9–19–95
Vol. 60 No. 181
Pages 48361–48622

federal register

Tuesday
September 19, 1995

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

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

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

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

The Federal Register is published in paper, 24x microfiche and as an online database through *GPO Access*, a service of the U.S. Government Printing Office. The online database is updated by 6 a.m. each day the Federal Register is published. The database includes both text and graphics from Volume 59, Number 1 (January 2, 1994) forward. It is available on a Wide Area Information Server (WAIS) through the Internet and via asynchronous dial-in. The annual subscription fee for a single workstation is $375. Six-month subscriptions are available for $200 and one month of access can be purchased for $35. Discounts are available for multiple-workstation subscriptions. To subscribe, Internet users should telnet to swais.access.gpo.gov and login as newuser (all lower case); no password is required. Dial-in users should use communications software and modem to call (202) 512–1661 and login as swais (all lower case); no password is required; at the second login prompt, login as newuser (all lower case); no password is required. Follow the instructions on the screen to register for a subscription for the Federal Register Online via *GPO Access.* For assistance, contact the *GPO Access* User Support Team by sending Internet e-mail to help@eids05.eids.gpo.gov, or a fax to (202) 512–1262, or by calling (202) 512–1530 between 7 a.m. and 5 p.m. Eastern time, Monday through Friday, except Federal holidays.

The annual subscription price for the Federal Register paper edition is $494, or $544 for a combined Federal Register, Federal Register Index and List of CFR Sections Affected (LSA) subscription; the microfiche edition of the Federal Register including the Federal Register Index and LSA is $433. Six month subscriptions are available for one-half the annual rate. The charge for individual copies in paper form is $8.00 for each issue, or $8.00 for each group of pages as actually bound; or $1.50 for each issue in microfiche form. All prices include regular domestic postage and handling. International customers please add 25% for foreign handling. Remit check or money order, made payable to the Superintendent of Documents, or charge to your GPO Deposit Account, VISA or MasterCard. Mail to: New Orders, Superintendent of Documents, P.O. Box 371954, Pittsburgh, PA 15250–7954.

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

How To Cite This Publication: Use the volume number and the page number. Example: 60 FR 12345.

SUBSCRIPTIONS AND COPIES

PUBLIC	
Subscriptions:	
Paper or fiche	202–512–1800
Assistance with public subscriptions	512–1806
Online:	
Telnet swais.access.gpo.gov, login as newuser <enter>, no password <enter>; or use a modem to call (202) 512–1661, login as swais, no password <enter>, at the second login as newuser <enter>, no password <enter>.	
Assistance with online subscriptions	202–512–1530
Single copies/back copies:	
Paper or fiche	512–1800
Assistance with public single copies	512–1803
FEDERAL AGENCIES	
Subscriptions:	
Paper or fiche	523–5243
Assistance with Federal agency subscriptions	523–5243

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

THE FEDERAL REGISTER
WHAT IT IS AND HOW TO USE IT

FOR: Any person who uses the Federal Register and Code of Federal Regulations.

WHO: Sponsored by 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 Sessions]

WHEN: October 17 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

ATLANTA, GA

WHEN: September 20 at 9:00 am
WHERE: Centers for Disease Control and Prevention
1600 Clifton Rd., NE.
Auditorium A
Atlanta, GA
RESERVATIONS: 404–639–3528 (Atlanta area)
1–800–688–9889 (Outside Atlanta area)

Printed on recycled paper containing 100% post consumer waste

Contents

Federal Register
Vol. 60, No. 181
Tuesday, September 19, 1995

Advisory Council on Historic Preservation
See Historic Preservation, Advisory Council

Agricultural Marketing Service
RULES
Onions (Vidalia) grown in Georgia, 48361–48362

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

Animal and Plant Health Inspection Service
RULES
Interstate transportation of animals and animal products (quarantine):
Tuberculosis and brucellosis in cattle and bison—Identification requirements, 48362–48369

Army Department
NOTICES
Meetings:
Military Clothing and Equipment Performance Criteria Industry/Government Working Group, 48507

Commerce Department
See Foreign-Trade Zones Board
See International Trade Administration
See National Oceanic and Atmospheric Administration
NOTICES
Agency information collection activities under OMB review, 48499–48502

Defense Department
See Army Department
See Defense Information Systems Agency
NOTICES
Meetings:
Ballistic Missile Defense Advisory Committee, 48507

Defense Information Systems Agency
NOTICES
Senior Executive Service:
Performance Review Board; membership, 48507–48508

Education Department
NOTICES
Agency information collection activities under OMB review:
Proposed agency information collection activities; comment request, 48508

Employment and Training Administration
NOTICES
Adjustment assistance:
Don Shapiro Industries, 48524
Fina Oil & Chemical Co., 48525
Johnson Controls et al., 48526–48527
Miller Brewing Co., 48527
Wirekraft Industries, Inc., 48527–48528
Adjustment assistance and NAFTA transitional adjustment assistance:
IBM Corp. et al., 48525–48526
Meetings:
Apprenticeship Federal Committee, 48528

Energy Department
See Federal Energy Regulatory Commission
See Hearings and Appeals Office, Energy Department
See Western Area Power Administration
NOTICES
Natural gas exportation and importation:
Phibro Inc., 48513
Universal Resources Corp., 48513

