.

(vii) A summary of any significant manufacturing or microbiological changes made during the past year.

(3) A description of the general investigational plan for the coming year to replace that submitted 1 year earlier. The general investigational plan shall contain the information required under § 312.23(a)(3)(iv).

(4) If the investigator brochure has been revised, a description of the revision and a copy of the new brochure.

(5) A description of any significant Phase 1 protocol modifications made during the previous year and not previously reported to the IND in a protocol amendment.

(6) A brief summary of significant foreign marketing developments with the drug during the past year, such as approval of marketing in any country or withdrawal or suspension from marketing in any country.

(7) If desired by the sponsor, a log of any outstanding business with respect to the IND for which the sponsor requests or expects a reply, comment, or meeting.

(b) *Semiannual reports.* A sponsor shall submit a report of the progress of the investigation with respect to safety issues for the 6-month period following the day the IND goes into effect, and for each 6-month period thereafter, until the end of the followup period specified in the protocol. The report shall be due within 60 days of the end of the reporting period. The semiannual safety report that is due during the same period as the annual report required under paragraph (a) of this section shall be submitted with the annual report. These semiannual reports shall include:

(1) A summary and analysis of all deaths, all serious adverse experiences, and all study discontinuations resulting from an adverse experience that occurred during the study or within the prescribed followup period, whether the deaths or adverse experiences were expected or unexpected and whether or not there is thought to be a possibility that the death or adverse experience or study discontinuation was caused by the drug. This summary shall include data not only from studies conducted under the IND, but also data from all premarketing studies of the drug conducted worldwide, with an analysis of all unexpected deaths, serious adverse experiences, and study discontinuations thought to be related to the study drug from foreign postmarketing clinical trials and from foreign postmarketing spontaneous or required reporting systems. For

purposes of this section, serious adverse events shall include laboratory changes identified in the study protocol as reportable events or that result in discontinuation. The sponsor shall present in the summary both the data that accumulated during the reporting period and cumulatively. The sponsor shall also submit an analysis of the data that assumes that the investigational drug is responsible for the deaths, serious adverse experiences, and study discontinuations, and refute, as feasible, this presumption with appropriate data and evaluations. The expected incidence of deaths and serious adverse experiences in the study population that may arise from the underlying disease or from medications used to treat the underlying disease that was estimated in the protocol should be considered in this evaluation.

(2) All available autopsy reports and terminal medical reports concerning all deaths reported in this summary, with a discussion of any inconsistencies between autopsy and medical reports and the cause of death reported to FDA by the sponsor.

(3) At the request of the sponsor, or on its own initiative, FDA may modify the requirements of paragraph (b) of this section. A sponsor requesting such a modification should submit to the division responsible for review of the IND a written request for modification and justification for such modification. FDA shall issue a written response to the sponsor either granting or denying, in whole or in part, the request for modification.

(Collection of information requirements approved by the Office of Management and Budget under control number 0910-0014)

9. Section 312.37 is added to read as follows:

**§ 312.37 Special safety summary and final clinical study report.**

(a) *Special safety summary.* Upon request of FDA, a sponsor shall prepare and submit special summaries of safety data regarding the investigational drug. These summaries may include safety data available to the sponsor from previous studies of the drug and of closely related drugs identified in consultation with FDA. Examples of types of events that may be requested to be summarized include, among others, deaths, serious adverse experiences, study discontinuations for safety reasons, patients who reach or exceed safety endpoints as defined in the protocol, and any unusual or extreme changes in study subjects. The special safety summary shall be submitted within 30 days after a request by the

agency unless the sponsor demonstrates that extraordinary circumstances warrant a later date and the agency has agreed to that later date.

(b) *Final clinical study report.* Upon request by FDA, a sponsor shall submit a final report on a clinical study. The final report shall be submitted within 90 calendar days after a request by the agency unless the sponsor demonstrates that extraordinary circumstances warrant a later date and the agency has agreed to that later date.

10. Section 312.42 is amended by adding paragraph (b)(1)(v) to read as follows:

**§ 312.42 Clinical holds and requests for modification.**

\* \* \* \* \*

(b) \* \* \*

(1) \* \* \*

(v) The sponsor has failed to submit a special safety summary or final clinical study report, as required by § 312.37, for the drug that is the subject of the investigation. This provision applies to special safety summaries and final clinical study reports from other investigations on the same drug and special safety summaries and final clinical study reports requested by FDA for investigations on closely related drugs conducted by the sponsor.

\* \* \* \* \*

11. Section 312.44 is amended by revising paragraph (b)(1)(viii) to read as follows:

**§ 312.44 Termination.**

\* \* \* \* \*

(b) \* \* \*

(1) \* \* \*

(viii) The sponsor fails to submit an accurate and timely annual or semiannual safety report of the investigations in accordance with § 312.33.

\* \* \* \* \*

12. Section 312.56 is amended by revising paragraph (c) to read as follows:

**§ 312.56 Review of ongoing investigations.**

\* \* \* \* \*

(c) Before the initiation of clinical studies, the sponsor shall develop a safety monitoring and evaluation program to evaluate safety data reported by the investigator(s). The sponsor shall review and evaluate the evidence relating to the safety and effectiveness of the drug as it is obtained from the investigator(s). The sponsor shall make such reports to FDA regarding information relevant to the safety of the drug as required under §§ 312.32 and 312.37. The sponsor shall make annual

and semiannual safety reports in accordance with § 312.33.

\* \* \* \* \*

13. Section 312.64 is amended by adding two sentences at the end of paragraph (b) to read as follows:

**§ 312.64 Investigator reports.**

\* \* \* \* \*

(b) \* \* \* An investigator shall report to the sponsor all adverse clinical and laboratory outcomes that are required to be reported under the protocol for the study. These reports shall be made within the time period specified within the protocol.

\* \* \* \* \*

**PART 314—APPLICATIONS FOR FDA APPROVAL TO MARKET A NEW DRUG OR AN ANTIBIOTIC DRUG**

14. The authority citation for 21 CFR part 314 continues to read as follows:

*Authority:* Secs. 201, 301, 501, 502, 503, 505, 506, 507, 701, 704, 721 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 351, 352, 353, 355, 356, 357, 371, 374, 379e).

15. Section 314.80 is amended in paragraph (a) by alphabetically adding definitions for "Data lock-point," "Disability," "International birth date," and "Life-threatening," and by revising the definition of "Serious;" by adding two new sentences at the end of paragraph (b); by revising paragraph (c), the second sentence in paragraph (d)(1), paragraphs (f)(1), (f)(3)(ii), and (f)(4), and the last sentence in paragraph (l); by removing in paragraphs (f)(2) and the introductory text of paragraph (f)(3) the words "Form FDA-1639" and adding in their place the words "FDA Form 3500A"; and by adding a new sentence at the end of paragraph (j) to read as follows:

**§ 314.80 Postmarketing reporting of adverse drug experiences.**

(a) \* \* \*

\* \* \* \* \*

*Data lock-point* means the date designated as the cutoff date for data to be incorporated into a specific postmarketing adverse drug experience periodic report. Data available to the applicant after this date will not be incorporated into the report, unless it represents important information.

*Disability* means a substantial disruption of a person's ability to carry out normal life functions.

\* \* \* \* \*

*International birth date* means the date that the first regulatory authority in the world approved the human drug product for marketing.

*Life-threatening* means that the patient was, in the view of the initial reporter, at immediate risk of death from the adverse experience as it occurred. It does not include an adverse experience that, had it occurred in a more serious form, might have caused death. For example, product-induced hepatitis that resolved without evidence of hepatic failure would not be considered life-threatening even though hepatitis of a more severe nature can be fatal. Similarly, an allergic reaction resulting in angioedema of the face would not be life-threatening, even though angioedema of the larynx, allergic bronchospasm, or anaphylaxis can be fatal.

*Serious* means an adverse drug experience occurring at any dose that is fatal or life-threatening, results in persistent or significant disability/incapacity, requires or prolongs inpatient hospitalization, necessitates medical or surgical intervention to preclude permanent impairment of a body function or permanent damage to a body structure, or is a congenital anomaly.

\* \* \* \* \*

(b) \* \* \* Applicants should not resubmit to FDA adverse product experience reports forwarded to the applicant by FDA; however, they should submit all followup information to FDA. Applicants shall also develop written procedures for the surveillance, receipt, evaluation, and reporting of adverse drug experiences.

(c) *Reporting requirements.* The applicant shall report to FDA adverse drug experience information, as described in this section. The applicant shall submit two copies of each report described in this section to the Central Document Room, Park Bldg., rm. 2-14, 12420 Parklawn Dr., Rockville, MD 20857. FDA may waive the requirement for the second copy in appropriate instances.

(1)(i) *Postmarketing 15-day "Alert reports"*. The applicant shall report each adverse drug experience that is both serious and unexpected as soon as possible but in any case within 15 calendar days of initial receipt of the information. These reports shall be submitted on FDA Form 3500A.

(ii) *Postmarketing Fifteen-day "Alert reports"—followup.* The applicant shall promptly investigate all adverse drug experiences that are the subject of these postmarketing 15-day Alert reports and shall submit followup reports within 15 calendar days of receipt of new information or as requested by FDA. If additional information is not obtainable, records should be maintained of the

unsuccessful steps taken to seek additional information. These postmarketing 15-day Alert reports and followups to them shall be submitted under separate cover and may not be included, except for summary or tabular purposes, in a postmarketing adverse drug experience periodic report.

(iii) *Increased frequency report.* The applicant shall review periodically (at least as often as the periodic reporting cycle) the frequency of reports of adverse drug experiences that are both serious and expected and reports of therapeutic failure (lack of effect), regardless of source, and report any significant increase in frequency as soon as possible but in any case within 15 calendar days of determining that a significant increase in frequency exists. Upon written notice, FDA may require that applicants review the frequency of reports of serious, expected adverse drug experiences at intervals different than the periodic reporting cycle. Reports of a significant increase in frequency are required to be submitted in narrative form (including the time period on which the increased frequency is based, the method of analysis, and the interpretation of the results), rather than using FDA Form 3500A. 15-day Alert reports based on increased frequency are required to be submitted under separate cover and may not be included, except for summary purposes, in a periodic report.

(iv) *Submission of reports.* The requirements of paragraphs (c)(1)(i), (c)(1)(ii), and (c)(1)(iii) of this section, concerning the submission of postmarketing 15-day Alert reports, shall also apply to any person (other than the applicant) whose name appears on the label of an approved drug product as a manufacturer, packer, or distributor. However, in order to avoid unnecessary duplication in the submission to FDA of reports required by paragraphs (c)(1)(i), (c)(1)(ii), and (c)(1)(iii) of this section, obligations of a nonapplicant may be met by submission of all reports of serious adverse drug experiences to the applicant. If a nonapplicant elects to submit adverse drug experience reports to the applicant rather than to FDA, it shall submit each report to the applicant within 3 calendar days of its receipt by the nonapplicant, and the applicant shall then comply with the requirements of this section. Under this circumstance, the nonapplicant shall maintain a record of this action which shall include:

(A) A copy of the drug experience report.

(B) Date the report was received by the nonapplicant.

(C) Date the report was submitted to the applicant.

(D) Name and address of the applicant.

(v) *Report identification.* Each report submitted under this paragraph shall bear prominent identification as to its contents, i.e., "15-day Alert report," "15-day Alert report—followup," or "Increased frequency report."

(2) *Periodic adverse drug experience reports.* (i) The applicant shall report every 6 months each adverse drug experience not reported under paragraphs (c)(1)(i) and (c)(1)(ii) of this section. The periodic reporting term shall be based upon the international birth date of the human drug product. The first 6-month anniversary of the international birth date after the application is approved in the United States is the data lock-point for the first periodic reporting term. Each subsequent 6-month anniversary of the international birth date is the data lock-point for subsequent periodic reporting terms for that particular product. Periodic reports shall be submitted to FDA within 45 days after the data lock-point. Upon written notice, FDA may require that the applicant submit reports under this section at times other than those stated. An applicant who wishes to submit periodic reports at different intervals must submit to FDA a request for a waiver under § 314.90. Followup information to adverse drug experiences submitted initially in a periodic report may be submitted in the next periodic report. If the applicant does not receive any adverse experience reports during the reporting period, the applicant shall, in place of a periodic report, send a copy of the current approved U.S. labeling and a letter identifying the product, the application number, and the reporting period, stating that no adverse drug experience reports were received.

(ii) *Reports.* Each periodic report shall contain:

(A) *Title page, table of contents, and introduction.* The introduction shall be a summary of the periodic report with page references to detailed data and information.

(B) *Applicant's core safety data sheet.* The applicant's core safety data sheet shall be a document prepared by the applicant that contains all relevant safety information, including adverse drug experiences, which the applicant believes should be listed for the drug in all countries where the drug is marketed. It may be used by the applicant as the reference document by which an adverse drug experience is judged to be expected or unexpected for purposes of this postmarketing periodic

report. For all other determinations of whether an adverse drug experience is expected or unexpected, the definition in paragraph (a) of this section shall apply.

(1) FDA recognizes that the postmarketing periodic report may be submitted by the applicant to multiple countries and the product may have different approved labels in the different countries. The use of the applicant's core safety data sheet as the reference document for determining whether an adverse drug experience is unexpected or not may result in some overreporting of unexpected adverse events that actually are expected by the U.S. approved product label. This is because the approved label for the United States may have more safety information included in it than the manufacturer's core safety data sheet. If an adverse event is not listed in the U.S. label, but is in the manufacturer's core safety data sheet, this shall be clearly noted in the "Overall safety evaluation" (see paragraph (c)(2)(ii)(H) of this section). This section also shall highlight clearly any changes and the reasons for the changes in the applicant's core safety data sheet since the previous postmarketing periodic report.

(2) An applicant may also use the approved U.S. label as the reference by which expected and unexpected adverse drug experiences are determined for the postmarketing periodic report. If an applicant chooses to use the approved U.S. label for this purpose, it shall clearly be stated in this section of the report.

(C) *The product's marketing status.* This section shall contain a table containing a chronological history of the marketing status of the product worldwide (all regulatory decisions affecting the product and all market launches) from the date it was first approved through its current status. Approvals or applications voluntarily withdrawn for safety reasons shall be included at a minimum. The product shall be listed by chemical (or proper name) and brand name(s).

(D) *Regulatory actions for safety reasons.* This section shall contain a narrative identifying the reasons for significant regulatory authority or manufacturer-initiated actions taken anywhere in the world, or to be taken imminently, for safety reasons during the reporting period. This includes, for example, application withdrawal or license suspension or failure to renew, distribution restrictions, clinical trial suspension, labeling changes due to significant safety concerns, dosage modifications, or pharmaceutical changes.

(E) *Patient exposure.* This section shall include the product's domestic and foreign marketing distribution data during the reporting period. This shall be used to calculate the extent of patient exposure. The method used by the manufacturer to estimate patient exposure shall always be described and shall include the total number of dosage units of each dosage form and strength or potency (e.g., 100,000/5-milligram tablets, 50,000/10-milliliter vials).

(F) *Individual case histories.* This section shall consist of individual case reports of adverse drug experiences thought possibly associated with the use of the drug that are:

(1) Serious, unexpected reports from published or unpublished clinical studies where the applicant has concluded that there is a reasonable possibility that the drug caused the adverse experience;

(2) Serious, expected or unexpected spontaneous adverse drug experience reports and nonserious, unexpected spontaneous adverse drug experience reports (causality always assumed in spontaneous reports) received directly by the applicant from the initial reporter or received by the applicant from a drug regulatory authority, both U.S. or foreign; and

(3) Serious, expected or unexpected, individual published case histories and nonserious, unexpected individual published case histories.

(4) All of these reports in paragraphs (c)(2)(ii)(F)(1) through (c)(2)(ii)(F)(3) of this section shall be presented in line listing format with the following 10 columns: country, source, age, gender, dose, duration of treatment (prior to event), time to onset, description of reaction (as reported), outcome (e.g., fatal, resolved), other comments (e.g., manufacturer's report number). This format is consistent with that suggested by CIOMS. In addition, a tabular summary of the number of adverse events by body system may be included. This section shall end with an analysis by the reporter, in narrative form, of the cases submitted. The applicant shall also attach to the end of the postmarketing periodic report a completed FDA Form 3500A for all U.S. spontaneous reports of adverse drug experiences except those reported under paragraphs (c)(1)(i) and (c)(1)(ii) of this section, or those sent by FDA to the applicant.

(G) *Safety studies.* This section shall contain an analysis and full critical discussion of all toxicological, clinical, and epidemiological studies containing important safety information.

(H) *Overall safety evaluation.* This section shall contain a critical analysis

and full discussion of the safety information provided in the periodic report as it pertains to serious unexpected reactions, increased frequencies of known toxicity, reactions listed in the manufacturer's core safety data sheet but not included in the U.S. label, drug interactions, overdose, drug abuse, experiences during pregnancy or lactation, chronic treatment, pediatric or geriatric treatment, and new safety issues. The applicant shall indicate when any significant information has not been obtained. The evaluation shall indicate whether the safety profile of the product remains consistent with cumulative experience to date and with the previous manufacturer's core safety data sheet. The evaluation shall specify any action recommended and the reasons for such recommendations.

(I) *Other information.* This section shall include important information received after the data lock-point.

(J) *FDA Form 3500A.* An FDA Form 3500A shall be used for each spontaneous U.S. adverse drug experience not reported under paragraphs (c)(1)(i) and (c)(1)(ii) of this section.

(K) *Location of adverse experience records.* The current addresses where all adverse experience reports and records are maintained.

(d) \* \* \*

(1) \* \* \* The 15-day reporting requirements in paragraph (c)(1)(iii) of this section (i.e., a significant increase in frequency of a serious, expected adverse drug experience, or of a therapeutic failure) apply only to the reports found in scientific and medical journals either as case reports or as the result of a formal clinical trial. \* \* \*

\* \* \* \* \*

(f) *Reporting FDA Form 3500A.* (1) Except as provided in paragraphs (c)(1)(iii) and (f)(3) of this section, the applicant shall complete FDA Form 3500A for each report of an adverse drug experience.

\* \* \* \* \*

(3) \* \* \*

(ii) The format is agreed to in advance by MedWatch: The FDA Medical Products Reporting Program.

(4) Ten copies or fewer of FDA Form 3500A and/or a copy of the instructions for completing the form may be obtained from the Division of Epidemiology and Surveillance (HFD-730), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. More than 10 copies of the form may be obtained by writing to the Consolidated Forms and Publications Distribution Center,

Washington Commerce Center, 3222 Hubbard Rd., Landover, MD 20785.

(j) \* \* \* Copies of this guideline may be obtained from the CDER Executive Secretariat Staff (HFD-8), Center for Drug Evaluation and Research, Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20857.

(l) \* \* \* For purposes of this provision, the term "applicant" also includes any person reporting under paragraph (c)(1)(iv) of this section.

#### PART 600—BIOLOGICAL PRODUCTS: GENERAL

16. The authority citation for 21 CFR part 600 continues to read as follows:

**Authority:** Secs. 201, 501, 502, 503, 505, 510, 519, 701, 704 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 351, 352, 353, 355, 360, 360i, 371, 374); secs. 215, 351, 352, 353, 361 of the Public Health Service Act (42 U.S.C. 216, 262, 263, 263a, 264).

17. Section 600.80 as added in a final rule published elsewhere in this issue of the *Federal Register* is amended in paragraph (a) by alphabetically adding definitions for "Data lock-point," "Disability," "International birth date," and "Life-threatening;" by revising the definition of "Serious;" by adding two new sentences at the end of paragraph (b); by revising paragraph (c), the third sentence in paragraph (d)(1), paragraph (g), and the last sentence in paragraph (m); and by adding a new sentence at the end of paragraph (j) to read as follows:

#### § 600.80 Postmarketing reporting of adverse experiences.

(a) \* \* \*

*Data lock-point* means the date designated as the cutoff date for data to be incorporated into a specific postmarketing adverse experience periodic report. Data available to the licensed manufacturer after this date will not be incorporated into the report, unless it represents important information.

*Disability* means a substantial disruption of a person's ability to carry out normal life functions.

*International birth date* means the date that the first regulatory authority in the world approved the biological drug product for marketing.

*Life-threatening* means that the patient was, in the view of the initial reporter, at immediate risk of death from the adverse experience as it occurred. It

does not include an adverse experience that, had it occurred in a more serious form, might have caused death. For example, product-induced hepatitis that resolved without evidence of hepatic failure would not be considered life-threatening even though hepatitis of a more severe nature can be fatal. Similarly, an allergic reaction resulting in angioedema of the face would not be life-threatening, even though angioedema of the larynx, allergic bronchospasm, or anaphylaxis can be fatal.

*Serious* means an adverse drug experience occurring at any dose that is fatal or life-threatening, results in persistent or significant disability/incapacity, requires or prolongs inpatient hospitalization, necessitates medical or surgical intervention to preclude permanent impairment of a body function or permanent damage to a body structure, or is a congenital anomaly.

(b) \* \* \* Licensed manufacturers should not resubmit to FDA adverse product experience reports forwarded to the licensed manufacturer by FDA; however, they should submit all followup information to FDA. Licensed manufacturers shall also develop written procedures for the surveillance, receipt, evaluation, and reporting of adverse experiences.

(c) *Reporting requirements.* The licensed manufacturer shall report to FDA adverse experience information, as described in this section. The licensed manufacturer shall submit two copies of each report described in this section for nonvaccine biological products to the Center for Biologics Evaluation and Research (HFM-210), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852-1448. Submit all vaccine adverse experience reports to the Vaccine Adverse Event Reporting System (VAERS), P.O. Box 1100, Rockville, MD 20849-1100. FDA may waive the requirement for the second copy in appropriate instances.

(1)(i) *Postmarketing 15-day "Alert reports"*. The licensed manufacturer shall report each adverse experience that is both serious and unexpected as soon as possible, but in any case within 15 calendar days of initial receipt of the information. These reports shall be submitted for nonvaccine biological products on FDA Form 3500A, and, for vaccines, on a VAERS form.

(ii) *Postmarketing 15-day "Alert reports"—followup.* The licensed manufacturer shall promptly investigate all adverse experiences that are the subject of these postmarketing 15-day

Alert reports and shall submit followup reports within 15 calendar days of receipt of new information or as requested by FDA. If additional information is not obtainable, records should be maintained of the unsuccessful steps taken to seek additional information. These postmarketing 15-day Alert reports and followups to them shall be submitted under separate cover and may not be included, except for summary or tabular purposes, in a postmarketing adverse experience periodic report.

(iii) *Increased frequency report.* The licensed manufacturer shall review periodically (at least as often as the periodic reporting cycle) the frequency of reports of adverse biological product experiences that are both serious and expected and reports of therapeutic failure (lack of effect), regardless of source, and report any significant increase in frequency as soon as possible but in any case within 15 calendar days of determining that a significant increase in frequency exists. Upon written notice, FDA may require that licensed manufacturers review the frequency of reports of serious, expected adverse biological experiences at intervals different than the periodic reporting cycle. Reports of a significant increase in frequency are required to be submitted in narrative form (including the time period on which the increased frequency is based, the method of analysis, and the interpretation of the results), rather than using the form designated by FDA. 15-day Alert reports based on increased frequency are required to be submitted under separate cover and may not be included, except for summary purposes, in a periodic report.

(iv) *Submission of reports.* The requirements of paragraphs (c)(1)(i), (c)(1)(ii), and (c)(1)(iii) of this section, concerning the submission of postmarketing 15-day Alert reports, shall also apply to any person (other than the licensed manufacturer of the final product) whose name appears on the label of a licensed biological product as a manufacturer, packer, distributor, shared manufacturer, joint manufacturer, or any other participant involved in divided manufacturing. However, in order to avoid unnecessary duplication in the submission to FDA of reports required by paragraphs (c)(1)(i), (c)(1)(ii), and (c)(1)(iii) of this section, obligations of a manufacturer other than the licensed manufacturer, including a licensed manufacturer of the product other than in its final form, may be met by submission of all reports of serious adverse experiences to the licensed manufacturer of the final product. If a

manufacturer, other than the licensed manufacturer, elects to submit reports to the licensed manufacturer rather than to FDA, it shall submit each report to the licensed manufacturer within 3 calendar days of its receipt, and the licensed manufacturer shall then comply with the requirements of this section. Under this circumstance, the manufacturer shall maintain a record of this action which shall include:

(A) A copy of all adverse biological product experience reports submitted to the licensed manufacturer.

(B) Date the report was received by the manufacturer other than the licensed manufacturer.

(C) Date the report was submitted to the licensed manufacturer.

(D) Name and address of the licensed manufacturer.

(v) *Report identification.* Each report submitted under this paragraph shall bear prominent identification as to its contents, i.e., "15-day Alert report," "15-day Alert report—followup," or "Increased frequency report."