Environmental Protection Agency
RULES
Air pollutants, hazardous; national emission standards:
Marine tank vessel loading and unloading operations, 48388–48417
PROPOSED RULES
Air quality planning purposes; designation of areas:
Pennsylvania, 48439–48442
Clean Air Act:
State operating permits programs—Virginia, 48435–48439
NOTICES
Agency information collection activities under OMB review, 48514
Meetings:
Alternative financing options for water infrastructure, 48514–48515

Executive Office of the President
See Management and Budget Office
See Presidential Documents
See Trade Representative, Office of United States

Federal Aviation Administration
PROPOSED RULES
Airworthiness directives:
Fairchild, 48431–48433
Flight Trails Helicopters, Inc., 48428–48429
Jetstream, 48429–48431
New Piper Aircraft, Inc., 48433–48435
NOTICES
Airport noise compatibility program:
Austin Straubel International Airport, WI, 48585–48586
Committees; establishment, renewal, termination, etc.:
Aviation Rulemaking Advisory Committee, 48586–48587
Meetings:
RTCA, Inc., 48587
Passenger facility charges; applications, etc.:
Seattle-Tacoma International Airport, WA, 48587–48588

Federal Communications Commission
RULES
Radio broadcasting:
Mass media: AM expanded band allotment plan; interpretation, 48426
Radio stations; table of assignments:
California, 48425–48426

PROPOSED RULES
Radio services, special:
Private land mobile services—
Efficient use of bands below 800 MHz; introduction of market forces; exclusivity, user fees, and competitive bidding options, 48490–48491
NOTICES
Public Safety Wireless Advisory Committee; contacts procedures, 48515

Federal Energy Regulatory Commission
NOTICES
Electric rate and corporate regulation filings:
Brooklyn Navy Yard Cogeneration Partners, L.P., et al., 48508–48510
Applications, hearings, determinations, etc.:
Frontier Gas Storage Co., 48510
Texas Gas Transmission Corp., 48510

Federal Reserve System
NOTICES
Meetings; Sunshine Act, 48593

Fish and Wildlife Service
PROPOSED RULES
Clean Vessel Act:
Pumpout symbol; slogan and program crediting, 48491–48497

Food and Drug Administration
RULES
Radiological health:
Radiation emitting electronic products; reporting and recordkeeping requirements, 48374–48387
NOTICES
Reports; availability, etc.:
Food labeling, questions and answers; guide for restaurants and other establishments; non-menu labeling, 48516–48518

Foreign-Trade Zones Board
NOTICES
Applications, hearings, determinations, etc.:
Texas, 48502

Forest Service
NOTICES
Meetings:
Willamette Provincial Interagency Executive Committee Advisory Committee, 48499

Health and Human Services Department
See Food and Drug Administration
See Health Care Financing Administration
See Public Health Service
NOTICES
Exchange visitor program:
International medical graduates; two-year home country physical presence requirement waiver; geographic shortage area designations, 48515–48516

Health Care Financing Administration
RULES
Medicare:
Non-experimental investigational devices and related services; criteria and procedures for extending coverage, 48417–48425
PROPOSED RULES
Medicaid:
Covered outpatient prescription drugs; rebate agreements with manufacturers, 48442–48490

Hearings and Appeals Office, Energy Department
NOTICES
Special refund procedures; implementation, 48510–48513

Historic Preservation, Advisory Council
NOTICES
Meetings, 48499

Housing and Urban Development Department
RULES
Environmental review procedures for entities assuming HUD environmental responsibilities
Technical amendments, 48610–48611
Mortgage and loan insurance programs:
Multifamily housing; conversion from coinsurance to full insurance, 48596–48601

Interior Department
See Fish and Wildlife Service
See Land Management Bureau
See National Park Service
See Reclamation Bureau

International Trade Administration
NOTICES
Antidumping:
Cut-to-length carbon steel plate from—
Sweden, 48502–48505
Applications, hearings, determinations, etc.:
Salk Institute for Biological Studies et al., 48505–48506
University of—
Michigan et al., 48506
Pennsylvania, 48507

Justice Department
NOTICES
Agency information collection activities under OMB review:
Proposed agency information collection activities; comment request, 48523–48524

Labor Department
See Employment and Training Administration

Land Management Bureau
NOTICES
Environmental statements; availability, etc.:
Round Mountain Mill and Tailings Facility, NV, 48518–48519
Realty actions; sales, leases, etc.:
Wyoming, 48519–48520

Management and Budget Office
NOTICES
Budget rescissions and deferrals, 48604–48607

National Highway Traffic Safety Administration
NOTICES
Meetings:
Research and development programs, 48588

National Oceanic and Atmospheric Administration
PROPOSED RULES
Fishery conservation and management:
Gulf of Mexico shrimp, 48497–48498

NOTICES
Meetings:
Monterey Bay National Marine Sanctuary Advisory Council, 48507

National Park Service
NOTICES
Environmental statements; availability, etc.:
Pecos National Historical Park, NM, 48520–48521
Saint Croix Island International Historic Site, ME, 48521
Meetings:
Delta Region Preservation Commission, 48521–48522
Maine Acadian Culture Preservation Commission, 48522
National Register of Historic Places:
Pending nominations, 48522
Native American human remains and associated funerary objects:
University of Nebraska State Museum, NE; Ponca Tribe inventory, 48522–48523