(2)(i) *Periodic adverse experience reports.* The licensed manufacturer shall report every 6 months each adverse experience not reported under paragraphs (c)(1)(i) and (c)(1)(ii) of this section. The periodic reporting term shall be based upon the international birth date of the biological product. The first 6-month anniversary of the international birth date after the application is approved in the United States is the data lock-point for the first periodic reporting term. Each subsequent 6-month anniversary of the international birth date is the data lock-point for subsequent periodic reporting terms for that particular product. Periodic reports shall be submitted to FDA within 45 days after the data lock-point. Upon written notice, FDA may require that the licensed manufacturer submit reports under this section at times other than those stated. A licensed manufacturer who wishes to submit periodic reports at different intervals must submit to FDA a request for a waiver under § 600.90. Followup information to adverse experiences submitted in a periodic report may be submitted in the next periodic report. If the licensed manufacturer does not receive any adverse experience reports during the reporting period, the licensed manufacturer shall, in place of a periodic report, send a copy of the current approved U.S. labeling and a letter identifying the product, the application number, and the reporting period, stating that no adverse experience reports were received.

(ii) *Reports.* Each periodic report shall contain:

(A) *Title page, table of contents, and introduction.* The introduction shall be a summary of the periodic report with page references to detailed data and information.

(B) *Licensed manufacturer's core safety data sheet.* The licensed manufacturer's core safety data sheet shall be a document prepared by the licensed manufacturer that contains all relevant safety information, including adverse experiences, which the licensed manufacturer believes should be listed for the licensed biological product in all countries where the licensed biological product is marketed. It may be used by the licensed manufacturer as the reference document by which an adverse experience is judged to be expected or unexpected for purposes of this postmarketing periodic report. For all other determinations of whether an adverse experience is expected or unexpected, the definition in paragraph (a) of this section shall apply.

(1) FDA recognizes that the postmarketing periodic report may be submitted by the licensed manufacturer to multiple countries and the product may have different approved labels in the different countries. The use of the licensed manufacturer's core safety data sheet as the reference document for determining whether an adverse drug experience is unexpected or not may result in some overreporting of unexpected adverse events that actually are expected by the U.S. approved product label. This is because the approved label for the United States may have more safety information included in it than the licensed manufacturer's core safety data sheet. If an adverse event is not listed in the U.S. label, but is in the licensed manufacturer's core safety data sheet, this shall be clearly noted in the "Overall safety evaluation" (see paragraph (c)(2)(ii)(H) of this section). This section also shall highlight clearly any changes and the reasons for the changes in the licensed manufacturer's core safety data sheet since the previous postmarketing periodic report.

(2) A licensed manufacturer may also use the approved U.S. label as the reference by which expected and unexpected adverse experiences are determined for the postmarketing periodic report. If a licensed manufacturer chooses to use the approved U.S. label for this purpose, it shall clearly be stated in this section of the report.

(C) *The product's marketing status.* This section shall contain a table containing a chronological history of the marketing status of the product worldwide (all regulatory decisions

affecting the product and all market launches) from the date it was first approved through its current status. Approvals or applications voluntarily withdrawn for safety reasons shall be included at a minimum. The product shall be listed by chemical (or proper name) and brand name(s).

(D) *Regulatory actions for safety reasons.* This section shall contain a narrative identifying the reasons for significant regulatory authority or manufacturer-initiated actions taken anywhere in the world, or to be taken imminently, for safety reasons during the reporting period. This includes, for example, licensed application withdrawal or license suspension or failure to renew, distribution restrictions, clinical trial suspension, labeling changes due to significant safety concerns, dosage modifications, or pharmaceutical changes.

(E) *Patient exposure.* This section shall include the product's domestic and foreign marketing distribution data during the reporting period. This shall be used to calculate the extent of patient exposure. The method used by the licensed manufacturer to estimate patient exposure shall always be described and shall include the total number of dosage units of each dosage form and strength or potency (e.g., 100,000/5-milligram tablets, 50,000/10-milliliter vials).

(F) *Individual case histories.* This section shall consist of individual case reports of adverse experiences thought possibly associated with the use of the licensed biological product that are:

(1) Serious, unexpected reports from published or unpublished clinical studies where the licensed manufacturer has concluded that there is a reasonable possibility that the licensed biological product caused the adverse experience;

(2) Serious, expected or unexpected spontaneous adverse experience reports and nonserious, unexpected spontaneous adverse experience reports (causality always assumed in spontaneous reports) received directly by the licensed manufacturer from the initial reporter or received by the licensed manufacturer from a drug regulatory authority, both U.S. or foreign; and

(3) Serious, expected or unexpected, individual published case histories and nonserious, unexpected individual published case histories.

(4) All of these reports under paragraphs (c)(2)(ii)(F)(1) through (c)(2)(ii)(F)(3) of this section shall be presented in line listing format with the following 10 columns: country, source, age, gender, dose, duration of treatment (prior to event), time to onset,

description of reaction (as reported), outcome (e.g., fatal, resolved), other comments (e.g., manufacturer's report number). This format is consistent with that suggested by CIOMS. In addition, a tabular summary of the number of adverse events by body system may be included. This section shall end with an analysis by the reporter, in narrative form, of the cases submitted. The licensed manufacturer shall also attach to the end of the postmarketing periodic report a completed FDA Form 3500A or VAERS form for all U.S. spontaneous reports of adverse experiences except those reported under paragraphs (c)(1)(i) and (c)(1)(ii) of this section, or those sent by FDA to the licensed manufacturer.

(G) *Safety studies.* This section shall contain an analysis and full critical discussion of all toxicological, clinical, and epidemiological studies containing important safety information.

(H) *Overall safety evaluation.* This section shall contain a critical analysis and full discussion of the safety information provided in the periodic report as it pertains to serious unexpected reactions, increased frequencies of known toxicity, reactions listed in the manufacturer's core safety data sheet but not included in the U.S. label, licensed biological product interactions, overdose, licensed biological product abuse, experiences during pregnancy or lactation, chronic treatment, pediatric or geriatric treatment, and new safety issues. The licensed manufacturer shall indicate when any significant information has not been obtained. The evaluation shall indicate whether the safety profile of the product remains consistent with cumulative experience to date and with the previous licensed manufacturer's core safety data sheet. The evaluation shall specify any action recommended and the reasons for such recommendations.

(I) *Other information.* This section shall include important information received after the data lock-point.

(J) *FDA Form 3500A or VAERS Form.* An FDA Form 3500A or VAERS form (for vaccines) shall be used for each spontaneous U.S. adverse experience

not reported under paragraphs (c)(1)(i) and (c)(1)(ii) of this section.

(K) *Location of adverse experience records.* The current addresses where all adverse experience reports and records are maintained.

(3) *Distribution reports.* The licensed manufacturer shall submit information about the quantity of the product distributed under the product license, including the quantity distributed to distributors. The interval between distribution reports shall be 6 months. The reporting term shall be based upon the international birth date of the biological product. The first 6-month anniversary of the international birth date after the application is approved in the United States is the data lock-point for the first reporting term. Each subsequent 6-month anniversary of the international birth date is the data lock-point for subsequent reporting terms for that particular product. Distribution reports shall be submitted to FDA within 45 calendar days after the data lock-point. Upon written notice, FDA may require that the licensed manufacturer submit distribution reports under this section at times other than every 6 months. The distribution report shall consist of the bulk lot number (from which the final container was filled), the fill lot numbers for the total number of dosage units of each strength or potency distributed (e.g., 50,000/10-milliliter vials), the label lot number (if different from fill lot number), labeled date of expiration, number of doses in fill lot/label lot, date of release of fill lot/label lot released for distribution at that time. If any significant amount of a fill lot/label lot is returned, include this information. Disclosure of financial or pricing data is not required. As needed, FDA may require submission of more detailed product distribution information. Upon written notice, FDA may require that the licensed manufacturer submit reports under this section at times other than those stated. A licensed manufacturer that wishes to submit reports at times other than those stated should submit a request for a waiver under § 600.90.

(d) \* \* \*

(1) \* \* \* The 15-day reporting requirements in paragraph (c)(1)(iii) of this section (i.e., a significant increase in frequency of a serious, expected adverse experience or of a therapeutic failure) apply only to reports found in scientific and medical journals either as the results of formal clinical trial, or from epidemiologic studies or analyses of experience in a monitored series of patients. \* \* \*

\* \* \* \* \*

(g) *Multiple reports.* A licensed manufacturer should not include in reports under this section any adverse experience that occurred in clinical trials if they were previously submitted as part of the license application. If a report applies to a licensed biological product for which a licensed manufacturer holds more than one biological product license, the licensed manufacturer should submit the report for the license that was first approved. If a report refers to more than one biological product marketed by a licensed manufacturer, the licensed manufacturer should submit the report to the license for the product listed first in the report.

\* \* \* \* \*

(j) \* \* \* Copies of this guideline may be obtained from the Congressional and Consumer Affairs Branch (HFM-12), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1448.

\* \* \* \* \*

(m) \* \* \* For purposes of this provision, this paragraph also includes any person reporting under paragraph (c)(1)(iv) of this section.

#### § 600.81 [Removed]

18. Section 600.81 *Distribution reports* (as added in a final rule published elsewhere in this issue of the **Federal Register**) is removed.

Dated: October 13, 1994.

**William K. Hubbard,**

*Interim Deputy Commissioner for Policy.*

[FR Doc. 94-26483 Filed 10-26-94; 8:45 am]

BILLING CODE 4160-01-F

# federal register

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Thursday  
October 27, 1994

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## Part IV

### Office of Management and Budget

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Budget Rescissions and Deferrals; Notice

**OFFICE OF MANAGEMENT AND  
BUDGET****Budget Rescissions and Deferrals**

The Honorable Albert Gore, Jr.  
President of the Senate  
Washington, D.C. 20510

Dear Mr. President:

In accordance with the Congressional Budget and Impoundment Control Act of 1974, I herewith report seven deferrals of budget authority, totaling \$3.5 billion.

These deferrals affect International Security Assistance programs as well as programs of the Agency for International Development and the Departments of Health and Human Services and State. The details of these deferrals are contained in the attached report

Sincerely,

**William J. Clinton**

The White House  
Washington  
October 18, 1994.

**Note:** Identical letter sent to the Speaker of the House of Representatives.

**BILLING CODE 3110-01-M**

**CONTENTS OF SPECIAL MESSAGE**  
(in thousands of dollars)

DEFERRAL NO.	ITEM	BUDGET AUTHORITY
<b>Funds Appropriated to the President:</b>		
<b>International Security Assistance:</b>		
D95-1	Economic support fund.....	53,300
D95-2	Foreign military financing grants.....	3,139,279
D95-3	Foreign military financing program.....	47,917
D95-4	Military-to-military contact program.....	2,000
<b>Agency for International Development:</b>		
D95-5	International disaster assistance, Executive....	169,998
<b>Department of Health and Human Services:</b>		
<b>Social Security Administration:</b>		
D95-6	Limitation on administrative expenses.....	7,319
<b>Department of State:</b>		
<b>Bureau for Refugee Programs:</b>		
D95-7	United States emergency refugee and migration fund.....	105,300
Total, deferrals.....		3,525,113

Deferral No. 95-1

**DEFERRAL OF BUDGET AUTHORITY**  
 Report Pursuant to Section 1013 of P.L. 93-344

<b>AGENCY:</b> Funds Appropriated to the President	<b>New budget authority.....</b> \$ <u>2,349,000,000</u> (P.L. 103-306)
<b>BUREAU:</b> International Security Assistance	<b>Other budgetary resources.....</b> \$ <u>60,727,863</u>
<b>Appropriation title and symbol:</b>  Economic support fund 1/  114/51037 11X1037	<b>Total budgetary resources.....</b> \$ <u>2,409,727,863</u>
	<b>Amount to be deferred:</b>
	<b>Part of year.....</b> \$ <u>53,300,000</u>
	<b>Entire year.....</b> \$ _____
<b>OMB identification code:</b> 11-1037-0-1-152	<b>Legal authority (in addition to sec. 1013):</b>
<b>Grant program:</b> <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input checked="" type="checkbox"/> Antideficiency Act <input type="checkbox"/> Other _____
<b>Type of account or fund:</b> <input type="checkbox"/> Annual <input checked="" type="checkbox"/> Multi-year: <u>September 30, 1995</u> (expiration date) <input checked="" type="checkbox"/> No-Year	<b>Type of budget authority:</b> <input checked="" type="checkbox"/> Appropriation <input type="checkbox"/> Contract authority <input type="checkbox"/> Other _____

## Coverage:

Appropriation	Account Symbol	OMB Identification Code	Deferred Amount Reported
Economic support fund.....	11X1037	11-1037-0-1-152	7,000,000
Economic support fund.....	114/51037	11-1037-0-1-152	46,300,000
			<u>53,300,000</u>

**JUSTIFICATION:** The President is authorized by the Foreign Assistance Act of 1961, as amended, to furnish assistance to countries and organizations, on such terms and conditions as he may determine, in order to promote economic or political stability. Section 531(b) of the Act makes the Secretary of State, in cooperation with the Administrator of the Agency for International Development, responsible for policy decisions and justifications for economic support programs, including whether there will be an economic support program for a country and the amount of the program for each country.

Funds are deferred pending the development of country-specific plans that assure that aid is provided in an efficient manner, and are reserved for unanticipated program needs. This action is taken pursuant to the Antideficiency Act (31 U.S.C. 1512).

**Estimated Program Effect:** None

**Outlay Effect:** None

1/ This account was the subject of a similar deferral in FY 1994 (D94-1B).

Deferral No. 95-2

**DEFERRAL OF BUDGET AUTHORITY**  
Report Pursuant to Section 1013 of P.L. 93-344

<b>AGENCY:</b> Funds Appropriated to the President	<b>New budget authority.....</b> \$ <u>3,151,279,000</u> (P.L. 103-306)
<b>BUREAU:</b> International Security Assistance	<b>Other budgetary resources.....</b> _____
<b>Appropriations title and symbol:</b> Foreign military financing grants (FMF) 1/  1151082	<b>Total budgetary resources.....</b> <u>3,151,279,000</u>
	<b>Amount to be deferred:</b>
	<b>Part of year.....</b> \$ <u>3,139,279,000</u>
	<b>Entire year.....</b> _____
<b>OMB identification code:</b> 11-1082-0-1-152	<b>Legal authority (in addition to sec. 1013):</b>
<b>Grant program:</b> <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input checked="" type="checkbox"/> Antideficiency Act
	<input type="checkbox"/> Other _____
<b>Type of account or fund:</b> <input checked="" type="checkbox"/> Annual <input type="checkbox"/> Multi-year: _____ (expiration date) <input type="checkbox"/> No-Year	<b>Type of budget authority:</b> <input checked="" type="checkbox"/> Appropriation <input type="checkbox"/> Contract authority <input type="checkbox"/> Other _____

**JUSTIFICATION:** The President is authorized by the Arms Export Control Act to finance by grant articles and defense services to friendly countries. The President also is authorized by the International Narcotics Control Act of 1989 to provide military and law enforcement assistance to counter illegal narcotics. These funds have been deferred in accordance with the provision of P.L. 103-306 requiring that funds appropriated under this heading be expended at the minimum rate necessary to make timely payment for defense articles and services. The deferral will also ensure, pending the approval of the Departments of State and Defense, that funds are used for the highest priority programs under this Act, including new programs that may result from developments that were not anticipated when these funds were requested or appropriated. This action is taken pursuant to the Antideficiency Act (31 U.S.C. 1512).

**Estimated Program Effect:** None

**Outlay Effect:** None

1/ This account was the subject of a similar deferral in FY 1994 (D94-9).

Deferral No. 95-3

**DEFERRAL OF BUDGET AUTHORITY**  
 Report Pursuant to Section 1013 of P.L. 93-344

<b>AGENCY:</b> Funds Appropriated to the President	<b>New budget authority.....</b> \$ <u>47,917,000</u> (P.L. 103-306)
<b>BUREAU:</b> International Security Assistance	<b>Other budgetary resources.....</b> \$ _____
<b>Appropriations title and symbol:</b>  Foreign military financing program <sup>1/</sup>  1151085	<b>Total budgetary resources.....</b> \$ <u>47,917,000</u>
	<b>Amount to be deferred:</b>
	<b>Part of year.....</b> \$ <u>47,917,000</u>
	<b>Entire year.....</b> _____
<b>OMB identification code:</b> 11-1085-0-1-152	<b>Legal authority (in addition to sec. 1013):</b>
<b>Grant program:</b> <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input checked="" type="checkbox"/> Antideficiency Act
	<input type="checkbox"/> Other _____
<b>Type of account or fund:</b> <input checked="" type="checkbox"/> Annual <input type="checkbox"/> Multi-year: _____ (expiration date) <input type="checkbox"/> No-Year	<b>Type of budget authority:</b> <input checked="" type="checkbox"/> Appropriation <input type="checkbox"/> Contract authority <input type="checkbox"/> Other

**JUSTIFICATION:** The President is authorized by the Arms Export Control Act to sell or finance by credit, loan guarantees, or grants, articles and defense services to friendly countries to facilitate the common defense. Under Section 2 of the Act, the Secretary of State, under the direction of the President, is responsible for sales made under this Act. Executive Order 11958 further requires the Secretary of State to obtain prior concurrence of the Secretaries of Defense and Treasury, respectively, regarding consistency of transactions with national security and financial policies.

As required by the Federal Credit Reform Act of 1990, this account records the subsidy costs associated with the direct loans obligated and loan guarantees for foreign military financing committed in FY 1992 and beyond. The foreign military financing credit program provides loans that finance sales of defense articles, defense services, and design and construction services to foreign countries and international organizations. The subsidy amounts are estimated on a present value basis.

This action defers funds pending review of specific loans to eligible countries by the Departments of State, Treasury, and Defense. The review process will ensure that in each proposed program the proposed recipients are qualified and that the limits of available funds are not exceeded. This action is taken pursuant to the Antideficiency Act (31 U.S.C. 1512).

**Estimated Program Effect:** None

**Outlay Effect:** None

<sup>1/</sup> This account was the subject of a similar deferral in FY 1994 (D94-10).

Deferral No. 95-4

**DEFERRAL OF BUDGET AUTHORITY**  
**Report Pursuant to Section 1013 of P.L. 93-344**

<b>AGENCY:</b> Funds Appropriated to the President	<b>New budget authority.....</b> \$ <u>12,000,000</u> (P.L. 103-306)
<b>BUREAU:</b> International Security Assistance	<b>Other budgetary resources.....</b> \$ _____
<b>Appropriations title and symbol:</b>  Military-to-military contact program  1151084	<b>Total budgetary resources.....</b> \$ <u>12,000,000</u>
	<b>Amount to be deferred:</b> <b>Part of year.....</b> \$ <u>2,000,000</u> <b>Entire year.....</b> _____
<b>OMB identification code:</b> 11-1084-0-1-152	<b>Legal authority (in addition to sec. 1013):</b> <input checked="" type="checkbox"/> Antideficiency Act <input type="checkbox"/> Other _____
<b>Grant program:</b> <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	
<b>Type of account or fund:</b> <input checked="" type="checkbox"/> Annual <input type="checkbox"/> Multi-year: _____ (expiration date) <input type="checkbox"/> No-Year	<b>Type of budget authority:</b> <input checked="" type="checkbox"/> Appropriation <input type="checkbox"/> Contract authority <input type="checkbox"/> Other

**JUSTIFICATION:** The President is authorized by the Defense Authorization Act of 1995 to conduct military-to-military contacts that are designed to encourage a democratic orientation of defense establishments and military forces in foreign countries. The Secretary of Defense, under the direction of the President, is responsible for activities conducted under this Act. However, the Act requires the Secretary of Defense to obtain prior approval of the Secretary of State for these activities.

This action defers funds pending development of programs by the Departments of State and Defense for specific countries under this Act. This action is taken pursuant to the Antideficiency Act (31 U.S.C. 1512).

**Estimated Program Effect:** None

**Outlay Effect:** None

Deferral No. 95-5

**DEFERRAL OF BUDGET AUTHORITY**  
**Report Pursuant to Section 1013 of P.L. 93-344**

<b>AGENCY:</b> Funds Appropriated to the President	New budget authority..... \$ <u>169,998,000</u> (P.L. 103-308)
<b>BUREAU:</b> Agency for International Development	Other budgetary resources..... \$ <u>4,000,000</u>
<b>Appropriations title and symbol:</b>  International disaster assistance, Executive 1/  11X1035	Total budgetary resources..... \$ <u>173,998,000</u>
	<b>Amount to be deferred:</b> Part of year..... \$ <u>169,998,000</u>  Entire year..... _____
<b>OMB identification code:</b>  11-1035-0-1-151	<b>Legal authority (in addition to sec. 1013):</b>  <input checked="" type="checkbox"/> Antideficiency Act  <input type="checkbox"/> Other _____
<b>Grant program:</b>  <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	
<b>Type of account or fund:</b>  <input type="checkbox"/> Annual <input type="checkbox"/> Multi-year: _____ (expiration date) <input checked="" type="checkbox"/> No-Year	<b>Type of budget authority:</b>  <input checked="" type="checkbox"/> Appropriation <input type="checkbox"/> Contract authority <input type="checkbox"/> Other _____

**JUSTIFICATION:** The International disaster assistance account allows the President to respond to humanitarian disaster relief efforts throughout the world. Funds are deferred pending the development of country-specific plans to ensure that aid is provided in an efficient manner to those most in need. This deferral action is taken pursuant to the Antideficiency Act (31 U.S.C. 1512).

**Estimated Program Effect:** None

**Outlay Effect:** None

1/ This account was the subject of a similar deferral in FY 1994 (D94-11).

Deferral No. 95-6

**DEFERRAL OF BUDGET AUTHORITY**  
**Report Pursuant to Section 1013 of P.L. 93-344**

<b>AGENCY:</b> Department of Health and Human Services	<b>New budget authority.....</b> \$ _____
<b>BUREAU:</b> Social Security Administration	<b>Other budgetary resources.....</b> \$ <u>180,368,808</u>
<b>Appropriation title and symbol:</b>  Limitation on administrative expenses 1/  75X8704	<b>Total budgetary resources.....</b> \$ <u>180,368,808</u>
	<b>Amount to be deferred:</b>
	<b>Part of year.....</b> \$ _____
	<b>Entire year.....</b> \$ <u>7,318,808</u>
<b>OMB identification code:</b> 20-8007-0-7-651	<b>Legal authority (in addition to sec. 1013):</b>
<b>Grant program:</b>  <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input checked="" type="checkbox"/> Antideficiency Act
	<input type="checkbox"/> Other _____
<b>Type of account or fund:</b>  <input type="checkbox"/> Annual <input type="checkbox"/> Multi-year: _____ (expiration date) <input checked="" type="checkbox"/> No-Year	<b>Type of budget authority:</b>  <input checked="" type="checkbox"/> Appropriation <input type="checkbox"/> Contract authority <input type="checkbox"/> Other _____

**JUSTIFICATION:** This account includes funding for construction, renovation, and expansion of Social Security Trust Fund-owned headquarters and field office buildings. In addition, funds remain available for costs associated with acquisition of land in Colonial Park Estates adjacent to the Social Security Administration complex in Baltimore, MD. In FY 1995, the Social Security Administration has received an approved apportionment for \$50,000 to cover potential upward adjustments of prior-year costs related to field office roof repair and replacement projects. Deferred funds are reserved for two purposes: (1) purchase of 9.8 acres of privately-owned land consisting of 14 scattered lots within the Social Security Administration complex that the Federal Government made a commitment to the original owners to purchase and to pay relocation costs contingent upon the owners' decision to sell at some future date; and (2) construction, renovation, and expansion projects when a need for such projects is identified and determined to be necessary for the efficient operation of the Social Security Administration. This action is taken pursuant to the Antideficiency Act (31 U.S.C. 1512).

**Estimated Program Effect:** None

**Outlay Effect:** None

1/ This account was the subject of a similar deferral in FY 1994 (D94-7A).

Deferral No. 95-7

**DEFERRAL OF BUDGET AUTHORITY**  
 Report Pursuant to Section 1013 of P.L. 93-344

<b>AGENCY:</b> Department of State	<b>New budget authority.....</b> \$ <u>50,000,000</u> (P.L. 103-306)
<b>BUREAU:</b> Bureau for Refugee Programs	<b>Other budgetary resources.....</b> \$ <u>59,700,000</u>
<b>Appropriation title and symbol:</b>  United States emergency refugee and migration assistance fund 1/  11X0040	<b>Total budgetary resources.....</b> \$ <u>109,700,000</u>
<b>OMB identification code:</b> 11-0040-0-1-151	<b>Amount to be deferred:</b>
<b>Grant program:</b>  <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<b>Part of year.....</b> \$ <u>105,300,000</u>
<b>Type of account or fund:</b>  <input type="checkbox"/> Annual <input type="checkbox"/> Multi-year: _____ (expiration date) <input checked="" type="checkbox"/> No-Year	<b>Entire year.....</b> \$ _____
	<b>Legal authority (in addition to sec. 1013):</b>  <input checked="" type="checkbox"/> Antideficiency Act <input type="checkbox"/> Other _____
	<b>Type of budget authority:</b>  <input checked="" type="checkbox"/> Appropriation <input type="checkbox"/> Contract authority <input type="checkbox"/> Other _____

**JUSTIFICATION:** Section 501(a) of the Foreign Relations Authorization Act of 1976 (Public Law 94-141) and Section 414(b) (1) of the Refugee Act of 1980 (Public Law 96-212) amended Section 2(c) of the Migration and Refugee Assistance Act of 1962 (22 U.S.C. 2601) by authorizing a fund to enable the President to provide emergency assistance for unexpected urgent refugee and migration needs.