Nuclear Regulatory Commission
RULES
Defects and noncompliance reports; rules of practice, etc.:
Nuclear power plant licensees; procurement of commercial grade items, 48369–48374
PROPOSED RULES
Production and utilization facilities; domestic licensing:
Nuclear power plant structures, systems, and components; purchased products acceptance; withdrawn, 48427–48428
NOTICES
Environmental statements; availability, etc.:
Power Authority of State of New York, 48528–48529
Export and import license applications for nuclear facilities or materials, 48529
Generic letters:
Individual plant examination of external events for severe accident vulnerabilities, 48529–48530
Meetings; Sunshine Act, 48593
Applications, hearings, determinations, etc.:
PECO Energy Co., 48530–48532
Virginia Electric & Power Co., 48532

Office of Management and Budget
See Management and Budget Office

Office of United States Trade Representative
See Trade Representative, Office of United States

Postal Service
NOTICES
Privacy Act:
Systems of records, 48533–48534

Presidential Documents
PROCLAMATIONS
Special observances:
Citizenship Day and Constitution Week (Proc. 6825), 48619–48620
Rehabilitation Week, National (Proc. 6824), 48615–48616
EXECUTIVE ORDERS
International Criminal Police Organization; amendment (EO 12971), 48617
ADMINISTRATIVE ORDERS
Angola, National Union for the Total Independence of (UNITA); continuation of U.S. national emergency (Notice of September 18, 1995), 48621

Public Health Service
See Food and Drug Administration
NOTICES
Organization, functions, and authority delegations:
National Institutes of Health, 48518

Reclamation Bureau
NOTICES
Central Valley Project Improvement Act:
Water conservation plans; evaluation criteria; decision, 48520

Research and Special Programs Administration
NOTICES
Hazardous materials:
Applications; exemptions, renewals, etc., 48588–48592

Securities and Exchange Commission
NOTICES
Agency information collection activities under OMB review, 48534
Electronic Data Gathering, Analysis, and Retrieval System (EDGAR):
Corporation Finance Division; phase-in list changes and corrections, 48534–48576
Meetings; Sunshine Act, 48593
Self-regulatory organizations; proposed rule changes:
New York Stock Exchange, Inc., 48576–48577
Applications, hearings, determinations, etc.:
CVD Financial Corp., 48577–48578
Integrity Life Insurance Co. et al., 48578–48580
Northstar Advantage Multi-Sector Bond Fund et al., 48580–48582
SAFECO Life Insurance Co. et al., 48582–48585

Small Business Administration
NOTICES
Disaster loan areas:
Ohio, 48585

Trade Representative, Office of United States
NOTICES
Meetings:
Africa Trade Advisory Commission, 48532

Transportation Department
See Federal Aviation Administration
See National Highway Traffic Safety Administration
See Research and Special Programs Administration

Veterans Affairs Department
RULES
Organization, functions, and authority delegations:
Missing children official mail program; contact person and organizational units, 48387–48388
NOTICES
Life insurance, National Service:
Variable loan interest rate, 48592

Western Area Power Administration
NOTICES
Power rate adjustments:
Pacific Northwest-Pacific Southwest Intertie Project, 48513–48514

Separate Parts In This Issue

Part II
Housing and Urban Development Department, 48596–48601

Part III
Office of Management and Budget, 48604–48607

Part IV
Housing and Urban Development Department, 48610–48611

Part V
The President, 48613–48621

Reader Aids

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

Electronic Bulletin Board

Free Electronic Bulletin Board service for Public Law numbers, Federal Register finding aids, and a list of 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:

6824 48615
6825 48619

Executive Orders:

12425 (Amended by EO 12971) 48617
12865 (Continued by Notice of Sept. 18, 1995) 48621
12971 48617

Administrative Orders:

Notice of September 18, 1995 48621

7 CFR

955 48361

9 CFR

50 48362
51 48362
77 48362
78 48362
80 48362

10 CFR

21 48369

Proposed Rules:

50 48427

14 CFR

Proposed Rules:

39 (4 documents) 48428, 48429, 48431, 48433

21 CFR

1000 48374
1002 48374

24 CFR

58 48610
251 48596
252 48596
255 48596

38 CFR

1 48387

40 CFR

9 48388
63 48388

Proposed Rules:

70 48435
81 48439

42 CFR

405 48417
411 48417

Proposed Rules:

441 48442
447 48442

47 CFR

73 (2 documents) 48425, 48426

Proposed Rules:

90 48490

50 CFR

Proposed Rules:

85 48491
658 48497

Rules and Regulations

Federal Register
Vol. 60, No. 181
Tuesday, September 19, 1995

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 955

[Docket No. FV95–955–2IFR]

Vidalia Onions Grown in Georgia; Expenses and Assessment Rate

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Interim final rule with request for comments.

SUMMARY: This interim final rule authorizes expenditures and establishes an assessment rate under Marketing Order No. 955 for the 1995–96 fiscal period. Authorization of this budget enables the Vidalia Onion Committee (Committee) to incur expenses that are reasonable and necessary to administer the program. Funds to administer this program are derived from assessments on handlers.

DATES: Effective September 16, 1995, through September 15, 1996. Comments received by October 19, 1995, will be considered prior to issuance of a final rule.

ADDRESSES: Interested persons are invited to submit written comments concerning this action. Comments must be sent in triplicate to the Docket Clerk, Fruit and Vegetable Division, AMS, USDA, P.O. Box 96456, room 2523–S, Washington, DC 20090–6456. Comments should reference the docket number and the date and page number of this issue of the Federal Register and will be available for public inspection in the Office of the Docket Clerk during regular business hours.

FOR FURTHER INFORMATION CONTACT: Martha Sue Clark, Marketing Order Administration Branch, Fruit and Vegetable Division, AMS, USDA, P.O. Box 96456, room 2523–S, Washington, DC 20090–6456, telephone 202–720–9918, or Aleck J. Jonas, Southeast Marketing Field Office, Fruit and Vegetable Division, AMS, USDA, P.O. Box 2276, Winter Haven, FL 33883–2276, telephone 941–299–4770.

SUPPLEMENTARY INFORMATION: This rule is issued under Marketing Agreement and Order No. 955 (7 CFR part 955), regulating the handling of Vidalia onions grown in Georgia. The marketing agreement and order are 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 interim final rule has been reviewed under Executive Order 12778, Civil Justice Reform. Under the provisions of the marketing order now in effect, Vidalia onions are subject to assessments. It is intended that the assessment rate as issued herein will be applicable to all assessable onions handled during the 1995–96 fiscal period, which begins September 16, 1995, and ends September 15, 1996. This interim final 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 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. Such handler is afforded the opportunity for a hearing 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 the entry of the ruling.

Pursuant to the requirements set forth in the Regulatory Flexibility Act (RFA), the Administrator of the Agricultural Marketing Service (AMS) has considered the economic impact of this rule 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 the 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 250 producers of Georgia Vidalia onions under this marketing order, and approximately 145 handlers. Small agricultural producers have been defined by the Small Business Administration (13 CFR 121.601) as those having annual receipts of less than $500,000, and small agricultural service firms are defined as those whose annual receipts are less than $5,000,000. The majority of Vidalia onion producers and handlers may be classified as small entities.

The budget of expenses for the 1995–96 fiscal period was prepared by the Vidalia Onion Committee, the agency responsible for local administration of the marketing order, and submitted to the Department of Agriculture for approval. The members of the Committee are producers and handlers of Vidalia onions. They are familiar with the Committee's needs and with the costs of goods and services in their local area and are thus in a position to formulate an appropriate budget. The budget was formulated and discussed in a public meeting. Thus, all directly affected persons have had an opportunity to participate and provide input.

The assessment rate recommended by the Committee was derived by dividing anticipated expenses by expected shipments of Vidalia onions. Because that rate will be applied to actual shipments, it must be established at a rate that will provide sufficient income to pay the Committee's expenses.

The Committee met July 20, 1995, and unanimously recommended a 1995–96 budget of $343,000, $11,000 more than the previous year. Budget items for 1995–96 which have increased compared to those budgeted for 1994–95 (in parentheses) are: Dues and subscriptions, $2,500 ($2,000), equipment maintenance, $1,600 ($750), office overhead, $6,000 ($3,000), office supplies, $3,500 ($3,000), telephone, $5,000 ($4,000), printing, $2,200 ($2,000), postage and courier, $6,000 ($5,000), employee salaries, $65,000

($60,000), miscellaneous general and administrative, $1,700 ($1,000), marketing, $146,500 ($132,000), $6,500 for retirement, which was included in the employee benefits category last year, and $25,400 for a newly created compliance category. Items which have decreased compared to those budgeted for 1994–95 (in parentheses) are: Equipment purchases, $2,000 ($3,000), FICA employer, $3,100 ($4,250), employee benefits (health and dental), $7,000 ($13,500), research, $48,500 ($80,000), and ($8,000) for contract outside labor, for which no funding was recommended this year.

The Committee also unanimously recommended an assessment rate of $0.10 per 50-pound bag or equivalent of Vidalia onions, the same as last year. This rate, when applied to anticipated shipments of 3,017,500 50-pound bags or equivalents of Vidalia onions, would yield $301,750. The Committee also anticipates shipments of 50,000 50-pound bags of previously unassessed Vidalia onions which have been in storage, which will yield an additional $5,000 in assessment income. This, along with $4,250 in interest income and $32,000 from the Committee's authorized reserve, will be adequate to cover budgeted expenses. Funds in the Committee's authorized reserve of $167,766 are within the maximum permitted by the order of three fiscal periods' expenses.

While this rule will impose some additional costs on handlers, the costs are in the form of uniform assessments on handlers. Some of the additional costs may be passed on to producers. However, these costs will be offset by the benefits derived by the operation of the marketing order. Therefore, the Administrator of the AMS has determined that 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 and other available information, it is hereby found that this rule, as hereinafter set forth, will tend to effectuate the declared policy of the Act.