Executive Order No. 11922 of June 16, 1976, allocated all funds appropriated to the President for the Emergency Fund to the Secretary of State but reserved for the President the determination of assistance to be furnished and the designation of refugees to be assisted by the Fund.

These funds have been deferred pending Presidential decisions required by Executive Order No. 11922. Funds will be released as the President determines assistance to be furnished and designates refugees to be assisted by the Fund. This deferral action is taken under the provisions of the Antideficiency Act (31 U.S.C. 1512).

**Estimated Program Effect:** None

**Outlay Effect:** None

1/ This account was the subject of a similar deferral in FY 1994 (D94-8A).

[FR Doc. 94-26551 Filed 10-26-94; 8:45 am]

BILLING CODE 3110-01-C

# Federal Register

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Thursday  
October 27, 1994

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Part V

## Department of Education

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Bilingual Vocational Training Program;  
Inviting Applications for New Grant  
Awards for Fiscal Year 1995; Notice

## DEPARTMENT OF EDUCATION

[CFDA No.: 84.077]

**Bilingual Vocational Training Program; Notice Inviting Applications for New Grant Awards for Fiscal Year (FY) 1995**

*Note to Applicants:* This notice is a complete application package. Together with the statute authorizing the program and applicable regulations governing the program, including the Education Department General Administrative Regulations (EDGAR), this notice contains all of the information, application forms, and instructions needed to apply for a grant under this competition.

*Purpose of Program:* The Bilingual Vocational Training Program provides financial assistance for bilingual vocational education and training for limited English proficient out-of-school youth and adults, to prepare these individuals for jobs in recognized occupations and new and emerging occupations.

The Bilingual Vocational Training Program supports the National Education Goal that, by the year 2000, every adult American will be literate and will possess the knowledge and skills necessary to compete in a global economy and exercise the rights and responsibilities of citizenship. The program furthers this goal by helping to improve vocational education and training for limited English proficient adults.

*Eligible Applicants:* State agencies, local educational agencies, postsecondary educational institutions, private non-profit vocational training institutions, other non-profit organizations specifically created to serve or currently serving individuals who normally use a language other than English.

*Deadline for Transmittal of Applications:* December 12, 1994.

*Deadline for Intergovernmental Review:* February 2, 1995.

*Available funds:* \$2,209,000.

*Estimated Range of Awards:* \$150,000-\$250,000.

*Estimated Average Size of Awards:* \$184,000.

*Estimated Number of Awards:* 12.

*Note:* The Department is not bound by any estimates in this notice.

*Project Period:* Up to 18 months.

**Applicable Regulations**

(a) The Education Department General Administrative Regulations (EDGAR) as follows:

(1) 34 CFR Part 74 (Administration of Grants to Institutions of Higher

Education, Hospitals and Nonprofit Organizations).

(2) 34 CFR Part 75 (Direct Grant Programs).

(3) 34 CFR Part 77 (Definitions that Apply to Department Regulations).

(4) 34 CFR Part 79 (Intergovernmental Review of Department of Education Programs and Activities).

(5) 34 CFR Part 80 (Uniform Administrative Requirements for Grants and Cooperative Agreements to State and Local Governments).

(6) 34 CFR Part 81 (General Education Provisions Act—Enforcement).

(7) 34 CFR Part 82 (New Restrictions on Lobbying).

(8) 34 CFR Part 85 (Governmentwide Debarment and Suspension (Nonprocurement) and Governmentwide Requirements for Drug-Free Workplace (Grants)).

(9) 34 CFR Part 86 (Drug-Free Schools and Campuses).

(b) The regulations for this program in 34 CFR Parts 400 and 427.

**Content of the Application**

(a) An application must—

(1) Provide an assurance that the activities and services for which assistance is sought will be administered by or under the supervision of the applicant;

(2) Propose a project of a size, scope and design that will make a substantial contribution toward carrying out the purpose of the Bilingual Vocational Training Program;

(3) Contain measurable goals for the enrollment, completion, and placement of program participants;

(4) Include a comparison of how the applicant's goals take into consideration any related standards and measures in the geographic area for the Job Opportunities and Basic Skills Training (JOBS) program (42 U.S.C. 681 *et seq.*) and any Job Training Partnership Act (JTPA) programs (29 U.S.C. 1501 *et seq.*) and any standards set by the State Board for Vocational Education for the occupational and geographic area;

(5) Describe, for each occupation for which training is to be provided, how successful program completion will be determined and reported to the Secretary in terms of the academic and vocational competencies to be demonstrated by enrollees prior to successful completion and any academic or work credentials expected to be acquired upon completion; and

(6) Be submitted to the State board for vocational education (State board) established under section 111 of the Carl D. Perkins Vocational and Applied Technology Education Act (the Act) for review and comment, including

comment on the relationship of the proposed project to the State's vocational education program.

(b) An applicant shall include any comments received under paragraph (a)(6) of this section with the application.

**Invitational Priority**

Under 34 CFR 75.105(c)(1) the Secretary is particularly interested in applications that meet the following invitational priority. However, an application that meets this invitational priority does not receive competitive or absolute preference over other applications:

Applications that include strategies for developing the applicant's capacity to continue, expand, or build upon its bilingual vocational education and training when Federal funding under this competition ends, as evidenced by such actions as—

(a) Extending training to additional sites that are not funded under this program;

(b) Integrating the project into the long-term planning of the applicant;

(c) Committing funding and staffing for continued implementation of the project;

(d) Incorporating the project into the applicant's organizational and program structure; or

(e) Establishing and strengthening relationships within the community, region, or State that will support continuation of the project.

**Selection Criteria**

The Secretary uses the following selection criteria to evaluate applications for new grants under this competition. The maximum score for all of these criteria is 100 points. The maximum score for each criterion is indicated in parentheses.

For this competition, the Secretary assigns the 15 points, reserved in 34 CFR 427.20(b), as follows:

*Plan of operation* (34 CFR 427.21(b)). Five points are added to this criterion for a possible total of 20 points.

*Demonstration and dissemination* (34 CFR 427.21(g)). Ten points are added to this criterion for a possible total of 20 points.

(a) *Need.* (15 points) The Secretary reviews each application for specific information that shows the need for the proposed bilingual vocational training project in the local geographic area, including—

(1) The employment training need of limited English proficient individuals to be met;

(2) The labor market need to be met; and

(3) The relationship of the proposed project to other employment training programs in the community.

(b) *Plan of operation.* (20 points)

(1) The Secretary reviews each application to determine the extent to which the project proposes measurable goals for student enrollment, completion, and placement and describes how the applicant sets the goals taking into consideration the standards and measures for JOBS programs and JTPA programs and any standards set by the State Board established under section 111 of the Act for the occupation and geographic area.

(2) The Secretary reviews each application to determine the extent to which the project defines successful program completion (or describes how successful program completion will be defined and reported to the Secretary) in a way consistent with the goals of the program for each occupation for which training is to be provided.

(3) (i) The Secretary reviews each application for specific information that, upon completion of their training, more than 65 percent of the trainees will be employed in jobs (including military specialties) related to their training, or will be enrolled for further training related to their training under this program. This information must correspond to the information described in paragraph (a) of this section.

(ii) The estimated job placement rate must be supported by past records, actual employer job commitments, anticipated job openings, or other pertinent information.

(4) The Secretary reviews each application for an effective plan of management that ensures proper and efficient administration of the project, including—

(i) Clearly defined project objectives that relate to the purpose of the Bilingual Vocational Training Program;

(ii) For each objective, the specific tasks to be performed in order to achieve the specified project objective;

(iii) How the applicant plans to use its resources and personnel to achieve each objective; and

(iv) If the applicant plans to use a project advisory committee, a clear plan for using a project advisory committee to assist in project development, to review curriculum materials, and to make recommendations about job placements.

(c) *Program factors.* (20 points)

(1) The Secretary reviews each application to determine the quality of training to be provided, including—

(i) Provision of vocational skills instruction in English and the trainees' native languages;

(ii) Provision of job-related English-as-a-second language instruction;

(iii) Coordination of the job-related English-as-a-second language instruction with the vocational skills instruction;

(iv) Recruitment procedures that are targeted towards limited English proficient out-of-school youth and adults who have the greatest need for bilingual vocational training;

(v) Assessment procedures that evaluate the language and vocational training needs of the trainees;

(vi) Provision of counseling activities and employability skills instruction that prepare trainees for employment in an English language environment; and

(vii) Job development and job placement procedures that provide opportunities for career advancement or entrepreneurship.

(2) The Secretary reviews each application to determine the project's potential to have a lasting impact in the local geographic area, including the potential impact of the project on—

(i) Program participants;

(ii) The agency or agencies responsible for administering the bilingual vocational training program;

(iii) Other employment training services in the local area; and

(iv) The community.

(d) *Key personnel.* (10 points)

(1) The Secretary reviews each application to determine the quality of key personnel the applicant plans to use on the project, including—

(i) The qualifications of the director and other key personnel to be used in the project;

(ii) The appropriateness of the time that each person referred to in paragraph (d)(1)(i) of this section will commit to the project; and

(iii) How the applicant, as part of its nondiscriminatory employment practices, will ensure that personnel will be selected without regard to race, color, national origin, gender, age, or disability.

(2) To determine personnel qualifications under paragraph (d)(1)(i) of this section, the Secretary considers—

(i) Experience and training in fields related to the objectives of the project;

(ii) Experience and training in project management; and

(iii) Any other qualifications that pertain to the quality of the project.

(e) *Budget and cost effectiveness.* (5 points) The Secretary reviews each application to determine the extent to which—

(1) The budget is sufficient to support the proposed project, and that it represents a cost effective use of Bilingual Vocational Training Program funds;

(2) Costs are necessary and reasonable in relation to the objectives of the proposed project; and

(3) The facilities, equipment, and supplies that the applicant plans to use are adequate for the proposed project.

(f) *Evaluation plan.* (10 points)

The Secretary reviews each application to determine the quality of the project's evaluation plan, including the extent to which the plan—

(1) Is clearly explained and appropriate for the project;

(2) Identifies at a minimum, types of data to be collected and reported with respect to the English-language competencies and academic and vocational competencies demonstrated by participants and the number and kinds of academic and work credentials acquired by individuals who complete the training;

(3) Identifies at a minimum, types of data to be collected and reported with respect to enrollment, completion, and placement of participants by sex, racial or ethnic group, socio-economic status, and if appropriate, by level of English proficiency, for each occupation for which training is provided;

(4) Includes activities during the formative stages of the project to help guide and improve the project, as well as a summative evaluation that includes recommendations for replicating project activities and results; and

(5) Makes use of an external evaluator.

(g) *Demonstration and dissemination.* (20 points) The Secretary reviews each application for information to determine the effectiveness and efficiency of the plan for demonstrating and disseminating information about project activities and results throughout the project period, including—

(1) High quality in the design of the demonstration and dissemination plan and procedures for evaluating the effectiveness of the dissemination plan;

(2) Provisions for publicizing the project at the local, State, and national levels by conducting or delivering presentations at conferences, workshops, and other professional meetings and by preparing materials for journal articles, newsletters, and brochures;

(3) Provisions for making available the methods and techniques used by the project to others interested in replicating these methods and techniques, such as by inviting them to observe project activities;

(4) A description of the types of materials the applicant plans to make available to help others replicate project activities and the methods for making the materials available; and

(5) Provisions for assisting others to adopt and successfully implement the project or methods and techniques used by the project.

#### Additional Factors

(a) After evaluating the applications according to the selection criteria and consulting with the appropriate State board established under section 111 of the Act, the Secretary determines whether the most highly rated applications are equitably distributed among populations of individuals with limited English proficiency within the affected State.

(b) The Secretary may select other applications for funding if doing so would improve the—

(1) Equitable distribution of assistance among populations of individuals with limited English proficiency within the affected State; or

(2) Geographical distribution of projects funded under this program.

#### Intergovernmental Review of Federal Programs

This program is subject to the requirements of Executive Order 12372 (Intergovernmental Review of Federal Programs) and the regulations in 34 CFR Part 79.

The objective of the Executive order is to foster an intergovernmental partnership and to strengthen federalism by relying on State and local processes for State and local government coordination and review of proposed Federal financial assistance.

Applicants must contact the appropriate State Single Point of Contact to find out about, and to comply with, the State's process under Executive order 12372. Applicants proposing to perform activities in more than one State should immediately contact the Single Point of Contact for each of those States and follow the procedure established in each State under the Executive order. If you want to know the name and address of any State Single Point of Contact, see the list published in the **Federal Register** on June 10, 1994 (59 FR 30214-30215).

In States that have not established a process or chosen a program for review, State, areawide, regional, and local entities may submit comments directly to the Department.

Any State Process Recommendation and other comments submitted by a State Single Point of Contact and any comments from State, areawide, regional, and local entities must be mailed or hand-delivered by the date indicated in this notice to the following address: The Secretary, E.O. 12372—CFDA# 84.077, U.S. Department of

Education, Room 4161, 400 Maryland Avenue, S.W., Washington, D.C. 20202-0125.

Proof of mailing will be determined on the same basis as applications (see 34 CFR 75.102). Recommendations or comments may be hand-delivered until 4:30 p.m. (Washington, D.C. time) on the date indicated in this notice.

Please note that the above address is not the same address as the one to which the applicant submits its completed application. Do not send applications to the above address.

#### Instructions for Transmittal of Applications

(a) If an applicant wants to apply for a grant, the applicant shall—

(1) Mail the original and six copies of the application on or before the deadline date to: U.S. Department of Education, Application Control Center, Attention: (CFDA# 84.077), Washington, D.C. 20202-4725 or

(2) Hand deliver the original and six copies of the application by 4:30 p.m. (Washington, D.C. time) on or before the deadline date to: U.S. Department of Education, Application Control Center, Attention: (CFDA# 84.077), Room #3633, Regional Office Building #3, 7th and D Streets, S.W., Washington, D.C. 20202-4725.

(b) An applicant must show one of the following as proof of mailing:

(1) A legibly dated U.S. Postal Service postmark.

(2) A legible mail receipt with the date of mailing stamped by the U.S. Postal Service.

(3) A dated shipping label, invoice, or receipt from a commercial carrier.

(4) Any other proof of mailing acceptable to the Secretary.

(c) If an application is mailed through the U.S. Postal Service, the Secretary does not accept either of the following as proof of mailing:

(1) A private metered postmark.

(2) A mail receipt that is not dated by the U.S. Postal Service.

Notes: (1) The U.S. Postal Service does not uniformly provide a dated postmark. Before relying on this method, an applicant should check with its local post office.

(2) The Application Control Center will mail a Grant Application Receipt Acknowledgement to each applicant. If an applicant fails to receive the notification of application receipt within 15 days from the date of mailing the application, the applicant should call the U.S. Department of Education Application Control Center at (202) 708-8493.

(3) The applicant *must* indicate on the envelope and—if not provided by the Department—in Item 10 of the Application for Federal Assistance (Standard Form 24) the CFDA number of the competition under which the application is being submitted.

#### Application Instructions and Forms:

The appendix to this application is divided into six parts, plus a statement regarding estimated public reporting burden and various assurances and certifications. These parts and additional materials are organized in the same manner that the submitted application should be organized. The parts and additional materials are as follows:

**Part I:** Application for Federal Assistance (Standard Form 424 (Rev. 4-88)) and instructions.

**Part II:** Instructions for ED Form No. 524.

**Part III:** Budget Information Non-construction Programs (ED Form No. 524).

**Part IV:** Budget Narrative.

**Part V:** Program Narrative.

**Part VI:** Additional Assurances and Certifications:

a. Assurances—Non-Construction Programs (Standard Form 424B).

b. Certifications Regarding Lobbying; Debarment, Suspension, and Other Responsibility Matters; and Drug-Free Workplace Requirements (ED 80-0013) and Instructions.

c. Certification Regarding Debarment, Suspension, Ineligibility and Voluntary Exclusion: Lower Tier Covered Transactions (ED 80-0014, 9/90) and Instructions. (NOTE: The grantee should keep this form on file. It should not be transmitted to the Department.)

d. Disclosure of Lobbying Activities (Standard Form LLL) (if applicable) and Instructions; and Disclosure of Lobbying Activities Continuation Sheet (Standard Form LLL-A.)

All forms and instructions are included as Appendix A of this notice. Questions and answers pertaining to this program are included, as Appendix B, to assist potential applicants.

All applicants must submit ONE original signed application, including ink signatures on all forms and assurances and SIX copies of the application. Please mark each application as original or copy. Local or State agencies may choose to submit two copies with the original. No grant may be awarded unless a complete application form has been received.

**For Further Information Contact:** Cindy Towsner, Special Programs Branch, Division of National Programs, Office of Vocational and Adult Education, U.S. Department of Education, 600 Independence Avenue, S.W. (Room 4512, Mary E. Switzer Building), Washington, D.C. 20202-7242. Telephone (202) 205-5864. Individuals who use a telecommunications device for the deaf

(TDD) may call the Federal Information Relay Service (FIRS) at 1-800-877-8339 between 8 a.m. and 8 p.m., Eastern time, Monday through Friday.

**Program Authority:** 20 U.S.C. 2441(a).

**Dated:** October 21, 1994.

**Augusta Souza Kappner,**

*Assistant Secretary, Office of Vocational and Adult Education.*

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## INSTRUCTIONS FOR THE SF 424

This is a standard form used by applicants as a required facesheet for preapplications and applications submitted for Federal assistance. It will be used by Federal agencies to obtain applicant certification that States which have established a review and comment procedure in response to Executive Order 12372 and have selected the program to be included in their process, have been given an opportunity to review the applicant's submission.

- | Item: | Entry:   | Item: | Entry:   |
|-------|--|-------|--|
| 1.    | Self-explanatory.  | 12.   | List only the largest political entities affected (e.g., State, counties, cities).   |
| 2.    | Date application submitted to Federal agency (or State if applicable) & applicant's control number (if applicable).  | 13.   | Self-explanatory.  |
| 3.    | State use only (if applicable).  | 14.   | List the applicant's Congressional District and any District(s) affected by the program or project.  |
| 4.    | If this application is to continue or revise an existing award, enter present Federal identifier number. If for a new project, leave blank.  | 15.   | Amount requested or to be contributed during the first funding/budget period by each contributor. Value of in-kind contributions should be included on appropriate lines as applicable. If the action will result in a dollar change to an existing award, indicate <u>only</u> the amount of the change. For decreases, enclose the amounts in parentheses. If both basic and supplemental amounts are included, show breakdown on an attached sheet. For multiple program funding, use totals and show breakdown using same categories as item 15. |
| 5.    | Legal name of applicant, name of primary organizational unit which will undertake the assistance activity, complete address of the applicant, and name and telephone number of the person to contact on matters related to this application.   | 16.   | Applicants should contact the State Single Point of Contact (SPOC) for Federal Executive Order 12372 to determine whether the application is subject to the State intergovernmental review process.  |
| 6.    | Enter Employer Identification Number (EIN) as assigned by the Internal Revenue Service.  | 17.   | This question applies to the applicant organization, not the person who signs as the authorized representative. Categories of debt include delinquent audit disallowances, loans and taxes.  |
| 7.    | Enter the appropriate letter in the space provided.  | 18.   | To be signed by the authorized representative of the applicant. A copy of the governing body's authorization for you to sign this application as official representative must be on file in the applicant's office. (Certain Federal agencies may require that this authorization be submitted as part of the application.)  |
| 8.    | Check appropriate box and enter appropriate letter(s) in the space(s) provided:<br>— "New" means a new assistance award.<br>— "Continuation" means an extension for an additional funding/budget period for a project with a projected completion date.<br>— "Revision" means any change in the Federal Government's financial obligation or contingent liability from an existing obligation. |       |  |
| 9.    | Name of Federal agency from which assistance is being requested with this application.   |       |  |
| 10.   | Use the Catalog of Federal Domestic Assistance number and title of the program under which assistance is requested.  |       |  |
| 11.   | Enter a brief descriptive title of the project. If more than one program is involved, you should append an explanation on a separate sheet. If appropriate (e.g., construction or real property projects), attach a map showing project location. For preapplications, use a separate sheet to provide a summary description of this project.  |       |  |

Public reporting burden for this collection of information is estimated to vary from 13 to 22 hours per response, with an average of 17.5 hours, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to the U.S. Department of Education, Information Management and Compliance Division, Washington, DC 20202-4651; and the Office of Management and Budget, Paperwork Reduction Project 1875-0102, Washington, DC 20503.

#### Instructions for Ed Form No. 524

##### General Instructions

This form is used to apply to individual U.S. Department of Education discretionary grant programs. Unless directed otherwise, provide the same budget information for each year of the multi-year funding request. Pay attention to applicable program specific instructions, if attached.

##### Section A—Budget Summary: U.S. Department of Education Funds

All applicants must complete Section A and provide a breakdown by the

applicable budget categories shown in lines 1-11.

Lines 1-11, columns (a)-(e):

For each project year for which funding is requested, show the total amount requested for each applicable budget category.

Lines 1-11, column (f):

Show the multi-year total for each budget category. If funding is requested for only one project year, leave this column blank.

Line 12, columns (a)-(e):

Show the total budget request for each project year for which funding is requested.

Line 12, column (f):

Show the total amount requested for all project years. If funding is requested for only one year, leave this space blank.

##### Section B—Budget Summary: Non-Federal Funds

If you are required to provide or volunteer to provide matching funds or other non-Federal resources to the project, these should be shown for each applicable budget category on lines 1-11 of Section B.

Lines 1-11, columns (a)-(e):

For each project year for which matching funds or other contributions are provided, show the total contribution for each applicable budget category.

Lines 1-11, column (f):

Show the multi-year total for each budget category. If non-Federal contributions are provided for only one year, leave this column blank.

Line 12, columns (a)-(e):

Show the total matching or other contribution for each project year.

Line 12, column (f):

Show the total amount to be contributed for all years of the multi-year project. If non-Federal contributions are provided for only one year, leave this space blank.

##### Section C—Other Budget Information

Pay attention to applicable program specific instructions, if attached.

1. Provide an itemized budget breakdown, by project year, for each budget category listed in Sections A and B.

2. If applicable to this program, enter the type of indirect rate (provisional, predetermined, final or fixed) that will be in effect during the funding period. In addition, enter the estimated amount of the base to which the rate is applied, and the total indirect expense.

3. If applicable to this program, provide the rate and base on which fringe benefits are calculated.

4. Provide other explanations or comments you deem necessary.

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**U.S. DEPARTMENT OF EDUCATION  
BUDGET INFORMATION  
NON-CONSTRUCTION PROGRAMS**

OMB Control No. 1875-0102

Expiration Date: 9/30/95

Name of Institution/Organization

Applicants requesting funding for only one year should complete the column under "Project Year 1." Applicants requesting funding for multi-year grants should complete all applicable columns. Please read all instructions before completing form.

**SECTION A - BUDGET SUMMARY  
U.S. DEPARTMENT OF EDUCATION FUNDS**

Budget Categories	Project Year 1 (a)	Project Year 2 (b)	Project Year 3 (c)	Project Year 4 (d)	Project Year 5 (e)	Total (f)
1. Personnel						
2. Fringe Benefits						
3. Travel						
4. Equipment						
5. Supplies						
6. Contractual						
7. Construction						
8. Other						
9. Total Direct Costs (lines 1-8)						
10. Indirect Costs						
11. Training Stipends						
12. Total Costs (lines 9-11)						

ED FORM NO. 524

Name of Institution/Organization		SECTION B - BUDGET SUMMARY NON-FEDERAL FUNDS					
		Project Year 1 (a)	Project Year 2 (b)	Project Year 3 (c)	Project Year 4 (d)	Project Year 5 (e)	Total (f)
Budget Categories							
1. Personnel							
2. Fringe Benefits							
3. Travel							
4. Equipment							
5. Supplies							
6. Contractual							
7. Construction							
8. Other							
9. Total Direct Costs (lines 1-8)							
10. Indirect Costs							
11. Training Stipends							
12. Total Costs (lines 9-11)							

SECTION C - OTHER BUDGET INFORMATION (see instructions)

ED FORM NO. 524

**Instructions for Part IV—Budget Narrative**

The budget narrative should explain, justify, and, if needed, clarify your budget summary. For each line item (personnel, fringe benefits, travel, etc.) in your budget, explain why it is there and how you computed the costs.

Please limit this section to no more than five pages. Be sure that each page of your application is numbered consecutively.

**Explanation of Budget Categories**

1. *Personnel*: Show salaries to be paid to project personnel.

2. *Fringe Benefits*: Indicate the rate and amount of fringe benefits.

3. *Travel*: Indicate the amount requested for both inter- and intra-State travel of project staff. Include funds for at least one trip for two people to attend a project director's meeting in Washington, DC.

4. *Equipment*: Indicate the cost of non-expendable personal property that has a useful life of more than one year and a cost of \$300 or more per unit (\$5,000 or more if State, Local or Tribal Government).

5. *Supplies*: Include the cost of consumable supplies and materials to be used during the project.

6. *Contractual*: Show the amount to be used for (1) procurement contracts (except those which belong on other lines such as supplies and equipment; and (2) sub-contracts.