Pursuant to 5 U.S.C. 553, it is also found and determined upon good cause that 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) The Committee needs to have sufficient funds to pay its expenses which are incurred on a continuous basis; (2) the fiscal period begins on September 16, 1995, and the marketing order requires that the rate of assessment for the fiscal period apply to all assessable onions handled during the fiscal period; (3) handlers are aware of this action which was unanimously recommended by the Committee at a public meeting and is similar to other budget actions issued in past years; and (4) this interim final rule provides a 30-day comment period, and all comments timely received will be considered prior to finalization of this action.

List of Subjects in 7 CFR Part 955

Marketing agreements, Onions, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, 7 CFR part 955 is amended as follows:

PART 955—VIDALIA ONIONS GROWN IN GEORGIA

1. The authority citation for 7 CFR part 955 is revised to read as follows:

Authority: 7 U.S.C. 601–674.

2. A new § 955.208 is added to read as follows:

Note: This section will not appear in the Code of Federal Regulations.

§ 955.208 Expenses and assessment rate.

Expenses of $343,000 by the Vidalia Onion Committee are authorized, and an assessment rate of $0.10 per 50-pound bag or equivalent of Vidalia onions is established for the fiscal period ending September 15, 1996. Unexpended funds may be carried over as a reserve.

Dated: September 13, 1995.

Sharon Bomer Lauritsen,

Deputy Director, Fruit and Vegetable Division.

[FR Doc. 95–23192 Filed 9–18–95; 8:45 am]

BILLING CODE 3410–02–P

Animal and Plant Health Inspection Service

9 CFR Parts 50, 51, 77, 78, and 80

[Docket No. 95–006–2]

Tuberculosis, Brucellosis, and Paratuberculosis in Cattle and Bison; Identification Requirements

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Final rule.

SUMMARY: We are amending the tuberculosis, brucellosis, and paratuberculosis regulations by requiring brands for certain cattle and bison to be placed on the hip rather than the jaw. This action will reduce distress to cattle and bison that need to be identified with a brand by moving the brand to a location that is less sensitive, but that is still clearly visible. We are also allowing certain cattle and bison to be moved interstate to slaughter without branding if they are accompanied directly to slaughter by an Animal and Plant Health Inspection Service or State representative or are moved in vehicles closed with official seals. These actions respond to increasing public concern that branding on the jaw causes unnecessary distress to cattle and bison.

EFFECTIVE DATE: October 19, 1995.

FOR FURTHER INFORMATION CONTACT: Dr. J.D. Kopec, Senior Staff Veterinarian, Cattle Diseases and Surveillance, VS, APHIS, Suite 3B08, 4700 River Road Unit 36, Riverdale, MD 20737–1231; (301) 734–6188.

SUPPLEMENTARY INFORMATION:

Background

In accordance with the regulations in 9 CFR parts 50, 51, 77, and 78 (referred to below as the regulations), the Animal and Plant Health Inspection Service (APHIS) administers programs designed to control and eradicate tuberculosis and brucellosis in cattle and bison. As part of these programs, hot-iron branding on the jaw and on the tailhead has been used to identify certain cattle and bison. Specifically, hot-iron branding on the jaw has been required or allowed in the following cases: (1) To identify cattle or bison that have contracted or been exposed to tuberculosis or brucellosis; (2) to identify certain cattle or bison to be moved interstate to slaughter because of tuberculosis or brucellosis; and (3) to identify adult cattle or bison that have been immunized against brucellosis.

There has been increasing public concern that hot-iron branding on the jaw may cause undue distress to cattle and bison. A number of animal rights groups and other members of the public have requested that APHIS remove hot-iron branding on the jaw from our regulatory programs.

On May 17, 1995, we published in the Federal Register (60 FR 26377–26381, Docket No. 95–006–1) a proposal to remove hot-iron branding on the jaw from the regulations in 9 CFR parts 50, 51, 77, and 78. In places where branding has been required to be on the jaw, we proposed to move the required location of the brand to high on the hip near the tailhead. In places where the regulations have offered an owner the option of branding either on the jaw or on the hip, we proposed to remove the option of

branding on the jaw, but retain the brand on the hip. We also proposed several alternatives to branding certain cattle and bison that are to be moved interstate for slaughter. We proposed to allow brucellosis reactor and exposed cattle or bison moving directly to slaughter to be moved without branding if they are accompanied directly to slaughter by an APHIS or State representative. We proposed to allow tuberculosis reactor and exposed cattle or bison moving interstate directly to slaughter to be moved without branding if they are moved in vehicles closed with official seals applied and removed by an APHIS representative, a State representative, an accredited veterinarian, or an individual authorized for this purpose by an APHIS representative. We proposed to allow brucellosis reactor and exposed cattle or bison moving interstate in slaughter channels (e.g, to a specifically approved stockyard or an approved intermediate handling facility, and then to slaughter) and brucellosis exposed cattle and bison moving interstate to quarantined feedlots to be moved without branding if they are moved in vehicles closed with official seals applied and removed by an APHIS representative, a State representative, an accredited veterinarian, or an individual authorized for this purpose by an APHIS representative. We also proposed that tuberculosis reactor cattle and bison would have to be identified by a permanent and legible ''TB'' tattooed in the left ear, and by spraying the left ear with yellow paint, in order to be moved interstate without branding.