7. *Construction*: Not Allowable.

8. *Other*: Indicate all direct costs not clearly covered by lines 1 through 7 above, including consultants.

9. *Total, Direct Cost*: Show the total for lines 1 through 8.

10. *Indirect Costs*: Indicate the rate and amount of indirect costs. NOTE: For training grants, the indirect cost rate cannot exceed 8%.

11. *Training/Stipend Cost*: (if allowable).

12. *TOTAL, Federal Funds Requested*: Show total for lines 9 through 11.

**Cost Sharing**

Indicate the actual rate and amount of cost sharing when there is a cost sharing requirement. If cost sharing is required by program regulations, the local share required refers to a percentage of *Total Project Cost*, not of Federal funds.

**Instructions for Part IV—Program Narrative**

The program narrative will comprise the largest portion of your application. This part is where you spell out the who, what, when, where, why, and how of your proposed project.

Although you will not have a form to fill out for your narrative, there is a format. This format is the selection criteria. Because your application will be reviewed and rated by a review panel on the basis of the selection criteria, your narrative should follow the order and format of the criteria.

Before preparing your application, you should carefully read the legislation and regulations of the program, eligibility requirements, information on any priority set by the Secretary, and the selection criteria for this competition.

Your program narrative should be clear, concise, and to the point. Begin the narrative with a one page abstract or summary of your proposed project. Then describe the project in detail, addressing each selection criterion in order.

The Secretary strongly suggests that the applicant limit the program narrative to no more than 40 double-spaced, typed pages (on one side only), although the Secretary will consider applications of greater length. Be sure to number consecutively ALL pages in your application.

You may include supporting documentation as appendices. Be sure that this material is concise and

pertinent to this program competition and is numbered consecutively.

Applicants are advised that: (a) The Department considers only information contained in the application in ranking applications for funding consideration. Letters of support sent separately from the formal application package are not considered in the review by the technical review panels. (34 CFR 75.217)

(b) The technical review panel evaluates each application solely on the basis of the established technical review criteria. Letters of support contained in the application will strengthen the application only insofar as they contain commitments that pertain to the established technical review criteria, such as commitment and resources.

**Additional Materials****Instructions for Estimated Public Reporting Burden**

Under terms of the Paperwork Reduction Act of 1980, as amended, and the regulations implementing that Act, the Department of Education invites comment on the public reporting burden in this collection of information. Public reporting burden for this collection of information is estimated to average 90 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. You may send comments regarding this burden to the U.S. Department of Education, Information Management and Compliance Division, Washington, DC 20202-4651; and to the Office of Management and Budget, Paperwork Reduction Project, OMB 1830-0013, Washington, DC 20503. (Information collection approved under OMB control number 1830-0013. Expiration date: 2/28/95.)

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### ASSURANCES — NON-CONSTRUCTION PROGRAMS

**Note:** Certain of these assurances may not be applicable to your project or program. If you have questions, please contact the awarding agency. Further, certain Federal awarding agencies may require applicants to certify to additional assurances. If such is the case, you will be notified.

As the duly authorized representative of the applicant I certify that the applicant:

- Has the legal authority to apply for Federal assistance, and the institutional, managerial and financial capability (including funds sufficient to pay the non-Federal share of project costs) to ensure proper planning, management and completion of the project described in this application.
- Will give the awarding agency, the Comptroller General of the United States, and if appropriate, the State, through any authorized representative, access to and the right to examine all records, books, papers, or documents related to the award; and will establish a proper accounting system in accordance with generally accepted accounting standards or agency directives.
- Will establish safeguards to prohibit employees from using their positions for a purpose that constitutes or presents the appearance of personal or organizational conflict of interest, or personal gain.
- Will initiate and complete the work within the applicable time frame after receipt of approval of the awarding agency.
- Will comply with the Intergovernmental Personnel Act of 1970 (42 U.S.C. §§ 4728-4763) relating to prescribed standards for merit systems for programs funded under one of the nineteen statutes or regulations specified in Appendix A of OPM's Standards for a Merit System of Personnel Administration (5 C.F.R. 900, Subpart F).
- Will comply with all Federal statutes relating to nondiscrimination. These include but are not limited to: (a) Title VI of the Civil Rights Act of 1964 (P.L. 88-352) which prohibits discrimination on the basis of race, color or national origin; (b) Title IX of the Education Amendments of 1972, as amended (20 U.S.C. §§ 1681-1683, and 1685-1686), which prohibits discrimination on the basis of sex; (c) Section 504 of the Rehabilitation Act of 1973, as amended (29 U.S.C. § 794), which prohibits discrimination on the basis of handicaps; (d) the Age Discrimination Act of 1975, as amended (42 U.S.C. §§ 6101-6107), which prohibits discrimination on the basis of age; (e) the Drug Abuse Office and Treatment Act of 1972 (P.L. 92-255), as amended, relating to nondiscrimination on the basis of drug abuse; (f) the Comprehensive Alcohol Abuse and Alcoholism Prevention, Treatment and Rehabilitation Act of 1970 (P.L. 91-616), as amended, relating to nondiscrimination on the basis of alcohol abuse or alcoholism; (g) §§ 523 and 527 of the Public Health Service Act of 1912 (42 U.S.C. 290 dd-3 and 290 ee-3), as amended, relating to confidentiality of alcohol and drug abuse patient records; (h) Title VIII of the Civil Rights Act of 1968 (42 U.S.C. § 3601 et seq.), as amended, relating to nondiscrimination in the sale, rental or financing of housing; (i) any other nondiscrimination provisions in the specific statute(s) under which application for Federal assistance is being made; and (j) the requirements of any other nondiscrimination statute(s) which may apply to the application.
- Will comply, or has already complied, with the requirements of Titles II and III of the Uniform Relocation Assistance and Real Property Acquisition Policies Act of 1970 (P.L. 91-646) which provide for fair and equitable treatment of persons displaced or whose property is acquired as a result of Federal or federally assisted programs. These requirements apply to all interests in real property acquired for project purposes regardless of Federal participation in purchases.
- Will comply with the provisions of the Hatch Act (5 U.S.C. §§ 1501-1508 and 7324-7328) which limit the political activities of employees whose principal employment activities are funded in whole or in part with Federal funds.
- Will comply, as applicable, with the provisions of the Davis-Bacon Act (40 U.S.C. §§ 276a to 276a-7), the Copeland Act (40 U.S.C. § 276c and 18 U.S.C. §§ 874), and the Contract Work Hours and Safety Standards Act (40 U.S.C. §§ 327-333), regarding labor standards for federally assisted construction subagreements.

10. Will comply, if applicable, with flood insurance purchase requirements of Section 102(a) of the Flood Disaster Protection Act of 1973 (P.L. 93-234) which requires recipients in a special flood hazard area to participate in the program and to purchase flood insurance if the total cost of insurable construction and acquisition is \$10,000 or more.
11. Will comply with environmental standards which may be prescribed pursuant to the following: (a) institution of environmental quality control measures under the National Environmental Policy Act of 1969 (P.L. 91-190) and Executive Order (EO) 11514; (b) notification of violating facilities pursuant to EO 11738; (c) protection of wetlands pursuant to EO 11990; (d) evaluation of flood hazards in floodplains in accordance with EO 11988; (e) assurance of project consistency with the approved State management program developed under the Coastal Zone Management Act of 1972 (16 U.S.C. §§ 1451 et seq.); (f) conformity of Federal actions to State (Clear Air) Implementation Plans under Section 176(c) of the Clear Air Act of 1955, as amended (42 U.S.C. § 7401 et seq.); (g) protection of underground sources of drinking water under the Safe Drinking Water Act of 1974, as amended, (P.L. 93-523); and (h) protection of endangered species under the Endangered Species Act of 1973, as amended, (P.L. 93-205).
12. Will comply with the Wild and Scenic Rivers Act of 1968 (16 U.S.C. §§ 1271 et seq.) related to protecting components or potential components of the national wild and scenic rivers system.
13. Will assist the awarding agency in assuring compliance with Section 106 of the National Historic Preservation Act of 1966, as amended (16 U.S.C. 470), EO 11593 (identification and protection of historic properties), and the Archaeological and Historic Preservation Act of 1974 (16 U.S.C. 469a-1 et seq.).
14. Will comply with P.L. 93-348 regarding the protection of human subjects involved in research, development, and related activities supported by this award of assistance.
15. Will comply with the Laboratory Animal Welfare Act of 1966 (P.L. 89-544, as amended, 7 U.S.C. 2131 et seq.) pertaining to the care, handling, and treatment of warm blooded animals held for research, teaching, or other activities supported by this award of assistance.
16. Will comply with the Lead-Based Paint Poisoning Prevention Act (42 U.S.C. §§ 4801 et seq.) which prohibits the use of lead based paint in construction or rehabilitation of residence structures.
17. Will cause to be performed the required financial and compliance audits in accordance with the Single Audit Act of 1984.
18. Will comply with all applicable requirements of all other Federal laws, executive orders, regulations and policies governing this program.

SIGNATURE OF AUTHORIZED CERTIFYING OFFICIAL	TITLE
APPLICANT ORGANIZATION	DATE SUBMITTED

## CERTIFICATIONS REGARDING LOBBYING; DEBARMENT, SUSPENSION AND OTHER RESPONSIBILITY MATTERS; AND DRUG-FREE WORKPLACE REQUIREMENTS

Applicants should refer to the regulations cited below to determine the certification to which they are required to attest. Applicants should also review the instructions for certification included in the regulations before completing this form. Signature of this form provides for compliance with certification requirements under 34 CFR Part 82, "New Restrictions on Lobbying," and 34 CFR Part 85, "Government-wide Debarment and Suspension (Nonprocurement) and Government-wide Requirements for Drug-Free Workplace (Grants)." The certifications shall be treated as a material representation of fact upon which reliance will be placed when the Department of Education determines to award the covered transaction, grant, or cooperative agreement.

### 1. LOBBYING

As required by Section 1352, Title 31 of the U.S. Code, and implemented at 34 CFR Part 82, for persons entering into a grant or cooperative agreement over \$100,000, as defined at 34 CFR Part 82, Sections 82.105 and 82.110, the applicant certifies that:

- (a) No Federal appropriated funds have been paid or will be paid, by or on behalf of the undersigned, to any person for influencing or attempting to influence an officer or employee of any agency, a Member of Congress, an officer or employee of Congress, or an employee of a Member of Congress in connection with the making of any Federal grant, the entering into of any cooperative agreement, and the extension, continuation, renewal, amendment, or modification of any Federal grant or cooperative agreement;
- (b) If any funds other than Federal appropriated funds have been paid or will be paid to any person for influencing or attempting to influence an officer or employee of any agency, a Member of Congress, an officer or employee of Congress, or an employee of a Member of Congress in connection with this Federal grant or cooperative agreement, the undersigned shall complete and submit Standard Form - LLL, "Disclosure Form to Report Lobbying," in accordance with its instructions;
- (c) The undersigned shall require that the language of this certification be included in the award documents for all subawards at all tiers (including subgrants, contracts under grants and cooperative agreements, and subcontracts) and that all subrecipients shall certify and disclose accordingly.

### 2. DEBARMENT, SUSPENSION, AND OTHER RESPONSIBILITY MATTERS

As required by Executive Order 12549, Debarment and Suspension, and implemented at 34 CFR Part 85, for prospective participants in primary covered transactions, as defined at 34 CFR Part 85, Sections 85.105 and 85.110 -

A. The applicant certifies that it and its principals:

- (a) Are not presently debarred, suspended, proposed for debarment, declared ineligible, or voluntarily excluded from covered transactions by any Federal department or agency;
- (b) Have not within a three-year period preceding this application been convicted of or had a civil judgment rendered against them for commission of fraud or a criminal offense in connection with obtaining, attempting to obtain, or performing a public (Federal, State, or local) transaction or contract under a public transaction; violation of Federal or State antitrust statutes or commission of embezzlement, theft, forgery, bribery, falsification or destruction of records, making false statements, or receiving stolen property;
- (c) Are not presently indicted for or otherwise criminally or civilly charged by a governmental entity (Federal, State, or local) with commission of any of the offenses enumerated in paragraph (1)(b) of this certification; and

(d) Have not within a three-year period preceding this application had one or more public transactions (Federal, State, or local) terminated for cause or default; and

B. Where the applicant is unable to certify to any of the statements in this certification, he or she shall attach an explanation to this application.

### 3. DRUG-FREE WORKPLACE (GRANTEES OTHER THAN INDIVIDUALS)

As required by the Drug-Free Workplace Act of 1988, and implemented at 34 CFR Part 85, Subpart F, for grantees, as defined at 34 CFR Part 85, Sections 85.605 and 85.610 -

A. The applicant certifies that it will or will continue to provide a drug-free workplace by:

- (a) Publishing a statement notifying employees that the unlawful manufacture, distribution, dispensing, possession, or use of a controlled substance is prohibited in the grantee's workplace and specifying the actions that will be taken against employees for violation of such prohibition;
- (b) Establishing an on-going drug-free awareness program to inform employees about-
- (1) The dangers of drug abuse in the workplace;
  - (2) The grantee's policy of maintaining a drug-free workplace;
  - (3) Any available drug counseling, rehabilitation, and employee assistance programs; and
  - (4) The penalties that may be imposed upon employees for drug abuse violations occurring in the workplace;
- (c) Making it a requirement that each employee to be engaged in the performance of the grant be given a copy of the statement required by paragraph (a);
- (d) Notifying the employee in the statement required by paragraph (a) that, as a condition of employment under the grant, the employee will-
- (1) Abide by the terms of the statement; and
  - (2) Notify the employer in writing of his or her conviction for a violation of a criminal drug statute occurring in the workplace no later than five calendar days after such conviction;
- (e) Notifying the agency, in writing, within 10 calendar days after receiving notice under subparagraph (d)(2) from an employee or otherwise receiving actual notice of such conviction. Employers of convicted employees must provide notice, including position title, to: Director, Grants and Contracts Service, U.S. Department of Education, 400 Maryland Avenue, S.W. (Room 3124, GSA Regional Office

Building No. 3), Washington, DC 20202-4571. Notice shall include the identification number(s) of each affected grant;

(f) Taking one of the following actions, within 30 calendar days of receiving notice under subparagraph (d)(2), with respect to any employee who is so convicted—

(1) Taking appropriate personnel action against such an employee, up to and including termination, consistent with the requirements of the Rehabilitation Act of 1973, as amended; or

(2) Requiring such employee to participate satisfactorily in a drug abuse assistance or rehabilitation program approved for such purposes by a Federal, State, or local health, law enforcement, or other appropriate agency;

(g) Making a good faith effort to continue to maintain a drug-free workplace through implementation of paragraphs (a), (b), (c), (d), (e), and (f).

B. The grantee may insert in the space provided below the site(s) for the performance of work done in connection with the specific grant:

Place of Performance (Street address, city, county, state, zip code)

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Check  if there are workplaces on file that are not identified here.

#### DRUG-FREE WORKPLACE (GRANTEES WHO ARE INDIVIDUALS)

As required by the Drug-Free Workplace Act of 1988, and implemented at 34 CFR Part 85, Subpart F, for grantees, as defined at 34 CFR Part 85, Sections 85.605 and 85.610—

A. As a condition of the grant, I certify that I will not engage in the unlawful manufacture, distribution, dispensing, possession, or use of a controlled substance in conducting any activity with the grant; and

B. If convicted of a criminal drug offense resulting from a violation occurring during the conduct of any grant activity, I will report the conviction, in writing, within 10 calendar days of the conviction, to: Director, Grants and Contracts Service, U.S. Department of Education, 400 Maryland Avenue, S.W. (Room 3124, GSA Regional Office Building No. 3), Washington, DC 20202-4571. Notice shall include the identification number(s) of each affected grant.

As the duly authorized representative of the applicant, I hereby certify that the applicant will comply with the above certifications.

NAME OF APPLICANT	PR/AWARD NUMBER AND/OR PROJECT NAME
PRINTED NAME AND TITLE OF AUTHORIZED REPRESENTATIVE	
SIGNATURE	DATE

## Certification Regarding Debarment, Suspension, Ineligibility and Voluntary Exclusion – Lower Tier Covered Transactions

This certification is required by the Department of Education regulations implementing Executive Order 12549, Debarment and Suspension, 34 CFR Part 85, for all lower tier transactions meeting the threshold and tier requirements stated at Section 85.110.

### Instructions for Certification

1. By signing and submitting this proposal, the prospective lower tier participant is providing the certification set out below.
2. The certification in this clause is a material representation of fact upon which reliance was placed when this transaction was entered into. If it is later determined that the prospective lower tier participant knowingly rendered an erroneous certification, in addition to other remedies available to the Federal Government, the department or agency with which this transaction originated may pursue available remedies, including suspension and/or debarment.
3. The prospective lower tier participant shall provide immediate written notice to the person to which this proposal is submitted if at any time the prospective lower tier participant learns that its certification was erroneous when submitted or has become erroneous by reason of changed circumstances.
4. The terms "covered transaction," "debarred," "suspended," "ineligible," "lower tier covered transaction," "participant," "person," "primary covered transaction," "principal," "proposal," and "voluntarily excluded," as used in this clause, have the meanings set out in the Definitions and Coverage sections of rules implementing Executive Order 12549. You may contact the person to which this proposal is submitted for assistance in obtaining a copy of those regulations.
5. The prospective lower tier participant agrees by submitting this proposal that, should the proposed covered transaction be entered into, it shall not knowingly enter into any lower tier covered transaction with a person who is debarred, suspended, declared ineligible, or voluntarily excluded from participation in this covered transaction, unless authorized by the department or agency with which this transaction originated.
6. The prospective lower tier participant further agrees by submitting this proposal that it will include the clause titled "Certification Regarding Debarment, Suspension, Ineligibility, and Voluntary Exclusion—Lower Tier Covered Transactions," without modification, in all lower tier covered transactions and in all solicitations for lower tier covered transactions.
7. A participant in a covered transaction may rely upon a certification of a prospective participant in a lower tier covered transaction that it is not debarred, suspended, ineligible, or voluntarily excluded from the covered transaction, unless it knows that the certification is erroneous. A participant may decide the method and frequency by which it determines the eligibility of its principals. Each participant may, but is not required to, check the Nonprocurement List.
8. Nothing contained in the foregoing shall be construed to require establishment of a system of records in order to render in good faith the certification required by this clause. The knowledge and information of a participant is not required to exceed that which is normally possessed by a prudent person in the ordinary course of business dealings.
9. Except for transactions authorized under paragraph 5 of these instructions, if a participant in a covered transaction knowingly enters into a lower tier covered transaction with a person who is suspended, debarred, ineligible, or voluntarily excluded from participation in this transaction, in addition to other remedies available to the Federal Government, the department or agency with which this transaction originated may pursue available remedies, including suspension and/or debarment.

### Certification

- (1) The prospective lower tier participant certifies, by submission of this proposal, that neither it nor its principals are presently debarred, suspended, proposed for debarment, declared ineligible, or voluntarily excluded from participation in this transaction by any Federal department or agency.
- (2) Where the prospective lower tier participant is unable to certify to any of the statements in this certification, such prospective participant shall attach an explanation to this proposal.

NAME OF APPLICANT	PR / AWARD NUMBER AND/OR PROJECT NAME
PRINTED NAME AND TITLE OF AUTHORIZED REPRESENTATIVE	
SIGNATURE	DATE



**DISCLOSURE OF LOBBYING ACTIVITIES  
CONTINUATION SHEET**

Approved by OMB  
0348-0046

Reporting Entity: \_\_\_\_\_

Page \_\_\_\_\_ of \_\_\_\_\_

**INSTRUCTIONS FOR COMPLETION OF SF-LLL, DISCLOSURE OF LOBBYING ACTIVITIES**

This disclosure form shall be completed by the reporting entity, whether subawardee or prime Federal recipient, at the initiation or receipt of a covered Federal action, or a material change to a previous filing, pursuant to title 31 U.S.C. section 1352. The filing of a form is required for each payment or agreement to make payment to any lobbying entity for influencing or attempting to influence an officer or employee of any agency, a Member of Congress, an officer or employee of Congress, or an employee of a Member of Congress in connection with a covered Federal action. Use the SF-LLL-A Continuation Sheet for additional information if the space on the form is inadequate. Complete all items that apply for both the initial filing and material change report. Refer to the implementing guidance published by the Office of Management and Budget for additional information.

1. Identify the type of covered Federal action for which lobbying activity is and/or has been secured to influence the outcome of a covered Federal action.
2. Identify the status of the covered Federal action.
3. Identify the appropriate classification of this report. If this is a followup report caused by a material change to the information previously reported, enter the year and quarter in which the change occurred. Enter the date of the last previously submitted report by this reporting entity for this covered Federal action.
4. Enter the full name, address, city, state and zip code of the reporting entity. Include Congressional District, if known. Check the appropriate classification of the reporting entity that designates if it is, or expects to be, a prime or subaward recipient. Identify the tier of the subawardee, e.g., the first subawardee of the prime is the 1st tier. Subawards include but are not limited to subcontracts, subgrants and contract awards under grants.
5. If the organization filing the report in item 4 checks "Subawardee", then enter the full name, address, city, state and zip code of the prime Federal recipient. Include Congressional District, if known.
6. Enter the name of the Federal agency making the award or loan commitment. Include at least one organizational level below agency name, if known. For example, Department of Transportation, United States Coast Guard.
7. Enter the Federal program name or description for the covered Federal action (item 1). If known, enter the full Catalog of Federal Domestic Assistance (CFDA) number for grants, cooperative agreements, loans, and loan commitments.
8. Enter the most appropriate Federal identifying number available for the Federal action identified in item 1 (e.g., Request for Proposal (RFP) number; Invitation for Bid (IFB) number; grant announcement number; the contract, grant, or loan award number; the application/proposal control number assigned by the Federal agency). Include prefixes, e.g., "RFP-DE-90-001."
9. For a covered Federal action where there has been an award or loan commitment by the Federal agency, enter the Federal amount of the award/loan commitment for the prime entity identified in item 4 or 5.
10. (a) Enter the full name, address, city, state and zip code of the lobbying entity engaged by the reporting entity identified in item 4 to influence the covered Federal action.  
(b) Enter the full names of the individual(s) performing services, and include full address if different from 10 (a). Enter Last Name, First Name, and Middle Initial (MI).
11. Enter the amount of compensation paid or reasonably expected to be paid by the reporting entity (item 4) to the lobbying entity (item 10). Indicate whether the payment has been made (actual) or will be made (planned). Check all boxes that apply. If this is a material change report, enter the cumulative amount of payment made or planned to be made.
12. Check the appropriate box(es). Check all boxes that apply. If payment is made through an in-kind contribution, specify the nature and value of the in-kind payment.
13. Check the appropriate box(es). Check all boxes that apply. If other, specify nature.
14. Provide a specific and detailed description of the services that the lobbyist has performed, or will be expected to perform, and the date(s) of any services rendered. Include all preparatory and related activity, not just time spent in actual contact with Federal officials. Identify the Federal official(s) or employee(s) contacted or the officer(s), employee(s), or Member(s) of Congress that were contacted.
15. Check whether or not a SF-LLL-A Continuation Sheet(s) is attached.
16. The certifying official shall sign and date the form, print his/her name, title, and telephone number.

Public reporting burden for this collection of information is estimated to average 30 minutes per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to the Office of Management and Budget, Paperwork Reduction Project (0348-0046), Washington, D.C. 20503.

## Appendix B

Potential applicants frequently direct questions to officials of the Department regarding application notices and programmatic and administrative regulations governing various direct grant programs. To assist potential applicants the Department has assembled the following most commonly asked questions.

Q. Can we get an extension of the deadline?

A. No. A closing date may be changed only under extraordinary circumstances. Any change must be announced in the *Federal Register* and apply to all applications. Waivers for individual applications cannot be granted regardless of the circumstances.

Q. How many copies of the application should I submit and must they be bound?

A. Our new policy calls for an original and six copies to be submitted. The binding of applications is optional.

Q. May we use this same application to compete for funds under a different grant program?

A. Yes, however, the likelihood of success is not good. A properly prepared application must meet the specifications of the grant program to which it is submitted.

Q. I'm not sure which grant program is most appropriate for my project. What should I do?

A. We are happy to provide general program information. Clearly, it would not be appropriate for staff to participate in the actual writing of an application, but we can respond to specific questions about application requirements, evaluation criteria, and the priorities. Applicants should understand that this previous contact is not required, nor will it in any way influence the success of an application.

Q. When will I find out if I'm going to be funded?

A. You can expect to receive notification within 3 to 4 months of the application closing date, depending on the number of applications received and the number of grant programs with closing dates at about the same time.

Q. Once my application has been reviewed by the review panel, can you tell me the outcome?

A. No. Every year we are called by a number of applicants who have legitimate reasons for needing to know the outcome of the review prior to official notification. Some applicants need to make job decisions, some need to notify a local school district, etc. Regardless of the reason, because final funding decisions have not been made at that point, we cannot share information about the review with anyone.

Q. Will my application be returned if I am not funded?

A. We no longer return unsuccessful applications. Thus applicants should retain at least one copy of the application.

Q. Can I obtain copies of reviewers' comments?

A. Upon written request, reviewers' comments will be mailed to unsuccessful applicants.

Q. Is travel allowed under these projects?

A. Travel associated with carrying out the project is allowed. Because we may request the project director of funded projects to attend an annual project directors meeting, you may also wish to include a trip or two to Washington, D.C. in the travel budget. Travel to conferences is sometimes allowed when it is for purposes of dissemination.

Q. If my application receives high scores from the reviewers, does that mean that I will receive funding?

A. Not necessarily. It is often the case that the number of applications scored highly by the reviewers exceeds the dollars available for funding projects under a particular competition. The order of selection, which is based on the scores of all the applications and other relevant factors, determines the applications that can be funded.

Q. What happens during negotiations?

A. During negotiations technical and budget issues may be raised. These are issues that have been identified during the panel and staff reviews that require clarification. Sometimes issues are stated as "conditions." These are issues that have been identified as so critical that the award cannot be made

unless those conditions are met. Questions may also be raised about the proposed budget. Generally, these issues are raised because there is inadequate justification or explanation of a particular budget item, or because the budget item seems unimportant to the successful completion of the project. If you are asked to make changes that you feel could seriously affect the project's success, you may provide reasons for not making the changes or provide alternative suggestions. Similarly, if proposed budget reductions will, in your opinion, seriously affect the project activities, you may explain why and provide additional justification for the proposed expenses. An award cannot be made until all negotiation issues have been resolved.

Q. How do I provide an assurance?

A. Except for SF-424B, "Assurances—Non-Construction Programs," which must be completed, simply state in writing that you are meeting a prescribed requirement.

Q. Where can copies of the *Federal Register*, a program's regulations, and Federal statutes be obtained?

Copies of these materials can usually be found at your local library. If not, most can be obtained from the Government Printing Office by writing to: Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402, Telephone: (202) 783-3238. When requesting copies of regulations or statutes, it is helpful to use the specific name, public law number, or part number. The material referenced in this notice would be referred to as follows:

(1) Carl D. Perkins Vocational and Applied Technology Education Act (Public Law 101-392) 104 Stat. 753 (1990).

(2) State Vocational and Applied Technology Education Programs and National Discretionary Programs of Vocational Education Final Regulations, 34 CFR parts 400 and 427.

(3) Education Department General Administrative Regulations, 34 CFR parts 74, 75, 77, 79, 80, 81, 82, 85 and 86.

[FR Doc. 94-26661 Filed 10-26-94; 8:45 am]  
BILLING CODE 4000-01-P

Department of  
Education

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Thursday  
October 27, 1994

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Part VI

**Department of  
Education**

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Bilingual Vocational Instructor Training  
Program; Inviting Applications for New  
Grant Awards for Fiscal Year 1995;  
Notice

## DEPARTMENT OF EDUCATION

[CFDA No.: 84.099]

**Bilingual Vocational Instructor Training Program; Notice Inviting Applications for New Grant Awards for Fiscal Year (FY) 1995**

*Note to Applicants:* This notice is a complete application package. Together with the statute authorizing the program and applicable regulations governing the program, including the Education Department General Administrative Regulations (EDGAR), this notice contains all of the information, application forms, and instructions needed to apply for a grant under this competition.

*Purpose of Program:* The Bilingual Vocational Instructor Training Program provides financial assistance for preservice and inservice training for personnel participating in or preparing to participate in bilingual vocational education and training programs for limited English proficient individuals.

The Bilingual Vocational Instructor Training Program supports the National Education Goal that, by the year 2000, every adult American will be literate and will possess the knowledge and skills necessary to compete in a global economy and exercise the rights and responsibilities of citizenship. The program helps further this goal by helping to improve vocational education and training for limited English proficient adults.

*Eligible Applicants:* State agencies or public and private non-profit educational institutions.

*Deadline for Transmittal of Applications:* December 12, 1994.

*Deadline for Intergovernmental Review:* February 2, 1995.

*Available Funds:* \$441,900.

*Estimated Range of Awards:* \$150,000-\$250,000.

*Estimated Average Size of Awards:* \$221,000.

*Estimated Number of Awards:* 2.

*Note:* The Department is not bound by any estimates in this notice.

*Project Period:* Up to 18 months.

*Applicable Regulations:* (a) The Education Department General Administrative Regulations (EDGAR) as follows:

(1) 34 CFR part 74 (Administration of Grants to Institutions of Higher Education, Hospitals and Nonprofit Organizations).

(2) 34 CFR part 75 (Direct Grant Programs).

(3) 34 CFR part 77 (Definitions that Apply to Department Regulations).

(4) 34 CFR part 79 (Intergovernmental Review of Department of Education Programs and Activities).

(5) 34 CFR part 80 (Uniform Administrative Requirements for Grants and Cooperative Agreements to State and Local Governments).

(6) 34 CFR part 81 (General Education Provisions Act—Enforcement).

(7) 34 CFR part 82 (New Restrictions on Lobbying).

(8) 34 CFR part 85 (Governmentwide Debarment and Suspension (Nonprocurement) and Governmentwide Requirements for Drug-Free Workplace (Grants)).

(9) 34 CFR part 86 (Drug-Free Schools and Campuses).

(b) The regulations for this program in 34 CFR parts 400 and 428.

**Content of the Application**

An application must—(a) Provide an assurance that the activities and services for which assistance is sought will be administered by or under the supervision of the applicant;

(b) Propose a project of a size, scope and design that will make a substantial contribution toward carrying out the purpose of the Bilingual Vocational Instructor Training Program;

(c) Describe the capabilities of the applicant, including vocational training or education courses offered by the applicant, accreditation, and any certification of courses by appropriate State agencies;

(d) Describe the qualifications of principal staff to be used in the bilingual vocational instructor training project;

(e) Describe the number of participants to be served, the minimum qualifications for project participants, and the selection process for project participants;

(f) Include the projected amount of the fellowships or traineeships, if any;

(g) Contain sufficient information for the Secretary to determine that the applicant has an ongoing vocational education program in the field in which participants will be trained, and can provide instructors with adequate language capabilities in the language other than English to be used in the bilingual vocational training project; and

(h) Provide an assurance that preservice training will be provided to individuals who have indicated their intent to engage as personnel in a vocational education program that serves limited English proficient individuals.

**Invitational Priority**

Under 34 CFR 75.105(c)(1) the Secretary is particularly interested in

applications that meet the following invitational priority. However, an application that meets this invitational priority does not receive competitive or absolute preference over other applications:

Applications that include strategies to developing the applicant's capacity to continue, expand, or build upon its bilingual vocational preservice and inservice training when Federal funding under this competition ends, as evidenced by such actions as—

(a) Extending training to additional sites that are not funded under this program;

(b) Integrating the project into the long-term planning of the applicant;

(c) Committing funding and staffing for continued implementation of the project;

(d) Incorporating the project into the applicant's organizational and program structure; or

(e) Establishing and strengthening relationships within the community, region, or State that will support continuation of the project.

**Selection Criteria**

The Secretary uses the following selection criteria to evaluate applications for new grants under this competition. The maximum score for all of these criteria is 100 points. The maximum score for each criterion is indicated in parentheses.

For this competition, the Secretary assigns the 15 points, reserved in 34 CFR 428.20(b), as follows:

*Program design* (34 CFR 428.21(b)). Five points are added to this criterion for a possible total of 25 points.

*Dissemination plan* (34 CFR 428.21(g)). Ten points are added to this criterion for a possible total of 20 points.

(a) *Need.* (15 points)

(1) The Secretary reviews each application to determine the need for the proposed bilingual vocational instructor training project, including—

(i) The need for the project in the specific geographic area or areas to be served by the proposed project;

(ii) The training needs of program participants to be served by the proposed project;

(iii) How these needs will be met through the proposed project; and

(iv) The relationship of the proposed project to other ongoing personnel development programs in the geographic area or areas to be served by the proposed project.

(2) The Secretary reviews each application to determine the extent to which, upon completion of their training, program participants will work with programs that provide vocational

education to limited English proficient individuals.

(b) *Program design.* (25 points) The Secretary reviews each application to determine the quality of the program design and the potential of the project to have a lasting impact on the geographic area or areas to be served by the proposed project, including—

(1) Potential to increase the skill level of program participants, with particular regard to the following areas:

(i) Knowledge of the needs of limited English proficient individuals enrolled in vocational education programs, and how those needs should influence teaching strategies and program design.

(ii) Understanding of bilingual vocational training methodologies.

(iii) Techniques for preparing limited English proficient individuals for employment; and

(2) Potential to increase access to vocational education for limited English proficient individuals.

(c) *Plan of operation.* (15 points) The Secretary reviews each application for an effective plan of management that ensures proper and efficient administration of the project, including—

(1) Clearly defined project objectives that relate to the purpose of the Bilingual Vocational Instructor Training Program;

(2) For each objective, the specific tasks to be performed in order to achieve the specified project objective; and

(3) How the applicant plans to use its resources and personnel to achieve each objective.

(d) *Key personnel.* (10 points)

(1) The Secretary reviews each application to determine the quality of key personnel the applicant plans to use on the project, including—

(i) The qualifications of the director and other key personnel to be used in the project;

(ii) The appropriateness of the time that each person referred to in paragraph (d)(1)(i) of this section will commit to the project; and

(iii) How the applicant, as part of its nondiscriminatory employment practices, will ensure that personnel will be selected without regard to race, color, national origin, gender, age, or disability.

(2) To determine personnel qualifications under paragraph (d)(1)(i) of this section, the Secretary considers—

(i) Experience and training in fields related to the objectives of the project;

(ii) Experience and training in project management; and

(iii) Any other qualifications that pertain to the quality of the project.

(e) *Budget and cost effectiveness.* (5 points) The Secretary reviews each application to determine the extent to which—

(1) The budget is sufficient to support the proposed project, and that it represents a cost effective use of Bilingual Vocational Instructor Training Program funds;

(2) Costs are necessary and reasonable in relation to the objectives of the proposed project; and

(3) The facilities that the applicant plans to use are adequate for the proposed project.

(f) *Evaluation plan.* (10 points) The Secretary reviews each application to determine the quality of the project's evaluation plan, including the extent to which the plan—

(1) Is clearly explained and appropriate for the bilingual vocational instructor training project;

(2) To the extent possible, is objective and will produce data that are quantifiable;

(3) Identifies outcomes of the project in terms of enrollment, completion and after-training work commitments of participants by sex, racial or ethnic group, and by level and kinds of language proficiency;

(4) Identifies expected learning and skills outcomes for participants and how those outcomes will be measured; and

(5) Includes activities during the formative stages of the project to help guide and improve the project, as well as a summative evaluation that includes recommendations for replicating project activities and results.

(g) *Dissemination plan.* (20 points) The Secretary reviews each application to determine the effectiveness and efficiency of the plan to disseminate information about the project and demonstrate project activities and results, including—

(1) High quality in its design and procedures for evaluating the effectiveness of the dissemination plan; and

(2) A description of the types of materials the applicant plans to develop and make available to help others replicate project activities, and the methods to be used to make the materials available.

#### Additional Factors

(a) After evaluating the applications according to the selection criteria and consulting with the appropriate State board established under section 111 of the Carl D. Perkins Vocational and Applied Technology Education Act, the Secretary determines whether the most highly rated applications are equitably

distributed among populations of individuals with limited English proficiency within the affected State.

(b) The Secretary may select other applications for funding if doing so would improve the—

(1) Equitable distribution of assistance among populations of individuals with limited English proficiency within the affected State; or

(2) Geographical distribution of projects funded under this program.

#### Intergovernmental Review of Federal Programs

This program is subject to the requirements of Executive Order 12372 (Intergovernmental Review of Federal Programs) and the regulations in 34 CFR part 79.

The objective of the Executive order is to foster an intergovernmental partnership and to strengthen federalism by relying on State and local processes for State and local government coordination and review of proposed Federal financial assistance.

Applicants must contact the appropriate State Single Point of Contact to find out about, and to comply with, the State's process under Executive order 12372. Applicants proposing to perform activities in more than one State should immediately contact the Single Point of Contact for each of those States and follow the procedure established in each State under the Executive order. If you want to know the name and address of any State Single Point of Contact, see the list published in the *Federal Register* on June 10, 1994 (59 FR 30214-30215).

In States that have not established a process or chosen a program for review, State, areawide, regional, and local entities may submit comments directly to the Department.

Any State Process Recommendation and other comments submitted by a State Single Point of Contact and any comments from State, areawide, regional, and local entities must be mailed or hand-delivered by the date indicated in this notice to the following address: The Secretary, E.O. 12372—CFDA# 84.099, U.S. Department of Education, Room 6213, 600 Independence Avenue, S.W., Washington, D.C. 20202-0125.

Proof of mailing will be determined on the same basis as applications (see 34 CFR 75.102). Recommendations or comments may be hand-delivered until 4:30 p.m. (Washington, D.C. time) on the date indicated in this notice.

Please note that the above address is not the same address as the one to which the applicant submits its

completed application. *Do not send applications to the above address.*

#### Instructions for Transmittal of Applications

(a) If an applicant wants to apply for a grant, the applicant shall—

(1) Mail the original and six copies of the application on or before the deadline date to: U.S. Department of Education, Application Control Center, Attention: (CFDA# 84.099), Washington, D.C. 20202-4725; or

(2) Hand deliver the original and six copies of the application by 4:30 p.m. (Washington, D.C. time) on or before the deadline date to: U.S. Department of Education, Application Control Center, Attention: (CFDA# 84.099), Room #3633, Regional Office Building #3, 7th and D Streets, S.W., Washington, D.C. 20202-4725.

(b) An applicant must show one of the following as proof of mailing:

(1) A legibly dated U.S. Postal Service postmark.

(2) A legible mail receipt with the date of mailing stamped by the U.S. Postal Service.

(3) A dated shipping label, invoice, or receipt from a commercial carrier.

(4) Any other proof of mailing acceptable to the Secretary.

(c) If an application is mailed through the U.S. Postal Service, the Secretary does not accept either of the following as proof of mailing:

(1) A private metered postmark.  
(2) A mail receipt that is not dated by the U.S. Postal Service.

**Notes:** (1) The U.S. Postal Service does not uniformly provide a dated postmark. Before relying on this method, an applicant should check with its local post office.

(2) The Application Control Center will mail a Grant Application Receipt Acknowledgement to each applicant. If an

applicant fails to receive the notification of application receipt within 15 days from the date of mailing the application, the applicant should call the U.S. Department of Education Application Control Center at (202) 708-8493.

(3) The applicant must indicate on the envelope and—if not provided by the Department—in Item 10 of the Application for Federal Assistance (Standard Form 424) the CFDA number of the competition under which the application is being submitted.

#### Application Instructions and Forms

The appendix to this application is divided into six parts, plus a statement regarding estimated public reporting burden and various assurances and certifications. These parts and additional materials are organized in the same manner that the submitted application should be organized. The parts and additional materials are as follows:

Part I: Application for Federal Assistance (Standard Form 424 (Rev. 4-88)) and instructions.

Part II: Instructions for ED Form No. 524.

Part III: Budget Information Non-construction Programs (ED Form No. 524).

Part IV: Budget Narrative.

Part V: Program Narrative.

Part VI: Additional Assurances and Certifications:

a. Assurances—Non-Construction Programs (Standard Form 424B).

b. Certifications Regarding Lobbying; Debarment, Suspension, and Other Responsibility Matters; and Drug-Free Workplace Requirements (ED 80-0013) and Instructions.

c. Certification Regarding Debarment, Suspension, Ineligibility and Voluntary Exclusion: Lower Tier Covered Transactions (ED 80-0014, 9/90) and Instructions. (NOTE: The grantee should

keep this form on file. It should not be transmitted to the Department.)

d. Disclosure of Lobbying Activities (Standard Form LLL) (if applicable) and Instructions; and Disclosure of Lobbying Activities Continuation Sheet (Standard Form LLL-A.)

All forms and instructions are included as Appendix A of this notice. Questions and answers pertaining to this program are included, as Appendix B, to assist potential applicants.

All applicants must submit ONE original signed application, including ink signatures on all forms and assurances and SIX copies of the application. Please mark each application as original or copy. Local or State agencies may choose to submit two copies with the original. No grant may be awarded unless a complete application form has been received.

**FOR FURTHER INFORMATION CONTACT:** Cindy Towsner, Special Programs Branch, Division of National Programs, Office of Vocational and Adult Education, U.S. Department of Education, 600 Independence Avenue, S.W. (Room 4512, Mary E. Switzer Building), Washington, D.C. 20202-7242. Telephone (202) 205-5864. Individuals who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1-800-877-8339 between 8 a.m. and 8 p.m., Eastern time, Monday through Friday.

Program Authority: 20 U.S.C. 2441(b).

Dated: October 21, 1994.

Augusta Souza Kappner,  
Assistant Secretary, Office of Vocational and Adult Education.

BILLING CODE 4000-01-P

Appendix A

OMB Approval No. 0348-0043

APPLICATION FOR FEDERAL ASSISTANCE		2. DATE SUBMITTED	Applicant Identifier																								
1. TYPE OF SUBMISSION: <table border="0"> <tr> <td>Application</td> <td>Preapplication</td> </tr> <tr> <td><input type="checkbox"/> Construction</td> <td><input type="checkbox"/> Construction</td> </tr> <tr> <td><input checked="" type="checkbox"/> Non-Construction</td> <td><input type="checkbox"/> Non-Construction</td> </tr> </table>		Application	Preapplication	<input type="checkbox"/> Construction	<input type="checkbox"/> Construction	<input checked="" type="checkbox"/> Non-Construction	<input type="checkbox"/> Non-Construction	3. DATE RECEIVED BY STATE	State Application Identifier																		
Application	Preapplication																										
<input type="checkbox"/> Construction	<input type="checkbox"/> Construction																										
<input checked="" type="checkbox"/> Non-Construction	<input type="checkbox"/> Non-Construction																										
		4. DATE RECEIVED BY FEDERAL AGENCY	Federal Identifier																								
5. APPLICANT INFORMATION																											
Legal Name:		Organizational Unit:																									
Address (give city, county, state, and zip code):		Name and telephone number of the person to be contacted on matters involving this application (give area code)																									
6. EMPLOYER IDENTIFICATION NUMBER (EIN):		7. TYPE OF APPLICANT: (enter appropriate letter in box) <input type="checkbox"/>																									
<table border="0"> <tr> <td><input type="checkbox"/></td><td><input type="checkbox"/></td><td><input type="checkbox"/></td><td><input type="checkbox"/></td><td><input type="checkbox"/></td><td><input type="checkbox"/></td><td><input type="checkbox"/></td><td><input type="checkbox"/></td><td><input type="checkbox"/></td><td><input type="checkbox"/></td> </tr> </table>		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<table border="0"> <tr> <td>A. State</td> <td>H. Independent School Dist.</td> </tr> <tr> <td>B. County</td> <td>I. State Controlled Institution of Higher Learning</td> </tr> <tr> <td>C. Municipal</td> <td>J. Private University</td> </tr> <tr> <td>D. Township</td> <td>K. Indian Tribe</td> </tr> <tr> <td>E. Interstate</td> <td>L. Individual</td> </tr> <tr> <td>F. Intermunicipal</td> <td>M. Profit Organization</td> </tr> <tr> <td>G. Special District</td> <td>N. Other (Specify): _____</td> </tr> </table>		A. State	H. Independent School Dist.	B. County	I. State Controlled Institution of Higher Learning	C. Municipal	J. Private University	D. Township	K. Indian Tribe	E. Interstate	L. Individual	F. Intermunicipal	M. Profit Organization	G. Special District	N. Other (Specify): _____
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>																		
A. State	H. Independent School Dist.																										
B. County	I. State Controlled Institution of Higher Learning																										
C. Municipal	J. Private University																										
D. Township	K. Indian Tribe																										
E. Interstate	L. Individual																										
F. Intermunicipal	M. Profit Organization																										
G. Special District	N. Other (Specify): _____																										
8. TYPE OF APPLICATION:		9. NAME OF FEDERAL AGENCY:																									
<input checked="" type="checkbox"/> New <input type="checkbox"/> Continuation <input type="checkbox"/> Revision If Revision, enter appropriate letter(s) in box(es): <input type="checkbox"/> <input type="checkbox"/> A. Increase Award    B. Decrease Award    C. Increase Duration D. Decrease Duration    Other (specify): _____																											
10. CATALOG OF FEDERAL DOMESTIC ASSISTANCE NUMBER:		11. DESCRIPTIVE TITLE OF APPLICANT'S PROJECT:																									
<table border="0"> <tr> <td>8</td><td>4</td><td>0</td><td>9</td><td>9</td> </tr> </table> TITLE: Bilingual Vocational Instructor Training Program		8	4	0	9	9																					
8	4	0	9	9																							
12. AREAS AFFECTED BY PROJECT (cities, counties, states, etc.):																											
13. PROPOSED PROJECT:																											
Start Date	Ending Date	14. CONGRESSIONAL DISTRICTS OF:																									
		a. Applicant																									
		b. Project																									
15. ESTIMATED FUNDING:		16. IS APPLICATION SUBJECT TO REVIEW BY STATE EXECUTIVE ORDER 12372 PROCESS?																									
a. Federal	\$ .00	a. YES THIS PREAPPLICATION/APPLICATION WAS MADE AVAILABLE TO THE STATE EXECUTIVE ORDER 12372 PROCESS FOR REVIEW ON DATE _____																									
b. Applicant	\$ .00	b. NO. <input type="checkbox"/> PROGRAM IS NOT COVERED BY E.O. 12372																									
c. State	\$ .00	<input type="checkbox"/> OR PROGRAM HAS NOT BEEN SELECTED BY STATE FOR REVIEW																									
d. Local	\$ .00																										
e. Other	\$ .00																										
f. Program Income	\$ .00	17. IS THE APPLICANT DELINQUENT ON ANY FEDERAL DEBT?																									
g. TOTAL	\$ .00	<input type="checkbox"/> Yes If "Yes," attach an explanation. <input type="checkbox"/> No																									
18. TO THE BEST OF MY KNOWLEDGE AND BELIEF, ALL DATA IN THIS APPLICATION/PREAPPLICATION ARE TRUE AND CORRECT, THE DOCUMENT HAS BEEN DULY AUTHORIZED BY THE GOVERNING BODY OF THE APPLICANT AND THE APPLICANT WILL COMPLY WITH THE ATTACHED ASSURANCES IF THE ASSISTANCE IS AWARDED																											
a. Typed Name of Authorized Representative		b. Title	c. Telephone number																								
d. Signature of Authorized Representative		e. Date Signed																									

Previous Editions Not Usable

Standard Form 424 (REV 4-88)  
Prescribed by OMB Circular A-102

Authorized for Local Reproduction

## INSTRUCTIONS FOR THE SF 424

This is a standard form used by applicants as a required facesheet for preapplications and applications submitted for Federal assistance. It will be used by Federal agencies to obtain applicant certification that States which have established a review and comment procedure in response to Executive Order 12372 and have selected the program to be included in their process, have been given an opportunity to review the applicant's submission.

- | Item: | Entry:   | Item: | Entry:   |
|-------|--|-------|--|
| 1.    | Self-explanatory.  | 12.   | List only the largest political entities affected (e.g., State, counties, cities).   |
| 2.    | Date application submitted to Federal agency (or State if applicable) & applicant's control number (if applicable).  | 13.   | Self-explanatory.  |
| 3.    | State use only (if applicable).  | 14.   | List the applicant's Congressional District and any District(s) affected by the program or project.  |
| 4.    | If this application is to continue or revise an existing award, enter present Federal identifier number. If for a new project, leave blank.  | 15.   | Amount requested or to be contributed during the first funding/budget period by each contributor. Value of in-kind contributions should be included on appropriate lines as applicable. If the action will result in a dollar change to an existing award, indicate <u>only</u> the amount of the change. For decreases, enclose the amounts in parentheses. If both basic and supplemental amounts are included, show breakdown on an attached sheet. For multiple program funding, use totals and show breakdown using same categories as item 15. |
| 5.    | Legal name of applicant, name of primary organizational unit which will undertake the assistance activity, complete address of the applicant, and name and telephone number of the person to contact on matters related to this application.   | 16.   | Applicants should contact the State Single Point of Contact (SPOC) for Federal Executive Order 12372 to determine whether the application is subject to the State intergovernmental review process.  |
| 6.    | Enter Employer Identification Number (EIN) as assigned by the Internal Revenue Service.  | 17.   | This question applies to the applicant organization, not the person who signs as the authorized representative. Categories of debt include delinquent audit disallowances, loans and taxes.  |
| 7.    | Enter the appropriate letter in the space provided.  | 18.   | To be signed by the authorized representative of the applicant. A copy of the governing body's authorization for you to sign this application as official representative must be on file in the applicant's office. (Certain Federal agencies may require that this authorization be submitted as part of the application.)  |
| 8.    | Check appropriate box and enter appropriate letter(s) in the space(s) provided:<br>— "New" means a new assistance award.<br>— "Continuation" means an extension for an additional funding/budget period for a project with a projected completion date.<br>— "Revision" means any change in the Federal Government's financial obligation or contingent liability from an existing obligation. |       |  |
| 9.    | Name of Federal agency from which assistance is being requested with this application.   |       |  |
| 10.   | Use the Catalog of Federal Domestic Assistance number and title of the program under which assistance is requested.  |       |  |
| 11.   | Enter a brief descriptive title of the project. If more than one program is involved, you should append an explanation on a separate sheet. If appropriate (e.g., construction or real property projects), attach a map showing project location. For preapplications, use a separate sheet to provide a summary description of this project.  |       |  |

Public reporting burden for this collection of information is estimated to vary from 13 to 22 hours per response, with an average of 17.5 hours, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to the U.S. Department of Education, Information Management and Compliance Division, Washington, D.C. 20202-4651; and the Office of Management and Budget, Paperwork Reduction Project 1875-0102, Washington, D.C. 20503.