We solicited comments concerning our proposal for 30 days ending June 16, 1995. We received 11 comments by that date. They were from livestock associations, animal welfare organizations, veterinarians, and members of Congress. Three commenters opposed the proposed rule; four commenters supported the proposed rule completely; and the remaining four commenters supported the proposed rule but asked APHIS to consider making some additions and changes. We carefully considered all of the comments we received. They are discussed below by topic.

Several commenters supported the proposed amendments to the tuberculosis and brucellosis regulations, but asked that we make the same amendments to the regulations in 9 CFR part 80, ''Paratuberculosis in Domestic Animals,'' which have required a ''T'' brand on the left jaw for paratuberculosis reactor cattle. We have chosen to make this amendment in our final rule. The amendment is in keeping with the intent of the proposal to remove branding on the jaw from all APHIS disease control programs, and our failure to include part 80 in the proposed rule was an oversight. In addition, we are making a change to require that paratuberculosis reactors be branded with the letter ''J'' instead of the letter ''T''. Paratuberculosis is also commonly known as Johne's disease. A ''J'' brand would distinguish paratuberculosis reactors from bovine tuberculosis reactors (which are branded with the letter ''T''). We are therefore amending 9 CFR part 80 to require that paratuberculosis reactors be branded with the letter ''J'' high on the left hip near the tailhead. We are also adding the option for paratuberculosis reactor cattle moving interstate directly to slaughter to be moved without branding if they are accompanied by an APHIS or State representative; and for paratuberculosis reactor cattle moving interstate in slaughter channels to be moved without branding if they are moved in vehicles closed with official seals applied and removed by an APHIS representative, a State representative, an accredited veterinarian, or an individual authorized for this purpose by an APHIS representative. We are also making another change to part 80. Section 80.4 currently states that the inscription on the metal eartags for paratuberculosis reactors must read ''U.S.B.A.I. Reacted'' or ''U.S. Reacted.'' These inscriptions are out of date, so we are amending § 80.4 to require that the inscription read ''U.S. Reactor.'' This inscription is consistent with the inscriptions required by the regulations for other disease reactors.

One commenter was opposed to the proposed options for moving tuberculosis and brucellosis reactor and exposed cattle and bison to slaughter without branding. The commenter argued that branding ensures that such animals are slaughtered, and said that the agency will be unable to accomplish its goals of disease eradication if identification requirements are weakened. We have made no changes based on this comment. As discussed in the proposed rule, we believe that the provisions under which we would allow disease-affected animals to be moved without branding will provide owners with an alternative to branding without negatively affecting APHIS' ability to conduct its disease eradication activities.

Two commenters stated that the location of the brands should either remain on the jaw or be moved to the neck or high on the shoulder. They argue that some State livestock agencies have set aside the jaw for brands used in State and Federal animal disease control programs. They also argue that a Federal brand on the hip may be confused or conflict with registered ownership brands on the hip—a number of which are similar to the ''S'', ''T'', ''B'', and ''V'' brands called for in the proposed rule. We have made no changes based on these comments. The same location specified in the proposed rule for all brands required by 9 CFR parts 50, 51, 77, and 78 has been used by APHIS for the placement of ''S'' and ''V'' brands under the regulations in 9 CFR part 78 since 1983, and for ''M'' brands under 9 CFR part 92 since the beginning of this year. We are unaware of any identification problems resulting from those existing brands. Further, the proposed location of ''high on the hip near the tailhead'' is a different location on the hip from where registered ownership brands are placed, and we therefore do not believe that any confusion will result.

One commenter stated that it is unnecessary to require tuberculosis reactors moved without branding in sealed vehicles to be tattooed and spray-painted on the ear. The commenter believes that properly sealed vehicles, eartags, accompanying shipping permits, and good communication with meat inspection personnel would provide adequate assurance that tuberculosis reactors are not diverted from slaughter. Conversely, another commenter stated that the proposed requirement to tattoo and spray-paint tuberculosis reactors should also be applied to tuberculosis exposed animals and brucellosis reactors and exposed animals that are moved interstate to slaughter without branding. The latter commenter argues there are numerous opportunities to divert cattle and bison from slaughter—for example, in slaughter pens, or when cattle and bison must be transferred from one truck to another due to equipment failure—and that for this reason it is important that all cattle and bison moving to slaughter because of tuberculosis or brucellosis be permanently identified.

We have made no changes to the rule based on these comments. We recognize that there may be incentives to divert valuable, but diseased, cattle or bison from slaughter channels in order to avoid the monetary loss from the slaughter of the animal. We stated in the proposed rule that we believe this incentive is significantly greater for tuberculosis reactors than for other diseased cattle or bison, because unlike tuberculosis exposed or brucellosis reactor and exposed cattle or bison, tuberculosis reactors can only be sold for consumption if the meat is cooked.

Currently, there are only four slaughtering facilities in the United States that have established markets for meat required to be cooked, so this option is not available to the majority of cattle and bison owners. Consequently, most tuberculosis reactor cattle and bison sent to slaughter constitute an average monetary loss of $400 or more to the owner, creating an incentive to divert valuable animals that are tuberculosis reactors from slaughter to be used for some other purpose. Since tuberculosis exposed animals and brucellosis reactor and exposed animals do not have to be cooked before they can be sold for consumption, their slaughter value is potentially greater, and the incentive to divert is not as significant. In light of this, we believe that the precautions we proposed for moving tuberculosis exposed animals and brucellosis reactor and exposed animals to slaughter without branding are adequate to prevent diversion of the animals and dissemination of the diseases they carry. Perhaps more importantly, the post-mortem examination and specific disposition of tuberculosis reactor carcasses required by the United States Department of Agriculture's Food Safety and Inspection Service (FSIS) regulations is more stringent than that required of tuberculosis exposed and brucellosis reactor and exposed carcasses. It is imperative that tuberculosis reactors are identified at slaughter to ensure they are properly examined and disposed of in accordance with FSIS requirements.