#### Instructions for ED Form No. 524

##### General Instructions

This form is used to apply to individual U.S. Department of Education discretionary grant programs. Unless directed otherwise, provide the same budget information for each year of the multi-year funding request. Pay attention to applicable program specific instructions, if attached.

##### Section A—Budget Summary, U.S. Department of Education Funds

All applicants must complete Section A and provide a breakdown by the applicable budget categories shown in lines 1-11.

##### Lines 1-11, columns (a)-(e):

For each project year for which funding is requested, show the total amount requested for each applicable budget category.

##### Lines 1-11, column (f):

Show the multi-year total for each budget category. If funding is requested for only one project year, leave this column blank.

##### Line 12, columns (a)-(e):

Show the total budget request for each project year for which funding is requested.

##### Line 12, column (f):

Show the total amount requested for all project years. If funding is requested for only one year, leave this space blank.

##### Section B—Budget Summary, Non-Federal Funds

If you are required to provide or volunteer to provide matching funds or other non-Federal resources to the project, these should be shown for each applicable budget category on lines 1-11 of Section B.

##### Lines 1-11, columns (a)-(e):

For each project year for which matching funds or other contributions are provided, show the total contribution for each applicable budget category.

##### Lines 1-11, column (f):

Show the multi-year total for each budget category. If non-Federal contributions are provided for only one year, leave this column blank.

##### Line 12, columns (a)-(e):

Show the total matching or other contribution for each project year.

##### Line 12, column (f):

Show the total amount to be contributed for all years of the multi-year project. If non-Federal contributions are provided for only one year, leave this space blank.

##### Section C—Other Budget Information, Pay attention to Applicable Program Specific Instructions, If Attached

1. Provide an itemized budget breakdown, by project year, for each budget category listed in Sections A and B.
2. If applicable to this program, enter the type of indirect rate (provisional, predetermined, final or fixed) that will be in effect during the funding period. In addition, enter the estimated amount of the base to which the rate is applied, and the total indirect expense.
3. If applicable to this program, provide the rate and base on which fringe benefits are calculated.
4. Provide other explanations or comments you deem necessary.

BILLING CODE 4000-01-P

**U.S. DEPARTMENT OF EDUCATION  
BUDGET INFORMATION  
NON-CONSTRUCTION PROGRAMS**

OMB Control No. 1875-0102

Expiration Date: 9/30/95

Name of Institution/Organization

Applicants requesting funding for only one year should complete the column under "Project Year 1." Applicants requesting funding for multi-year grants should complete all applicable columns. Please read all instructions before completing form.

**SECTION A - BUDGET SUMMARY  
U.S. DEPARTMENT OF EDUCATION FUNDS**

Budget Categories	Project Year 1 (a)	Project Year 2 (b)	Project Year 3 (c)	Project Year 4 (d)	Project Year 5 (e)	Total (f)
1. Personnel						
2. Fringe Benefits						
3. Travel						
4. Equipment						
5. Supplies						
6. Contractual						
7. Construction						
8. Other						
9. Total Direct Costs (lines 1-8)						
10. Indirect Costs						
11. Training Stipends						
12. Total Costs (lines 9-11)						

ED FORM NO. 524

Name of Institution/Organization

Applicants requesting funding for only one year should complete the column under "Project Year 1." Applicants requesting funding for multi-year grants should complete all applicable columns. Please read all instructions before completing form.

**SECTION B - BUDGET SUMMARY  
NON-FEDERAL FUNDS**

Budget Categories	Project Year 1 (a)	Project Year 2 (b)	Project Year 3 (c)	Project Year 4 (d)	Project Year 5 (e)	Total (f)
1. Personnel						
2. Fringe Benefits						
3. Travel						
4. Equipment						
5. Supplies						
6. Contractual						
7. Construction						
8. Other						
9. Total Direct Costs (lines 1-8)						
10. Indirect Costs						
11. Training Stipends						
12. Total Costs (lines 9-11)						

**SECTION C - OTHER BUDGET INFORMATION (see instructions)**

ED FORM NO. 524

**Instructions for Part IV—Budget Narrative**

The budget narrative should explain, justify, and, if needed, clarify your budget summary. For each line item (personnel, fringe benefits, travel, etc.) in your budget, explain why it is there and how you computed the costs.

Please limit this section to no more than five pages. Be sure that each page of your application is numbered consecutively.

**Explanation of Budget Categories**

1. **Personnel:** Show salaries to be paid to project personnel.
2. **Fringe Benefits:** Indicate the rate and amount of fringe benefits.
3. **Travel:** Indicate the amount requested for both inter- and intra-State travel of project staff. Include funds for at least one trip for two people to attend a project director's meeting in Washington, D.C.
4. **Equipment:** Indicate the cost of non-expendable personal property that has a useful life of more than one year and a cost of \$300 or more per unit (\$5,000 or more if State, Local or Tribal Government).
5. **Supplies:** Include the cost of consumable supplies and materials to be used during the project.
6. **Contractual:** Show the amount to be used for (1) Procurement contracts (except those which belong on other lines such as supplies and equipment; and (2) sub-contracts.
7. **Construction:** NOT ALLOWABLE.
8. **Other:** Indicate all direct costs not clearly covered by lines 1 through 7 above, including consultants.
9. **Total, Direct Cost:** Show the total for lines 1 through 8.
10. **Indirect Costs:** Indicate the rate and amount of indirect costs. NOTE: For training grants, the indirect cost rate cannot exceed 8%.
11. **Training/Stipend Cost:** (if allowable)

12. **TOTAL, Federal Funds Requested:** Show total for lines 9 through 11.

**Cost Sharing**

Indicate the actual rate and amount of cost sharing when there is a cost sharing requirement. If cost sharing is required by program regulations, the local share required refers to a percentage of *Total Project Cost*, not of Federal funds.

**Instructions for Part V—Program Narrative**

The program narrative will comprise the largest portion of your application. This part is where you spell out the who, what, when, where, why, and how of your proposed project.

Although you will not have a form to fill out for your narrative, there is a format. This format is the selection criteria. Because your application will be reviewed and rated by a review panel on the basis of the selection criteria, your narrative should follow the order and format of the criteria.

Before preparing your application, you should carefully read the legislation and regulations of the program, eligibility requirements, information on any priority set by the Secretary, and the selection criteria for this competition.

Your program narrative should be clear, concise, and to the point. Begin the narrative with a one page abstract or summary of your proposed project. Then describe the project in detail, addressing each selection criterion in order.

The Secretary strongly suggests that the applicant limit the program narrative to no more than 40 double-spaced, typed pages (on one side only), although the Secretary will consider applications of greater length. Be sure to number consecutively ALL pages in your application.

You may include supporting documentation as appendices. Be sure that this material is concise and pertinent to this

program competition and is numbered consecutively.

Applicants are advised that: (a) The Department considers only information contained in the application in ranking applications for funding consideration. Letters of support sent separately from the formal application package are not considered in the review by the technical review panels. (34 CFR 75.217)

(b) The technical review panel evaluates each application solely on the basis of the established technical review criteria. Letters of support contained in the application will strengthen the application only insofar as they contain commitments that pertain to the established technical review criteria, such as commitment and resources.

**Additional Materials****Instructions for Estimated Public Reporting Burden**

Under terms of the Paperwork Reduction Act of 1980, as amended, and the regulations implementing that Act, the Department of Education invites comment on the public reporting burden in this collection of information. Public reporting burden for this collection of information is estimated to average 90 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. You may send comments regarding this burden to the U.S. Department of Education, Information Management and Compliance Division, Washington, DC 20202-4651; and to the Office of Management and Budget, Paperwork Reduction Project, OMB 1830-0013, Washington, DC 20503. (Information collection approved under OMB control number 1830-0013. Expiration date: 2/28/95.)

BILLING CODE 4000-01-P

**ASSURANCES — NON-CONSTRUCTION PROGRAMS**

**Note:** Certain of these assurances may not be applicable to your project or program. If you have questions, please contact the awarding agency. Further, certain Federal awarding agencies may require applicants to certify to additional assurances. If such is the case, you will be notified.

As the duly authorized representative of the applicant I certify that the applicant:

1. Has the legal authority to apply for Federal assistance, and the institutional, managerial and financial capability (including funds sufficient to pay the non-Federal share of project costs) to ensure proper planning, management and completion of the project described in this application.
2. Will give the awarding agency, the Comptroller General of the United States, and if appropriate, the State, through any authorized representative, access to and the right to examine all records, books, papers, or documents related to the award; and will establish a proper accounting system in accordance with generally accepted accounting standards or agency directives.
3. Will establish safeguards to prohibit employees from using their positions for a purpose that constitutes or presents the appearance of personal or organizational conflict of interest, or personal gain.
4. Will initiate and complete the work within the applicable time frame after receipt of approval of the awarding agency.
5. Will comply with the Intergovernmental Personnel Act of 1970 (42 U.S.C. §§ 4728-4763) relating to prescribed standards for merit systems for programs funded under one of the nineteen statutes or regulations specified in Appendix A of OPM's Standards for a Merit System of Personnel Administration (5 C.F.R. 900, Subpart F).
6. Will comply with all Federal statutes relating to nondiscrimination. These include but are not limited to: (a) Title VI of the Civil Rights Act of 1964 (P.L. 88-352) which prohibits discrimination on the basis of race, color or national origin; (b) Title IX of the Education Amendments of 1972, as amended (20 U.S.C. §§ 1681-1683, and 1685-1686), which prohibits discrimination on the basis of sex; (c) Section 504 of the Rehabilitation Act of 1973, as amended (29 U.S.C. § 794), which prohibits discrimination on the basis of handicaps; (d) the Age Discrimination Act of 1975, as amended (42 U.S.C. §§ 6101-6107), which prohibits discrimination on the basis of age; (e) the Drug Abuse Office and Treatment Act of 1972 (P.L. 92-255), as amended, relating to nondiscrimination on the basis of drug abuse; (f) the Comprehensive Alcohol Abuse and Alcoholism Prevention, Treatment and Rehabilitation Act of 1970 (P.L. 91-616), as amended, relating to nondiscrimination on the basis of alcohol abuse or alcoholism; (g) §§ 523 and 527 of the Public Health Service Act of 1912 (42 U.S.C. 290 dd-3 and 290 ee-3), as amended, relating to confidentiality of alcohol and drug abuse patient records; (h) Title VIII of the Civil Rights Act of 1968 (42 U.S.C. § 3601 et seq.), as amended, relating to nondiscrimination in the sale, rental or financing of housing; (i) any other nondiscrimination provisions in the specific statute(s) under which application for Federal assistance is being made; and (j) the requirements of any other nondiscrimination statute(s) which may apply to the application.
7. Will comply, or has already complied, with the requirements of Titles II and III of the Uniform Relocation Assistance and Real Property Acquisition Policies Act of 1970 (P.L. 91-646) which provide for fair and equitable treatment of persons displaced or whose property is acquired as a result of Federal or federally assisted programs. These requirements apply to all interests in real property acquired for project purposes regardless of Federal participation in purchases.
8. Will comply with the provisions of the Hatch Act (5 U.S.C. §§ 1501-1508 and 7324-7328) which limit the political activities of employees whose principal employment activities are funded in whole or in part with Federal funds.
9. Will comply, as applicable, with the provisions of the Davis-Bacon Act (40 U.S.C. §§ 276a to 276a-7), the Copeland Act (40 U.S.C. § 276c and 18 U.S.C. §§ 874), and the Contract Work Hours and Safety Standards Act (40 U.S.C. §§ 327-333), regarding labor standards for federally assisted construction subagreements.

10. Will comply, if applicable, with flood insurance purchase requirements of Section 102(a) of the Flood Disaster Protection Act of 1973 (P.L. 93-234) which requires recipients in a special flood hazard area to participate in the program and to purchase flood insurance if the total cost of insurable construction and acquisition is \$10,000 or more.
11. Will comply with environmental standards which may be prescribed pursuant to the following: (a) institution of environmental quality control measures under the National Environmental Policy Act of 1969 (P.L. 91-190) and Executive Order (EO) 11514; (b) notification of violating facilities pursuant to EO 11738; (c) protection of wetlands pursuant to EO 11990; (d) evaluation of flood hazards in floodplains in accordance with EO 11988; (e) assurance of project consistency with the approved State management program developed under the Coastal Zone Management Act of 1972 (16 U.S.C. §§ 1451 et seq.); (f) conformity of Federal actions to State (Clear Air) Implementation Plans under Section 176(c) of the Clear Air Act of 1955, as amended (42 U.S.C. § 7401 et seq.); (g) protection of underground sources of drinking water under the Safe Drinking Water Act of 1974, as amended, (P.L. 93-523); and (h) protection of endangered species under the Endangered Species Act of 1973, as amended, (P.L. 93-205).
12. Will comply with the Wild and Scenic Rivers Act of 1968 (16 U.S.C. §§ 1271 et seq.) related to protecting components or potential components of the national wild and scenic rivers system.
13. Will assist the awarding agency in assuring compliance with Section 106 of the National Historic Preservation Act of 1966, as amended (16 U.S.C. 470), EO 11593 (identification and protection of historic properties), and the Archaeological and Historic Preservation Act of 1974 (16 U.S.C. 469a-1 et seq.).
14. Will comply with P.L. 93-348 regarding the protection of human subjects involved in research, development, and related activities supported by this award of assistance.
15. Will comply with the Laboratory Animal Welfare Act of 1966 (P.L. 89-544, as amended, 7 U.S.C. 2131 et seq.) pertaining to the care, handling, and treatment of warm blooded animals held for research, teaching, or other activities supported by this award of assistance.
16. Will comply with the Lead-Based Paint Poisoning Prevention Act (42 U.S.C. §§ 4801 et seq.) which prohibits the use of lead based paint in construction or rehabilitation of residence structures.
17. Will cause to be performed the required financial and compliance audits in accordance with the Single Audit Act of 1984.
18. Will comply with all applicable requirements of all other Federal laws, executive orders, regulations and policies governing this program.

SIGNATURE OF AUTHORIZED CERTIFYING OFFICIAL	TITLE
APPLICANT ORGANIZATION	DATE SUBMITTED

## CERTIFICATIONS REGARDING LOBBYING; DEBARMENT, SUSPENSION AND OTHER RESPONSIBILITY MATTERS; AND DRUG-FREE WORKPLACE REQUIREMENTS

Applicants should refer to the regulations cited below to determine the certification to which they are required to attest. Applicants should also review the instructions for certification included in the regulations before completing this form. Signature of this form provides for compliance with certification requirements under 34 CFR Part 82, "New Restrictions on Lobbying," and 34 CFR Part 85, "Government-wide Debarment and Suspension (Nonprocurement) and Government-wide Requirements for Drug-Free Workplace (Grants)." The certifications shall be treated as a material representation of fact upon which reliance will be placed when the Department of Education determines to award the covered transaction, grant, or cooperative agreement.

### 1. LOBBYING

As required by Section 1352, Title 31 of the U.S. Code, and implemented at 34 CFR Part 82, for persons entering into a grant or cooperative agreement over \$100,000, as defined at 34 CFR Part 82, Sections 82.105 and 82.110, the applicant certifies that:

(a) No Federal appropriated funds have been paid or will be paid, by or on behalf of the undersigned, to any person for influencing or attempting to influence an officer or employee of any agency, a Member of Congress, an officer or employee of Congress, or an employee of a Member of Congress in connection with the making of any Federal grant, the entering into of any cooperative agreement, and the extension, continuation, renewal, amendment, or modification of any Federal grant or cooperative agreement;

(b) If any funds other than Federal appropriated funds have been paid or will be paid to any person for influencing or attempting to influence an officer or employee of any agency, a Member of Congress, an officer or employee of Congress, or an employee of a Member of Congress in connection with this Federal grant or cooperative agreement, the undersigned shall complete and submit Standard Form - LLL, "Disclosure Form to Report Lobbying," in accordance with its instructions;

(c) The undersigned shall require that the language of this certification be included in the award documents for all subawards at all tiers (including subgrants, contracts under grants and cooperative agreements, and subcontracts) and that all subrecipients shall certify and disclose accordingly.

### 2. DEBARMENT, SUSPENSION, AND OTHER RESPONSIBILITY MATTERS

As required by Executive Order 12549, Debarment and Suspension, and implemented at 34 CFR Part 85, for prospective participants in primary covered transactions, as defined at 34 CFR Part 85, Sections 85.105 and 85.110 -

A. The applicant certifies that it and its principals:

(a) Are not presently debarred, suspended, proposed for debarment, declared ineligible, or voluntarily excluded from covered transactions by any Federal department or agency;

(b) Have not within a three-year period preceding this application been convicted of or had a civil judgment rendered against them for commission of fraud or a criminal offense in connection with obtaining, attempting to obtain, or performing a public (Federal, State, or local) transaction or contract under a public transaction; violation of Federal or State antitrust statutes or commission of embezzlement, theft, forgery, bribery, falsification or destruction of records, making false statements, or receiving stolen property;

(c) Are not presently indicted for or otherwise criminally or civilly charged by a governmental entity (Federal, State, or local) with commission of any of the offenses enumerated in paragraph (1)(b) of this certification; and

(d) Have not within a three-year period preceding this application had one or more public transactions (Federal, State, or local) terminated for cause or default; and

B. Where the applicant is unable to certify to any of the statements in this certification, he or she shall attach an explanation to this application.

### 3. DRUG-FREE WORKPLACE (GRANTEES OTHER THAN INDIVIDUALS)

As required by the Drug-Free Workplace Act of 1988, and implemented at 34 CFR Part 85, Subpart F, for grantees, as defined at 34 CFR Part 85, Sections 85.605 and 85.610 -

A. The applicant certifies that it will or will continue to provide a drug-free workplace by:

(a) Publishing a statement notifying employees that the unlawful manufacture, distribution, dispensing, possession, or use of a controlled substance is prohibited in the grantee's workplace and specifying the actions that will be taken against employees for violation of such prohibition;

(b) Establishing an on-going drug-free awareness program to inform employees about-

(1) The dangers of drug abuse in the workplace;

(2) The grantee's policy of maintaining a drug-free workplace;

(3) Any available drug counseling, rehabilitation, and employee assistance programs; and

(4) The penalties that may be imposed upon employees for drug abuse violations occurring in the workplace;

(c) Making it a requirement that each employee to be engaged in the performance of the grant be given a copy of the statement required by paragraph (a);

(d) Notifying the employee in the statement required by paragraph (a) that, as a condition of employment under the grant, the employee will-

(1) Abide by the terms of the statement; and

(2) Notify the employer in writing of his or her conviction for a violation of a criminal drug statute occurring in the workplace no later than five calendar days after such conviction;

(e) Notifying the agency, in writing, within 10 calendar days after receiving notice under subparagraph (d)(2) from an employee or otherwise receiving actual notice of such conviction. Employers of convicted employees must provide notice, including position title, to: Director, Grants and Contracts Service, U.S. Department of Education, 400 Maryland Avenue, S.W. (Room 3124, GSA Regional Office

Building No. 3), Washington, DC 20202-4571. Notice shall include the identification number(s) of each affected grant;

(f) Taking one of the following actions, within 30 calendar days of receiving notice under subparagraph (d)(2), with respect to any employee who is so convicted—

(1) Taking appropriate personnel action against such an employee, up to and including termination, consistent with the requirements of the Rehabilitation Act of 1973, as amended; or

(2) Requiring such employee to participate satisfactorily in a drug abuse assistance or rehabilitation program approved for such purposes by a Federal, State, or local health, law enforcement, or other appropriate agency;

(g) Making a good faith effort to continue to maintain a drug-free workplace through implementation of paragraphs (a), (b), (c), (d), (e), and (f).

B. The grantee may insert in the space provided below the site(s) for the performance of work done in connection with the specific grant:

Place of Performance (Street address, city, county, state, zip code)

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Check  if there are workplaces on file that are not identified here.

#### DRUG-FREE WORKPLACE (GRANTEES WHO ARE INDIVIDUALS)

As required by the Drug-Free Workplace Act of 1988, and implemented at 34 CFR Part 85, Subpart F, for grantees, as defined at 34 CFR Part 85, Sections 85.605 and 85.610—

A. As a condition of the grant, I certify that I will not engage in the unlawful manufacture, distribution, dispensing, possession, or use of a controlled substance in conducting any activity with the grant; and

B. If convicted of a criminal drug offense resulting from a violation occurring during the conduct of any grant activity, I will report the conviction, in writing, within 10 calendar days of the conviction, to: Director, Grants and Contracts Service, U.S. Department of Education, 400 Maryland Avenue, S.W. (Room 3124, GSA Regional Office Building No. 3), Washington, DC 20202-4571. Notice shall include the identification number(s) of each affected grant.

As the duly authorized representative of the applicant, I hereby certify that the applicant will comply with the above certifications.

NAME OF APPLICANT	PR/AWARD NUMBER AND/OR PROJECT NAME
PRINTED NAME AND TITLE OF AUTHORIZED REPRESENTATIVE	
SIGNATURE	DATE

## Certification Regarding Debarment, Suspension, Ineligibility and Voluntary Exclusion – Lower Tier Covered Transactions

This certification is required by the Department of Education regulations implementing Executive Order 12549, Debarment and Suspension, 34 CFR Part 85, for all lower tier transactions meeting the threshold and tier requirements stated at Section 85.110.

### Instructions for Certification

1. By signing and submitting this proposal, the prospective lower tier participant is providing the certification set out below.
2. The certification in this clause is a material representation of fact upon which reliance was placed when this transaction was entered into. If it is later determined that the prospective lower tier participant knowingly rendered an erroneous certification, in addition to other remedies available to the Federal Government, the department or agency with which this transaction originated may pursue available remedies, including suspension and/or debarment.
3. The prospective lower tier participant shall provide immediate written notice to the person to which this proposal is submitted if at any time the prospective lower tier participant learns that its certification was erroneous when submitted or has become erroneous by reason of changed circumstances.
4. The terms "covered transaction," "debarred," "suspended," "ineligible," "lower tier covered transaction," "participant," "person," "primary covered transaction," "principal," "proposal," and "voluntarily excluded," as used in this clause, have the meanings set out in the Definitions and Coverage sections of rules implementing Executive Order 12549. You may contact the person to which this proposal is submitted for assistance in obtaining a copy of those regulations.
5. The prospective lower tier participant agrees by submitting this proposal that, should the proposed covered transaction be entered into, it shall not knowingly enter into any lower tier covered transaction with a person who is debarred, suspended, declared ineligible, or voluntarily excluded from participation in this covered transaction, unless authorized by the department or agency with which this transaction originated.
6. The prospective lower tier participant further agrees by submitting this proposal that it will include the clause titled "Certification Regarding Debarment, Suspension, Ineligibility, and Voluntary Exclusion—Lower Tier Covered Transactions," without modification, in all lower tier covered transactions and in all solicitations for lower tier covered transactions.
7. A participant in a covered transaction may rely upon a certification of a prospective participant in a lower tier covered transaction that it is not debarred, suspended, ineligible, or voluntarily excluded from the covered transaction, unless it knows that the certification is erroneous. A participant may decide the method and frequency by which it determines the eligibility of its principals. Each participant may, but is not required to, check the Nonprocurement List.
8. Nothing contained in the foregoing shall be construed to require establishment of a system of records in order to render in good faith the certification required by this clause. The knowledge and information of a participant is not required to exceed that which is normally possessed by a prudent person in the ordinary course of business dealings.
9. Except for transactions authorized under paragraph 5 of these instructions, if a participant in a covered transaction knowingly enters into a lower tier covered transaction with a person who is suspended, debarred, ineligible, or voluntarily excluded from participation in this transaction, in addition to other remedies available to the Federal Government, the department or agency with which this transaction originated may pursue available remedies, including suspension and/or debarment.

### Certification

- (1) The prospective lower tier participant certifies, by submission of this proposal, that neither it nor its principals are presently debarred, suspended, proposed for debarment, declared ineligible, or voluntarily excluded from participation in this transaction by any Federal department or agency.
- (2) Where the prospective lower tier participant is unable to certify to any of the statements in this certification, such prospective participant shall attach an explanation to this proposal.