One commenter stated that APHIS should consider eliminating the need for branding altogether by requiring that all brucellosis and tuberculosis reactor and exposed cattle and bison moved interstate to slaughter be accompanied by an APHIS or State representative or be moved in vehicles closed with official seals applied and removed by an APHIS representative, a State representative, an accredited veterinarian, or an individual authorized for this purpose by an APHIS representative. We have made no changes based on this comment.

It is our belief that most cattle and bison owners will choose to move their animals to slaughter without branding using one of the options provided in the proposed rule. Branding a herd of cattle or bison is time-consuming, difficult, and costly because of the effort and personnel needed to restrain each animal. It is far easier to simply herd the animals into a truck which is then sealed by the APHIS representative, State representative, or accredited veterinarian who identified the herd. However, there are always circumstances under which it is impractical or unfeasible for owners to move their animals in this manner, such as lack of a proper vehicle, unavailability of APHIS or State personnel, or inability to market the animals immediately. Under such circumstances, it would be necessary for owners to have the cattle or bison branded.

The same commenter also asked that we amend numerous paragraphs in § 78.9 of the brucellosis regulations, ''Cattle from herds not known to be affected,'' to allow such cattle to be moved interstate without branding if they are accompanied directly to slaughter by an APHIS or State representative. Section 78.9 concerns movement of cattle from brucellosis Class Free, Class A, Class B, and Class C States and areas to quarantined feedlots, specifically approved stockyards, or approved intermediate handling facilities, and then to slaughter. Section 78.9 requires certain cattle moving from Class B and Class C States and areas to be branded. We proposed to amend this section to allow those cattle which are required to be branded to be moved without branding if they are moved in vehicles closed with official seals applied and removed by an APHIS representative, a State representative, an accredited veterinarian, or an individual authorized for this purpose by an APHIS representative. We have made no changes based on this comment.

We did not propose the option which the commenter requests because, given the large number of movements under § 78.9 to feedlots, stockyards, and handling facilities, and given the limited number of APHIS and State personnel available to accompany such shipments, it would be impractical, if not impossible, to offer this option. It is for this reason that we proposed to allow reactor and exposed cattle and bison to be moved without branding and accompanied by an APHIS or State representative only if they are moving directly to slaughter. We believe that allowing cattle that would otherwise be branded to be moved without branding in slaughter channels if they are moved in a sealed vehicle is adequate to allow owners to move their animals without branding if they so choose. Further, there are currently no Class B or Class C States or areas. Therefore, no cattle are branded under the regulations in § 78.9.

One commenter asked that APHIS allow owners to mark their cattle in some way other than with a hot iron, such as freeze-branding. The commenter said that, according to previous APHIS policy, a mark for a disease-affected animal must be ''permanent, distinct, and legible''; APHIS' assertion in the proposed rule that a mark must also be ''instantly recognizable'' is a novel criteria. Relative to this, the commenter said that ''(c)learly what APHIS intends here is not that all letter marks be instantaneously readable, but, rather, that letter marks be readable *at the time animals begin their interstate journeys to slaughter*.'' Accordingly, even though freeze-branding takes a minimum of 18 to 21 days to become readable, and in order to claim indemnity for cattle and bison destroyed because of tuberculosis or brucellosis the owner must destroy the animals within 15 days, APHIS should allow identification options such as freeze-branding for cattle and bison owners who do not wish to claim indemnity. We have made no changes based on this comment.

In the past, APHIS has set forth its criteria that a mark for identifying cattle and bison must be permanent, distinct, and legible. In a recent rulemaking, which is cited by the commenter, we offered these criteria as justification for allowing marking methods such as freeze-branding to be employed when identifying certain cattle from Mexico for importation into the United States (Docket No. 93–006–3, 59 FR 65893–65897). The Mexican cattle of concern in that rulemaking are not known to be diseased. We require that such animals be identified by a distinct, permanent, and legible mark for traceback purposes, in the event that they are diseased and U.S. livestock are exposed to them. The mark must be visible at the time the Mexican cattle are presented for importation, but the owner may brand them at any time prior to the importation, making branding methods that take several weeks to become visible a viable option.

This rulemaking, in contrast, concerns cattle and bison which are known to be affected with tuberculosis or brucellosis, or are known to have been exposed to an animal that is affected with tuberculosis or brucellosis. It is imperative that animals known to be affected with a disease as destructive as brucellosis or tuberculosis be either identified immediately or moved to slaughter in such a manner that there is no significant risk the animals will be diverted from their destination. For this reason we did not propose to allow marking methods that are not instantly recognizable for identifying brucellosis and tuberculosis reactor and exposed cattle and bison.