NAME OF APPLICANT	PR/AWARD NUMBER AND/OR PROJECT NAME
PRINTED NAME AND TITLE OF AUTHORIZED REPRESENTATIVE	
SIGNATURE	DATE



**DISCLOSURE OF LOBBYING ACTIVITIES  
CONTINUATION SHEET**

Approved by OMB  
0348-0046

Reporting Entity: \_\_\_\_\_ Page \_\_\_\_\_ of \_\_\_\_\_

**INSTRUCTIONS FOR COMPLETION OF SF-LLL, DISCLOSURE OF LOBBYING ACTIVITIES**

This disclosure form shall be completed by the reporting entity, whether subawardee or prime Federal recipient, at the initiation or receipt of a covered Federal action, or a material change to a previous filing, pursuant to title 31 U.S.C. section 1352. The filing of a form is required for each payment or agreement to make payment to any lobbying entity for influencing or attempting to influence an officer or employee of any agency, a Member of Congress, an officer or employee of Congress, or an employee of a Member of Congress in connection with a covered Federal action. Use the SF-LLL-A Continuation Sheet for additional information if the space on the form is inadequate. Complete all items that apply for both the initial filing and material change report. Refer to the implementing guidance published by the Office of Management and Budget for additional information.

1. Identify the type of covered Federal action for which lobbying activity is and/or has been secured to influence the outcome of a covered Federal action.
2. Identify the status of the covered Federal action.
3. Identify the appropriate classification of this report. If this is a followup report caused by a material change to the information previously reported, enter the year and quarter in which the change occurred. Enter the date of the last previously submitted report by this reporting entity for this covered Federal action.
4. Enter the full name, address, city, state and zip code of the reporting entity. Include Congressional District, if known. Check the appropriate classification of the reporting entity that designates if it is, or expects to be, a prime or subaward recipient. Identify the tier of the subawardee, e.g., the first subawardee of the prime is the 1st tier. Subawards include but are not limited to subcontracts, subgrants and contract awards under grants.
5. If the organization filing the report in item 4 checks "Subawardee", then enter the full name, address, city, state and zip code of the prime Federal recipient. Include Congressional District, if known.
6. Enter the name of the Federal agency making the award or loan commitment. Include at least one organizational level below agency name, if known. For example, Department of Transportation, United States Coast Guard.
7. Enter the Federal program name or description for the covered Federal action (item 1). If known, enter the full Catalog of Federal Domestic Assistance (CFDA) number for grants, cooperative agreements, loans, and loan commitments.
8. Enter the most appropriate Federal identifying number available for the Federal action identified in item 1 (e.g., Request for Proposal (RFP) number; Invitation for Bid (IFB) number; grant announcement number; the contract, grant, or loan award number; the application/proposal control number assigned by the Federal agency). Include prefixes, e.g., "RFP-DE-90-001."
9. For a covered Federal action where there has been an award or loan commitment by the Federal agency, enter the Federal amount of the award/loan commitment for the prime entity identified in item 4 or 5.
10. (a) Enter the full name, address, city, state and zip code of the lobbying entity engaged by the reporting entity identified in item 4 to influence the covered Federal action.  
(b) Enter the full names of the individual(s) performing services, and include full address if different from 10 (a). Enter Last Name, First Name, and Middle Initial (MI).
11. Enter the amount of compensation paid or reasonably expected to be paid by the reporting entity (item 4) to the lobbying entity (item 10). Indicate whether the payment has been made (actual) or will be made (planned). Check all boxes that apply. If this is a material change report, enter the cumulative amount of payment made or planned to be made.
12. Check the appropriate box(es). Check all boxes that apply. If payment is made through an in-kind contribution, specify the nature and value of the in-kind payment.
13. Check the appropriate box(es). Check all boxes that apply. If other, specify nature.
14. Provide a specific and detailed description of the services that the lobbyist has performed, or will be expected to perform, and the date(s) of any services rendered. Include all preparatory and related activity, not just time spent in actual contact with Federal officials. Identify the Federal official(s) or employee(s) contacted or the officer(s), employee(s), or Member(s) of Congress that were contacted.
15. Check whether or not a SF-LLL-A Continuation Sheet(s) is attached.
16. The certifying official shall sign and date the form, print his/her name, title, and telephone number.

Public reporting burden for this collection of information is estimated to average 30 minutes per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to the Office of Management and Budget, Paperwork Reduction Project (0348-0046), Washington, D.C. 20503.

## Appendix B

Potential applicants frequently direct questions to officials of the Department regarding application notices and programmatic and administrative regulations governing various direct grant programs. To assist potential applicants the Department has assembled the following most commonly asked questions.

Q. Can we get an extension of the deadline?

A. No. A closing date may be changed only under extraordinary circumstances. Any change must be announced in the **Federal Register** and apply to all applications. Waivers for individual applications cannot be granted regardless of the circumstances.

Q. How many copies of the application should I submit and must they be bound?

A. Our new policy calls for an original and six copies to be submitted. The binding of applications is optional.

Q. May we use this same application to compete for funds under a different grant program?

A. Yes, however, the likelihood of success is not good. A properly prepared application must meet the specifications of the grant program to which it is submitted.

Q. I'm not sure which grant program is most appropriate for my project. What should I do?

A. We are happy to provide general program information. Clearly, it would not be appropriate for staff to participate in the actual writing of an application, but we can respond to specific questions about application requirements, evaluation criteria, and the priorities. Applicants should understand that this previous contact is not required, nor will it in any way influence the success of an application.

Q. When will I find out if I'm going to be funded?

A. You can expect to receive notification within 3 to 4 months of the application closing date, depending on the number of applications received and the number of grant programs with closing dates at about the same time.

Q. Once my application has been reviewed by the review panel, can you tell me the outcome?

A. No. Every year we are called by a number of applicants who have legitimate reasons for needing to know the outcome of the review prior to official notification. Some applicants need to make job decisions, some need to notify a local school district, etc. Regardless of the reason, because final funding decisions have not been made at that point, we cannot share information about the review with anyone.

Q. Will my application be returned if I am not funded?

A. We no longer return unsuccessful applications. Thus applicants should retain at least one copy of the application.

Q. Can I obtain copies of reviewers' comments?

A. Upon written request, reviewers' comments will be mailed to unsuccessful applicants.

Q. Is travel allowed under these projects?

A. Travel associated with carrying out the project is allowed. Because we may request the project director of funded projects to attend an annual project directors meeting, you may also wish to include a trip or two to Washington, D.C. in the travel budget. Travel to conferences is sometimes allowed when it is for purposes of dissemination.

Q. If my application receives high scores from the reviewers, does that mean that I will receive funding?

A. Not necessarily. It is often the case that the number of applications scored highly by the reviewers exceeds the dollars available for funding projects under a particular competition. The order of selection, which is based on the scores of all the applications and other relevant factors, determines the applications that can be funded.

Q. What happens during negotiations?

A. During negotiations technical and budget issues may be raised. These are issues that have been identified during the panel and staff reviews that require clarification. Sometimes issues are stated as "conditions." These are issues that have been identified as so critical that the award cannot be made

unless those conditions are met. Questions may also be raised about the proposed budget. Generally, these issues are raised because there is inadequate justification or explanation of a particular budget item, or because the budget item seems unimportant to the successful completion of the project. If you are asked to make changes that you feel could seriously affect the project's success, you may provide reasons for not making the changes or provide alternative suggestions. Similarly, if proposed budget reductions will, in your opinion, seriously affect the project activities, you may explain why and provide additional justification for the proposed expenses. An award cannot be made until all negotiation issues have been resolved.

Q. How do I provide an assurance?

A. Except for SF-424B, "Assurances—Non-Construction Programs," which must be completed, simply state in writing that you are meeting a prescribed requirement.

Q. Where can copies of the **Federal Register**, a program's regulations, and Federal statutes be obtained?

A. Copies of these materials can usually be found at your local library. If not, most can be obtained from the Government Printing Office by writing to: Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402, Telephone: (202) 783-3238. When requesting copies of regulations or statutes, it is helpful to use the specific name, public law number, or part number. The material referenced in this notice would be referred to as follows:

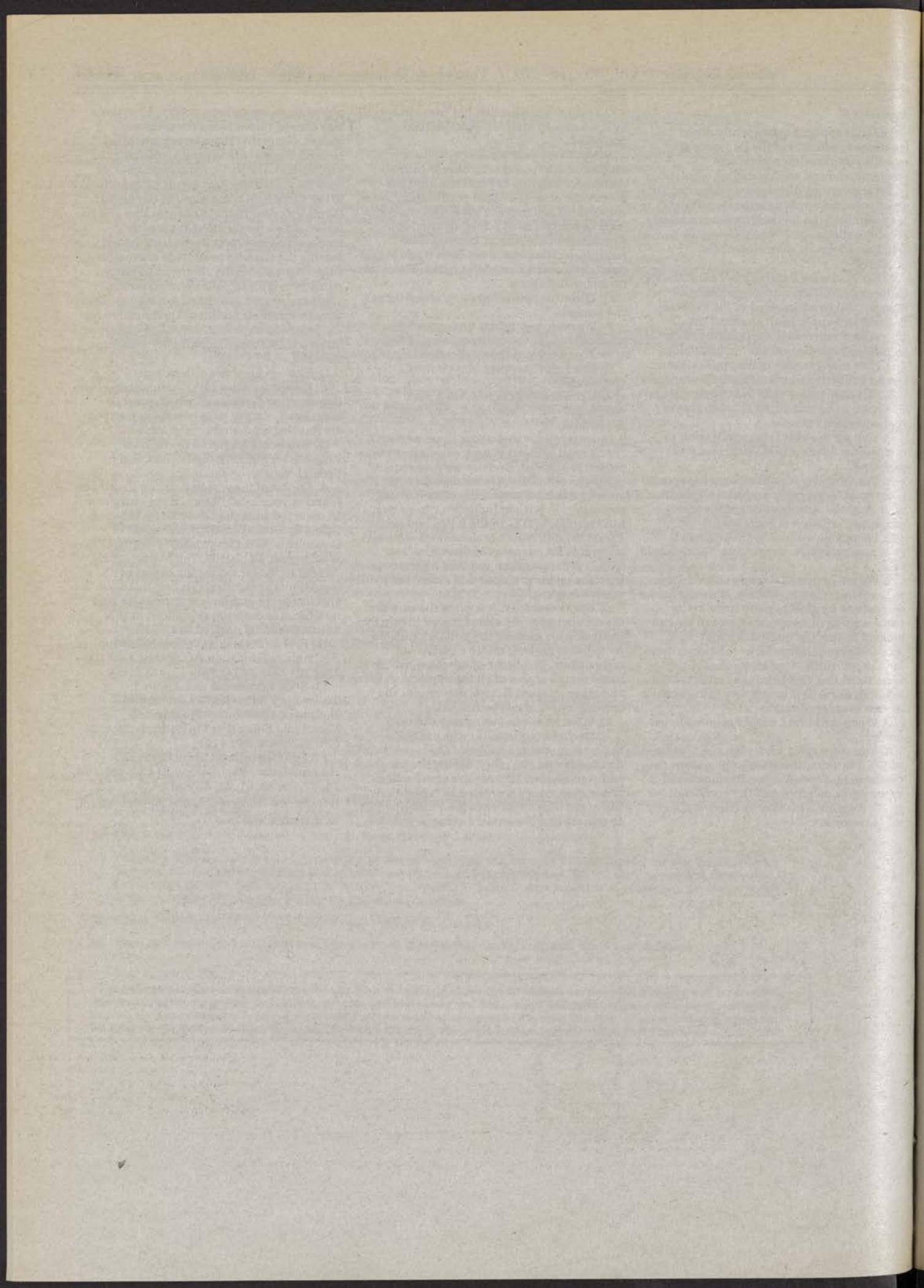
(1) Carl D. Perkins Vocational and Applied Technology Education Act (Public Law 101-392) 104 Stat. 753 (1990).

(2) State Vocational and Applied Technology Education Programs and National Discretionary Programs of Vocational Education Final Regulations, 34 CFR parts 400 and 428.

(3) Education Department General Administrative Regulations, 34 CFR parts 74, 75, 77, 79, 80, 81, 82, 85 and 86.

[FR Doc. 94-26660 Filed 10-26-94; 8:45 am]

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Thursday  
October 27, 1994

1994  
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Part VII

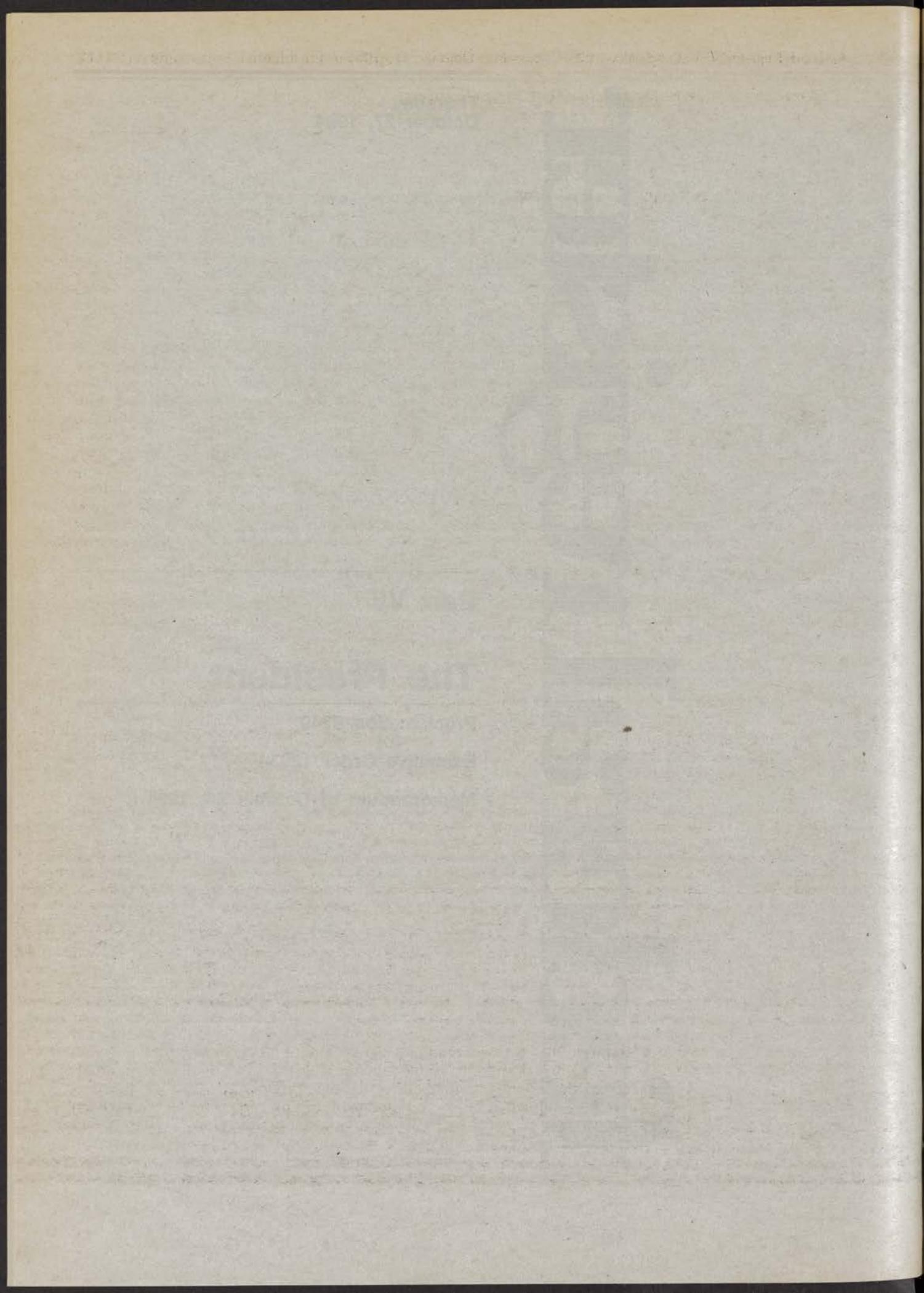
The President

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Proclamation 6749

Executive Order 12934

Memorandum of October 24, 1994



## Presidential Documents

Executive Order 12934 of October 25, 1994

### Blocking Property and Additional Measures With Respect to the Bosnian Serb-Controlled Areas of the Republic of Bosnia and Herzegovina

By the authority vested in me as President by the Constitution and the laws of the United States of America, including the International Emergency Economic Powers Act (50 U.S.C. 1701 *et seq.*), the National Emergencies Act (50 U.S.C. 1601 *et seq.*), section 5 of the United Nations Participation Act of 1945, as amended (22 U.S.C. 287c), and section 301 of title 3, United States Code, in view of United Nations Security Council Resolution 942 of September 23, 1994, and in order to take additional steps with respect to the crisis in the former Yugoslavia, I hereby expand the scope of the national emergency declared in Executive Order No. 12808 to address the unusual and extraordinary threat to the national security, foreign policy, and economy of the United States posed by the actions and policies of the Bosnian Serb forces and the authorities in the territory that they control, including their refusal to accept the proposed territorial settlement of the conflict in the Republic of Bosnia and Herzegovina.

I, WILLIAM J. CLINTON, President of the United States of America, hereby order:

**Section 1.** Notwithstanding the existence of any rights or obligations conferred or imposed by any international agreement or any contract entered into or any license or permit granted before the effective date of this order, except to the extent provided in regulations, orders, directives, or licenses, which may hereafter be issued pursuant to this order, all property and interests in property of: (a) the Bosnian Serb military and paramilitary forces and the authorities in those areas of the Republic of Bosnia and Herzegovina under the control of those forces;

(b) any entity, including any commercial, industrial, or public utility undertaking, organized or located in those areas of the Republic of Bosnia and Herzegovina under the control of Bosnian Serb forces;

(c) any entity, wherever organized or located, which is owned or controlled directly or indirectly by any person in, or resident in, those areas of the Republic of Bosnia and Herzegovina under the control of Bosnian Serb forces;

(d) any person acting for or on behalf of any person included within the scope of paragraph (a), (b), or (c) of this section; that are in the United States, that hereafter come within the United States, or that are or hereafter come within the possession or control of United States persons, including their overseas branches, are blocked.

**Sec. 2.** Notwithstanding the existence of any rights or obligations conferred or imposed by any international agreement or any contract entered into or any license or permit granted before the effective date of this order, except to the extent provided in regulations, orders, directives, or licenses, which may hereafter be issued pursuant to this order: (a) the provision or exportation of services to those areas of the Republic of Bosnia and Herzegovina under the control of Bosnian Serb forces, or to any person for the purpose of any business carried on in those areas, either from the United States or by a United States person, is prohibited; and

(b) no vessel registered in the United States or owned or controlled by a United States person, other than a United States naval vessel, may enter the riverine ports of those areas of the Republic of Bosnia and Herzegovina under the control of Bosnian Serb forces.

**Sec. 3.** Any transaction by any United States person that evades or avoids, or has the purpose of evading or avoiding, or attempts to violate, any of the prohibitions set forth in this order is prohibited.

**Sec. 4.** The Secretary of the Treasury, in consultation with the Secretary of State, is hereby authorized to take such actions, including the promulgation of rules and regulations, and to employ all powers granted to me by the International Emergency Economic Powers Act and the United Nations Participation Act of 1945, as amended, as may be necessary to carry out the purposes of this order. The Secretary of the Treasury may redelegate the authority set forth in this order to other officers and agencies of the United States Government, all agencies of which are hereby directed to take all appropriate measures within their authority to carry out the provisions of this order, including suspension or termination of licenses or other authorizations in effect as of the date of this order.

**Sec. 5.** Nothing in this order shall apply to activities related to the United Nations Protection Force, the International Conference on the Former Yugoslavia, or the European Community Monitoring Missions.

**Sec. 6.** For the purposes of this order:

(a) The term "person" means an individual or entity;

(b) The term "entity" means a corporation, partnership, association, or other organization;

(c) The term "United States person" is as defined in section 5 of Executive Order No. 12810.

**Sec. 7.** Nothing contained in this order shall create any right or benefit, substantive or procedural, enforceable by any party against the United States, its agencies or instrumentalities, its officers or employees, or any other person.

**Sec. 8 (a)** This order shall take effect at 11:59 p.m. eastern daylight time on October 25, 1994.

(b) This order shall be transmitted to the Congress and published in the Federal Register.

*William Clinton*

THE WHITE HOUSE,  
October 25, 1994.

# Presidential Documents

Title 3—

Proclamation 6749 of October 25, 1994

The President

## Immigration Measures With Respect to United Nations Security Council Resolution 942

By the President of the United States of America

### A Proclamation

In light of the actions of the Bosnian Serb forces and the authorities in the territory they control, including their refusal to accept the proposed territorial settlement of the conflict in the Republic of Bosnia and Herzegovina, and of United Nations Security Council Resolution 942 of September 23, 1994, I have determined that it is in the interests of the United States to restrict the entry to the United States of all aliens described in paragraph 14 of United Nations Security Council Resolution 942.

NOW, THEREFORE, I, WILLIAM J. CLINTON, President of the United States of America, acting under the authority vested in me by the Constitution and laws of the United States, including sections 212(f) and 215 of the Immigration and Nationality Act of 1952, as amended (8 U.S.C. 1182(f) and 1185), and section 301 of title 3, United States Code, hereby find that the unrestricted immigrant and nonimmigrant entry into the United States of aliens described in section 1 of this proclamation would, except as provided for in section 2 of this proclamation, be detrimental to the interests of the United States. I do therefore proclaim that:

**Section 1.** The immigrant and nonimmigrant entry into the United States of aliens described in paragraph 14 of United Nations Security Council Resolution 942 is hereby suspended. These aliens are: (a) members of the authorities, including legislative authorities, in those areas of the Republic of Bosnia and Herzegovina under the control of Bosnian Serb forces; officers of the Bosnian Serb military and paramilitary forces; and those acting on behalf of such authorities or forces;

(b) persons found, after September 23, 1994, to have provided financial, material, logistical, military, or other tangible support to Bosnian Serb forces in violation of relevant United Nations Security Council resolutions; and

(c) persons in or resident in those areas of the Republic of Bosnia and Herzegovina under the control of Bosnian Serb forces found to have violated or contributed to the violation of the measures set out in United Nations Security Council Resolution 820 of April 17, 1993, and United Nations Security Council Resolution 942 of September 23, 1994.

**Sec. 2.** Section 1 shall not apply with respect to any alien otherwise covered by section 1 where the entry of such alien is in the interests of the United States, including where such entry has been approved as prescribed by paragraph 14 of United Nations Security Council Resolution 942.

**Sec. 3.** Aliens covered by sections 1 and 2 shall be identified pursuant to procedures established by the Secretary of State, as authorized in section 5 below.

**Sec. 4.** This proclamation shall take effect at 11:59 p.m. eastern daylight time on October 25, 1994, and shall remain in effect until such time as the Secretary of State determines that it is no longer necessary and should be terminated.

**Sec. 5.** The Secretary of State shall have responsibility to implement this proclamation pursuant to procedures that the Secretary may establish.

IN WITNESS WHEREOF, I have hereunto set my hand this twenty-fifth day of October, in the year of our Lord nineteen hundred and ninety-four, and of the Independence of the United States of America the two hundred and nineteenth.

*William Clinton*

[FR Doc. 94-26833  
Filed 10-25-94; 4:58 pm]  
Billing code 3195-01-P

## Presidential Documents

Memorandum of October 24, 1994

### Delegation of Authority

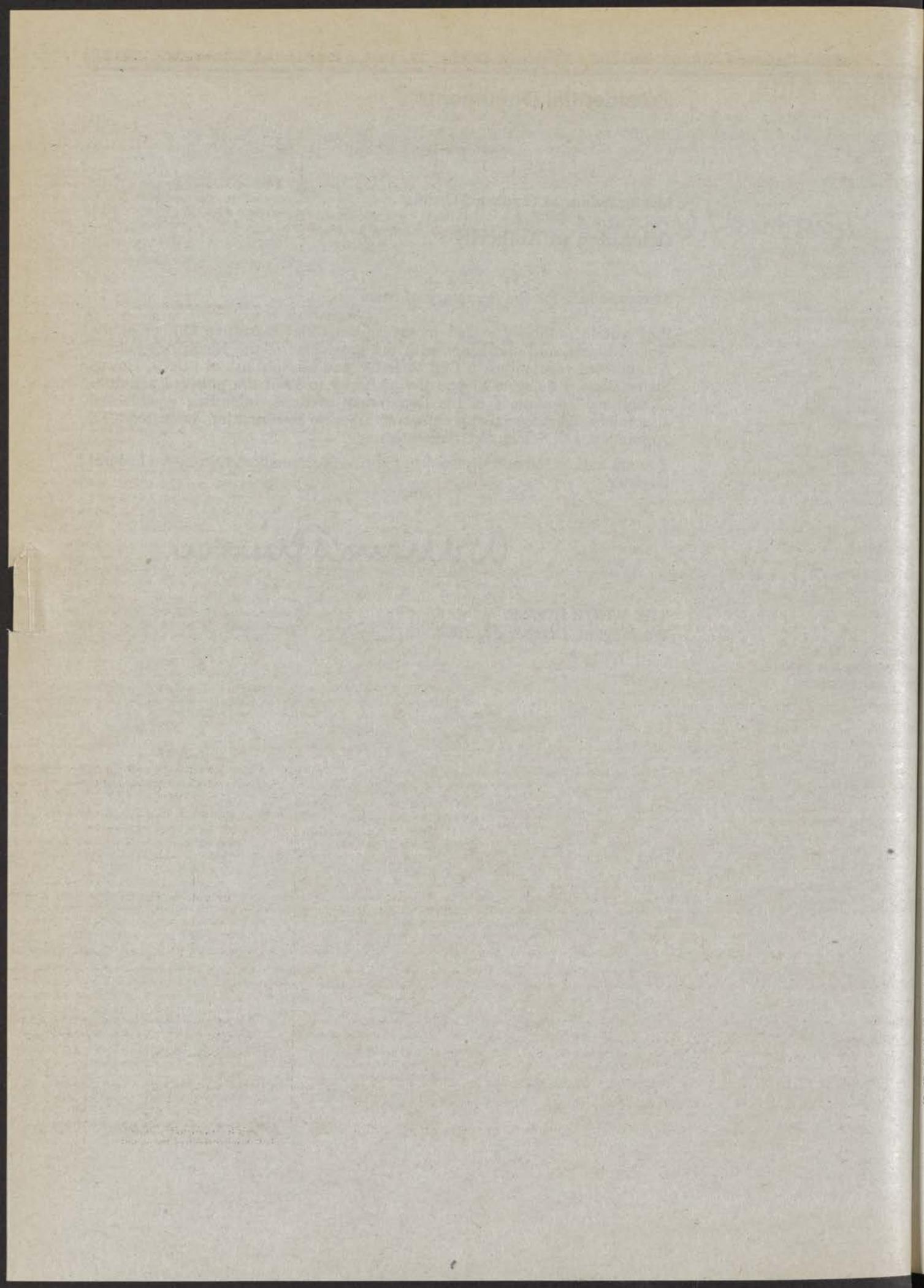
#### Memorandum for the Secretary of State

Pursuant to authority vested in me as the Chief Executive Officer of the United States, and consistent with the provisions of the Hatch Act Reform Amendment regulations, 5 CFR 734.104, and section 301 of title 3, United States Code, I delegate to you the authority to limit the political activities of political appointees of the Department of State, including Presidential appointees, Presidential appointees with Senate confirmation, noncareer SES appointees, and Schedule C appointees.

You are authorized and directed to publish this memorandum in the *Federal Register*.

*William Clinton*

THE WHITE HOUSE,  
Washington, October 24, 1994.



# Reader Aids

## Federal Register

Vol. 59, No. 207

Thursday, October 27, 1994

### INFORMATION AND ASSISTANCE

#### Federal Register

Index, finding aids & general information	202-523-5227
Public inspection announcement line	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

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### FEDERAL REGISTER PAGES AND DATES, OCTOBER

50153-50480.....3	52233-52398.....17
50481-50678.....4	52399-52654.....18
50679-50812.....5	52655-52890.....19
50813-51080.....6	52891-53032.....20
51081-51350.....7	53033-53346.....21
51351-51482.....11	53347-53562.....24
51483-51838.....12	53563-53718.....25
51839-52070.....13	53719-53926.....26
52071-52232.....14	53927-54122.....27

### CFR PARTS AFFECTED DURING OCTOBER

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

<b>Proclamations:</b>	
6728.....	50679
6729.....	50681
6730.....	50683
6731.....	51081
6732.....	51351
6733.....	51489
6734.....	52061
6735.....	52063
6736.....	52065
6737.....	52067
6738.....	52069
6739.....	52231
6740.....	52399
6741.....	53033
6742.....	53035
6743.....	53037
6744.....	53039
6745.....	53041
6746.....	53557
6747.....	53719
6748.....	53925
6749.....	54119

#### Executive Orders:

July 2, 1910 (Revoked in part by PLO 7092).....	50508
12352 (Revoked by EO 12931).....	52387
12775 (Continued by Notice of September 30, 1994).....	50479
12775 (See DOT final rule of Oct. 6).....	51066
12775 (Revoked by EO 12932).....	52403
12779 (See DOT final rule of Oct. 6).....	51066
12779 (Revoked by EO 12932).....	52403
12784 (See EO 12929).....	50473
12808 (See EO 12934).....	54117
12853 (See DOT final rule of Oct. 6).....	51066
12853 (Revoked by EO 12932).....	52403
12868 (Revoked by EO 12930).....	50475
12872 (See DOT final rule of Oct. 6).....	51066
12872 (Revoked by EO 12932).....	52403
12914 (See DOT final rule of Oct. 6).....	51066
12914 (Revoked by EO 12932).....	52403
12917 (See DOT final rule of Oct. 6).....	51066
12917 (Revoked by	

EO 12932).....	52403
12920 (See DOT final rule of Oct. 6).....	51066
12920 (Revoked by EO 12932).....	52403
12922 (See DOT final rule of Oct. 6).....	51066
12922 (Revoked by EO 12932).....	52403
12953 (See DOT final rule of Oct. 6).....	51066
12929.....	50473
12930.....	50475
12931.....	52387
12932.....	52403
12933.....	53559
12934.....	54117

#### Administrative Orders:

<b>Presidential Determinations:</b>	
No. 94-52 of September 29, 1994.....	50477
No. 94-53 of September 30, 1994.....	51483
No. 94-54 of September 30, 1994.....	51485
No. 94-55 of September 30, 1994.....	51487
No. 94-56 of September 30, 1994.....	52389
No. 94-57 of September 30, 1994.....	52057
No. 94-58 of September 30, 1994.....	52391
No. 94-59 of September 30, 1994.....	52059
No. 95-1 of October 1, 1994.....	52393
<b>Memorandums:</b>	
September 27, 1994.....	50685
September 30, 1994.....	50809
October 7, 1994.....	52395
October 13, 1994.....	52397
October 24, 1994.....	54121
<b>Notices:</b>	
September 30, 1994.....	50479
<b>5 CFR</b>	
213.....	50813
316.....	46895
532.....	52405
591.....	53721
846.....	50687
890.....	51353

1320.....	50813	Proposed Rules:	327.....	50710	239.....	52689		
1633.....	50816	3.....	53946	345.....	51232	240.....	52689	
Ch. LXXVI.....	50816	<b>9 CFR</b>	563e.....	51232	270.....	52689		
<b>Proposed Rules:</b>		51.....	51102, 52233	<b>13 CFR</b>	274.....	52689		
214.....	52459	78.....	51102	121.....	50964	402.....	53728	
315.....	52925	92.....	52235, 52237	<b>Proposed Rules:</b>	121.....	53947	405.....	53728
317.....	52459	94.....	52237	124.....	53947	<b>Proposed Rules:</b>		
319.....	52459	75.....	50860	143.....	53706, 53708	240.....	50866, 52723	
359.....	52459	102.....	50861	<b>14 CFR</b>		<b>18 CFR</b>		
531.....	52467	113.....	51390	11.....	52683	161.....	52896	
534.....	52459	391.....	53726	25.....	52683	250.....	52896	
843.....	50705	<b>Proposed Rules:</b>	117.....	53612	27.....	50380	375.....	53349
1650.....	53874	110 CFR		29.....	50380	<b>Proposed Rules:</b>		
1653.....	53874	34.....	50688	39.....	50481, 51103, 51361,	1310.....	53948	
2604.....	50171	35.....	50688	51840, 51841, 51842, 51846,		<b>19 CFR</b>		
<b>7 CFR</b>		50.....	50688	52414, 53572, 53573, 53577,		19.....	51492	
Ch. I.....	51083	73.....	50688	53579, 53581, 53582, 53931,		101.....	50689	
Ch. IX.....	51083	110.....	50688	53933		111.....	53086	
Ch. X.....	51083	600.....	53260	53284		112.....	51492	
Ch. XI.....	51083	<b>Proposed Rules:</b>		71.....	51362, 51491, 51851,	113.....	51492	
52.....	52624, 52630	2.....	50706	51852, 52241, 52242, 52894,		118.....	51492	
55.....	52636	21.....	53372	52895		125.....	51492	
56.....	52636	50.....	50513, 52255, 52707,	53583		146.....	51492	
59.....	52636	52.....	53613, 53869	91.....	53583	178.....	51492	
70.....	52636	61.....	52941	93.....	51363, 53727	<b>Proposed Rules:</b>		
210.....	51083, 52588	100.....	52255	97.....	52243, 52244, 52246,	101.....	50717	
246.....	50818	150.....	50706	52417, 52418, 52419		122.....	50717	
271.....	51353	430.....	50706, 51140	101.....	50390	<b>20 CFR</b>		
272.....	50153	600.....	53706, 53708	121.....	52640, 52683, 53085,	<b>Proposed Rules:</b>		
273.....	50173	<b>11 CFR</b>		125.....	52640, 52683	404.....	52380, 53769	
301.....	51839, 52405, 52891	<b>Proposed Rules:</b>		135.....	52640, 52683	416.....	52380, 53769	
400.....	52407	1.....	53946	<b>Proposed Rules:</b>		<b>21 CFR</b>		
735.....	51355	110.....	50708	Ch. I.....	50864	11.....	50793	
736.....	51355	9003.....	51006	11.....	50676	74.....	53584	
737.....	51355	9004.....	51006	39.....	51151, 51392, 51875,	101.....	50828	
738.....	51355	9006.....	51006	51877, 51879, 52273, 52479,		314.....	50338	
739.....	51355	9007.....	51006	52481, 52482, 52483, 52485,		450.....	50484	
740.....	51355	9033.....	51006	52720, 53613, 53615		452.....	52077	
741.....	51355	9034.....	51006	61.....	53226	510.....	50828	
742.....	51355	9037.....	51006	67.....	53226	520.....	50829, 53585	
800.....	52071, 52655	9038.....	51006	71.....	50865, 51394, 51395,	522.....	53585	
906.....	50824	<b>12 CFR</b>		53763, 53764, 53766		524.....	53585	
920.....	53347, 53563	220.....	53565	93.....	53768	556.....	50829	
928.....	52409	230.....	52657	221.....	53377	558.....	51497	
945.....	50793, 52411	303.....	52658	292.....	53377	600.....	54034	
966.....	51087	304.....	50826	302.....	53380	812.....	52078	
967.....	52411	338.....	52658	380.....	51881	900.....	53586	
981.....	52413	346.....	53568	381.....	51881	1308.....	52905	
987.....	52411	500.....	53568	399.....	51881	1310.....	51364, 51365, 52588	
989.....	53927	506.....	53568	<b>15 CFR</b>		1313.....	51365, 52588	
993.....	52411	508.....	53568	770.....	50156	<b>Proposed Rules:</b>		
1036.....	53726	545.....	53568	771.....	50156	20.....	54046	
1493.....	52866	552.....	53568	773.....	52685	101.....	51030, 52275	
1703.....	53929	558.....	53568	775.....	50156	170.....	51030	
1755.....	53043	563.....	53568	778.....	52685	310.....	51030, 54046	
1951.....	53079	564.....	53568	799.....	52685	312.....	54046	
<b>Proposed Rules:</b>		574.....	53568	801.....	53934	314.....	54046	
1.....	51389	590.....	53568	925.....	51105	600.....	54046	
70.....	52469	614.....	50964	940.....	53348	1307.....	51887	
273.....	52928	701.....	52862	<b>Proposed Rules:</b>		1309.....	51887	
300.....	53606	1403.....	53083	24.....	53706, 53708	1310.....	51887	
319.....	53606	1609.....	52669	<b>16 CFR</b>		1313.....	51887	
782.....	52931	<b>Proposed Rules:</b>		1615.....	53584	1316.....	51887	
1220.....	52475	3.....	52100	1616.....	53584	1403.....	53706, 53709	
1751.....	53939	25.....	51232	<b>Proposed Rules:</b>		<b>22 CFR</b>		
3016.....	53706, 53708	203.....	51323	1615.....	53616	40.....	51367	
<b>8 CFR</b>		208.....	52100	1616.....	53616	<b>Proposed Rules:</b>		
103.....	51091	225.....	52100, 53761	<b>17 CFR</b>		135.....	53706, 53709	
204.....	51358	228.....	51232	200.....	52689, 53936	<b>24 CFR</b>		
212.....	51091	325.....	52714	229.....	52689	200.....	50466	
214.....	51101							
217.....	51091							
245.....	51091, 53020							
274a.....	52894							

203.....50456, 52905, 53890	950.....53094	<b>40 CFR</b>	PLO 7093).....52921
204.....50456	<b>Proposed Rules:</b>	15.....50691	5023 (removed by
206.....50456	773.....53884	32.....50691	PLO 7096).....52922
207.....53731	913.....52487	51.....50693	7081.....53869
213.....53731	914.....52941, 52943	52.....50493, 50495, 50498,	7091.....50698
221.....53731	916.....51911	50500, 50502, 50504, 50844,	7092.....50508
234.....53890	935.....53122	51108, 51376, 51379, 51381,	7093.....52921
236.....53731	943.....53949	51382, 51506, 51514, 51517,	7094.....52921
267.....50456	944.....53123	51860, 51863, 52425, 52427,	7095.....52921
291.....52905		52429, 52431, 52588, 52704,	7096.....52922
791.....50158	<b>31 CFR</b>	52911, 52915, 52916, 53586,	7097.....53362
905.....51852	103.....52250	53589, 53741	<b>Proposed Rules:</b>
990.....51852	205.....51855	55.....50845	11.....52749
3500.....53890	550.....51106	60.....51383	12.....53706, 53711
<b>Proposed Rules:</b>	<b>Proposed Rules:</b>	62.....50506	
Ch. I.....52104	103.....52275	63.....53109, 53359	<b>44 CFR</b>
85.....53706, 53709	247.....53125	81.....50848, 52431, 53741	59.....53592
200.....51519	334.....50874	86.....51114	60.....53592
760.....51519	<b>32 CFR</b>	112.....53742	64.....53110, 53592
813.....50870	90.....53735	180.....53745, 53746, 53748,	65.....52436, 52438, 53592
905.....50870	91.....53735	53750, 53751	67.....52439
908.....50870	706.....52909, 52910, 53097	227.....52650	70.....53592
913.....50870	806.....50834	261.....52862	75.....53592
<b>25 CFR</b>	806b.....53098	271.....53753	205.....53362
<b>Proposed Rules:</b>	<b>Proposed Rules:</b>	272.....52084, 52918	206.....53362
309.....51908, 52588	33.....53706, 53710	271.....51115, 51116, 51122	<b>Proposed Rules:</b>
<b>26 CFR</b>	323.....51911	355.....51821	13.....53706, 53711
1.....50159, 50161, 50485,	<b>33 CFR</b>	<b>Proposed Rules:</b>	67.....52501
51105, 51369	100.....51500, 51503	31.....53706, 53710	<b>45 CFR</b>
301.....53087	117.....50166, 52423, 53351	51.....50718	801.....51387
602.....50161, 51369	151.....51332	52.....50211, 50533, 50536,	<b>Proposed Rules:</b>
<b>Proposed Rules:</b>	155.....53286	50884, 51153, 51397, 51521,	92.....53706, 53711
1.....52105, 52110, 53771	156.....53286	51912, 52495, 52496, 52743,	602.....53706, 53711
40.....52735	165.....50489, 50490, 50491,	52946, 52947, 53128, 53389,	233.....51536
48.....52735	50492, 52424, 53353	53626	1157.....53706, 53712
<b>28 CFR</b>	<b>Proposed Rules:</b>	62.....50536	1174.....53706, 53712
82.....50830	Ch. I.....52646	63.....51913, 53392, 53395	1183.....53706, 53712
545.....53342	117.....50528, 50529, 50530,	70.....50214, 50537, 52122,	1355.....50646
550.....53342	50531	52123, 52743	1356.....50646
570.....53937	165.....52945	81.....52496	1357.....50646, 52951
<b>Proposed Rules:</b>	166.....50533	82.....52126	2541.....53706, 53712
66.....53706, 53709	167.....50533	85.....53396	<b>46 CFR</b>
542.....50179	<b>34 CFR</b>	131.....52496	10.....50964, 53754
<b>29 CFR</b>	396.....52218	141.....51522	15.....53754
1601.....52704	685.....52704	142.....51522	69.....50508
1910.....51672	<b>Proposed Rules:</b>	180.....53130, 53771	<b>Proposed Rules:</b>
1928.....51672	80.....53706, 53710	228.....53951	Ch. I.....50537, 52276
1952.....50793	682.....51346, 52038, 53951	258.....51523, 52498	30.....52133
2610.....52079	<b>35 CFR</b>	264.....51523	31.....52133
2619.....52081	135.....52862	265.....51523	32.....52133
2622.....52079	<b>36 CFR</b>	271.....53132	34.....52133
2644.....52083	242.....51855	281.....53955	35.....52133
2676.....52081	<b>Proposed Rules:</b>	300.....50884, 51933, 52747,	70.....52133
<b>Proposed Rules:</b>	800.....50395	52949, 53773	72.....52133
97.....53706, 53709	1207.....53706, 53710	355.....51816	76.....52133
1470.....53706, 53709	<b>37 CFR</b>	721.....50537	77.....52133
1609.....51396	<b>Proposed Rules:</b>	<b>41 CFR</b>	78.....52133
<b>30 CFR</b>	1.....50181	101-17.....50507	90.....52133
250.....53091	<b>38 CFR</b>	101-45.....50696	92.....52133
256.....53091	17.....53354	101-46.....50696	95.....52133
280.....53091	<b>Proposed Rules:</b>	201-20.....53360	159.....52590
281.....53091	43.....53706, 53710	<b>Proposed Rules:</b>	160.....52590
701.....53022	<b>39 CFR</b>	105-71.....53706, 53711	190.....52133
780.....53022	111.....50690	<b>42 CFR</b>	193.....52133
784.....53022	962.....51860	403.....51125	540.....52133
816.....53022	<b>Proposed Rules:</b>	488.....52862	<b>47 CFR</b>
817.....53022	111.....50690	489.....52862	0.....50167
880.....52374	111.....51397	1003.....52862	1.....53363, 53759
914.....52906, 53732	<b>Proposed Rules:</b>	<b>Proposed Rules:</b>	21.....53363
935.....51498	111.....51397	418.....52129	24.....50509, 53364
		<b>43 CFR</b>	25.....53294
		Public Land Orders:	73.....50168, 50169, 50850,
		3862 (corrected by	

51130, 51518, 51866, 51867,
51868, 51869, 52086, 52441,
52442, 53363, 53602, 53603,
53604, 53760
76.....51869, 52087, 53113,
53363
94.....53294
<b>Proposed Rules:</b>
1.....51538
73.....50719, 50886, 50887,
51153, 51398, 51539, 51540,
53626, 53775
76.....50538, 51934

**48 CFR**

6.....53718
8.....53718
13.....53718
38.....53718
209.....51130, 51132
213.....50851
216.....53116
225.....50511, 51132
235.....52442
242.....53116
247.....50851
252.....51130, 51132, 53116
538.....52450
552.....52253, 52450
570.....52253

**Proposed Rules:**

22.....51399
31.....51399
42.....51399
45.....52277
52.....52277
242.....50539
252.....51130, 51132, 52277
970.....52505
1815.....51154
1819.....51154
1827.....51936
1852.....51154, 51936
1870.....51154

**49 CFR**

171.....53116
219.....50899
397.....51824
571.....51229
572.....52089
591.....52095
592.....52095
1249.....52099
604.....51133
1002.....52372
1039.....51134

**Proposed Rules:**

18.....53706, 53712
171.....51157
177.....51157
178.....51157
179.....51157
180.....51157
192.....52863
195.....52863
229.....52953
231.....52953
232.....52953
391.....50887
393.....51540
571.....51158
1002.....51546
1039.....53775
1145.....53775

1160.....51546
1161.....51546
1162.....51546
1163.....51546

**50 CFR**

17.....50796, 50852
20.....50424, 53334
100.....51855
215.....50372
216.....50372, 52922
285.....51871
301.....51871, 53117
625.....50512
640.....53118
642.....53120
658.....53604
663.....50857, 51871
672.....50169, 50170, 50899,
51134, 51872, 51873, 52099,
52923, 53937
675.....50699, 50858, 51387,
51873, 51874, 52452, 53121
676.....51135, 51874
678.....51388, 52453
685.....52924

**Proposed Rules:**

17.....50540, 50550, 50557,
51404, 53627, 53628, 53776
18.....53956
32.....53338
216.....51552
285.....52277
638.....52136
640.....52136
642.....52136
646.....52136
649.....53410
650.....53410
651.....53133, 53410
654.....52507
659.....52136
675.....50893, 52277
676.....52862
678.....52277

**LIST OF PUBLIC LAWS**

This is a continuing list of public bills from the current session of Congress which have become Federal laws. It may be used in conjunction with "PLUS" (Public Laws Update Service) on 202-523-6641. The text of laws is not published in the Federal Register but may be ordered in individual pamphlet form (referred to as "slip laws") from the Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402 (phone, 202-512-2470).

**H.R. 2135/P.L. 103-384**

Native American Veterans' Memorial Establishment Act of 1994 (Oct. 22, 1994; 108 Stat. 4067; 2 pages)

**H.R. 2294/P.L. 103-385**

To redesignate the Post Office building located at 1000 Lamar Street in Wichita Falls,

Texas, as the "Graham B. Purcell, Jr. Post Office Building". (Oct. 22, 1994; 108 Stat. 4069; 1 page)

**H.R. 4192/P.L. 103-386**

To designate the United States Post Office building located at 3000 Veterans Drive in Saint Thomas, Virgin Islands, as the "Arturo R. Wallington, Sr. Post Office". (Oct. 22, 1994; 108 Stat. 4070; 1 page)

**H.R. 4278/P.L. 103-387**

Social Security Domestic Employment Reform Act of 1994 (Oct. 22, 1994; 108 Stat. 4071; 8 pages)

**H.R. 4351/P.L. 103-388**

Federal Employees Family Friendly Leave Act (Oct. 22, 1994; 108 Stat. 4079; 2 pages)

**H.R. 4535/P.L. 103-389**

Unlisted Trading Privileges Act of 1994 (Oct. 22, 1994; 108 Stat. 4081; 4 pages)

**H.R. 4896/P.L. 103-390**

To grant the Consent of the Congress to the Kansas and Missouri Metropolitan Culture District Compact. (Oct. 22, 1994; 108 Stat. 4085; 9 pages)

**H.R. 4924/P.L. 103-391**

Rhinoceros and Tiger Conservation Act of 1994 (Oct. 22, 1994; 108 Stat. 4094; 4 pages)

**H.R. 4950/P.L. 103-392**

Jobs Through Trade Expansion Act of 1994 (Oct. 22, 1994; 108 Stat. 4098; 7 pages)

**H.R. 5053/P.L. 103-393**

Water Bank Extension Act of 1994 (Oct. 22, 1994; 108 Stat. 4105; 1 page)

**H.R. 5116/P.L. 103-394**

Bankruptcy Reform Act of 1994 (Oct. 22, 1994; 108 Stat. 4106; 46 pages)

**H.J. Res. 425/P.L. 103-395**

Providing for the convening of the First Session of the One Hundred Fourth Congress. (Oct. 22, 1994; 108 Stat. 4152; 1 page)

**S. 340/P.L. 103-396**

Animal Medicinal Drug Use Clarification Act of 1994 (Oct. 22, 1994; 108 Stat. 4153; 3 pages)

**S. 455/P.L. 103-397**

Payments in Lieu of Taxes Act (Oct. 22, 1994; 108 Stat. 4156; 6 pages)

**S. 528/P.L. 103-398**

Lincoln County, Montana, Lands Transfer Act of 1994

(Oct. 22, 1994; 108 Stat. 4162; 2 pages)

**S. 720/P.L. 103-399**

Indian Lands Open Dump Cleanup Act of 1994 (Oct. 22, 1994; 108 Stat. 4164; 5 pages)

**S. 1225/P.L. 103-400**

United States-Mexico Border Health Commission Act (Oct. 22, 1994; 108 Stat. 4169; 3 pages)

**S. 1312/P.L. 103-401**

Pension Annuitants Protection Act of 1994 (Oct. 22, 1994; 108 Stat. 4172; 2 pages)

**S. 1457/P.L. 103-402**

To amend the Aleutian and Pribilof Islands Restitution Act to increase authorization for appropriation to compensate Aleut villages for church property lost, damaged, or destroyed during World War II. (Oct. 22, 1994; 108 Stat. 4174; 1 page)

**S. 2060/P.L. 103-403**

Small Business Administration Reauthorization and Amendments Act of 1994 (Oct. 22, 1994; 108 Stat. 4175; 31 pages)

**S. 2073/P.L. 103-404**

To designate the Warren B. Rudman United States Courthouse, the Jamie L. Whitten Federal Building, and the William H. Natcher Federal Building and United States Courthouse. (Oct. 22, 1994; 108 Stat. 4206; 2 pages)

**S. 2395/P.L. 103-405**

To designate the United States Courthouse in Detroit, Michigan, as the "Theodore Levin Courthouse", and for other purposes. (Oct. 22, 1994; 108 Stat. 4208; 1 page)

**S. 2466/P.L. 103-406**

Energy Policy and Conservation Act Amendments Act of 1994 (Oct. 22, 1994; 108 Stat. 4209; 1 page)

**S. 2500/P.L. 103-407**

Sheep Promotion, Research, and Information Act of 1994 (Oct. 22, 1994; 108 Stat. 4210; 18 pages)

**S.J. Res. 90/P.L. 103-408**

To recognize the achievements of radio amateurs, and to establish support for such amateurs as national policy. (Oct. 22, 1994; 108 Stat. 4228; 2 pages)

Last List October 24, 1994

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