As we stated in the proposal, the necessity for an instantly recognizable mark is so that the animals are not unknowingly commingled with healthy

animals after they leave the premises where they were identified for slaughter. Even if the ''instantly recognizable'' requirement were to be waived to allow freeze-branding, the owners of reactor or exposed cattle and bison would have to keep those animals under quarantine for the 18–21 days that it takes for a freeze-brand to become visible. That extra time on the farm would increase the chances that healthy animals might become exposed or infected. A central goal of the brucellosis and tuberculosis eradication programs is to identify diseased animals and get them away from other animals before the disease can spread. To require the animals to be kept on the farm runs counter to that goal. The owners of the quarantined cattle and bison would also be subject to economic losses associated with feeding and caring for the animals, potential decreases in market prices, and animals dying before sale.

The same commenter asked that we allow a tattoo and paint as an alternative to hot-iron branding. Since we say in the proposal that we believe a tattoo and yellow paint would be permanent and legible, the commenter asserts that it follows that it would be distinct as well, and would therefore fulfill the three criteria of distinct, permanent, and legible. We have made no changes based on this comment. We proposed that tuberculosis reactor cattle and bison that are moved to slaughter without branding be moved in a sealed vehicle or accompanied by an APHIS or State representative, and also be marked in the left ear with a tattoo and the ear be sprayed with yellow paint. Marking the ear with a permanent and legible tattoo will help eliminate the possibility that a tuberculosis reactor could be sold for any purpose other than slaughter, because the seller would risk a civil lawsuit should the buyer discover the tattoo in the reactor's ear. We proposed this type of mark as an alternative to branding in this case because we needed to provide an alternative, but did not believe we could safely allow tuberculosis reactors to move to slaughter without some sort of permanent mark.

There are problems with tattooing that prevent us from offering it as a general alternative for all disease-affected animals. One is that the tattoo must be on skin (not hair) in order to be legible. We have chosen the inside of the ear as the most accessible and reliable area on which to place a tattoo. Further, the animal's head must be restrained in order to tattoo the ear, and in order to see the tattoo at a later time. Yellow paint on the ear can help identify an animal which has a ''TB'' tattoo, but it is not foolproof, as paint can wear or rub off. Tuberculosis reactor animals are moved directly to slaughter, making it less likely that this will occur. Brucellosis exposed animals are often shipped through feedlots and other slaughter channels, increasing the possibility that the paint will have worn off by the time the animal reaches the slaughtering facility. For these reasons, we have chosen to confine the use of a tattoo as disease identification to tuberculosis reactors that are moved to slaughter without branding.

One commenter asked that we state in the regulations that the proposed shipments in sealed vehicles for unmarked cattle and bison would be subject to the requirements of the Twenty-Eight Hour Law. In conjunction with this, the commenter asked that we add to the regulations definitions for ''moved directly'' and ''sealed vehicle'' to clarify that these stipulations do not conflict with the requirements of the Twenty-Eight Hour Law. We have made no changes based on this comment.

The commenter is referring to a statute at 45 U.S.C 71–74, which requires, among other things, that animals may not be confined during transport for a period longer than 28 consecutive hours without unloading them in a humane manner for rest, water, and feeding. The regulations in 9 CFR part 89, ''Statement of Policy Under the Twenty-Eight Hour Law,'' set forth APHIS policy concerning the authorizing statute at 45 U.S.C. 71–74, and are written to apply only to transport by railcar. Virtually no transportation of tuberculosis and brucellosis affected cattle and bison is done today by railcar, as nearly all such transport today is by truck. The Twenty-Eight Hour Law does not apply to transport by truck.

In our proposal, we state that the official seals on a sealed vehicle must be ''applied and removed by an APHIS representative, State representative, accredited veterinarian, or an individual authorized for this purpose by an APHIS representative.'' The operator of the conveyance in which the animals are being transported will have been furnished with the telephone numbers of APHIS representatives in the States of origin and destination prior to his or her departure from the State of origin. If, for any reason, the operator is unable to reach the slaughtering establishment as planned, or otherwise determines that it is necessary to unload the animals from the sealed vehicle, the operator will be able to contact an APHIS representative, who will make the necessary arrangements for APHIS or State personnel to travel to the location of the conveyance in order to remove the seal, apply a new seal when the animals are reloaded, and take whatever precautions are necessary in the interim to ensure that the animals are maintained in isolation sufficient to prevent dissemination of the diseases they carry. This practice is standard, and we do not believe it is necessary to describe it in the regulations.

The same commenter suggested that APHIS create an incentive for cattle and bison owners to ship their tuberculosis- and brucellosis-affected cattle and bison to slaughter without branding by awarding certificates of recognition to owners who regularly opt to ship their animals in sealed vehicles or under APHIS or State escort as an alternative to branding. The commenter said that APHIS should publicize the award of these certificates periodically through agency press releases and reports. The commenter reasons that most cattle producers and brokers will continue to brand their disease-affected animals despite the alternative offered in the proposed rule, and that if APHIS is committed to reducing distress to cattle and bison, some further incentive will need to be offered.

We are making no changes based on this comment. As stated in response to a previous comment, it is our belief that most cattle and bison owners will choose to move their animals to slaughter without branding using one of the options provided in this rule. Branding a herd of cattle or bison is time-consuming, difficult, and costly because of the effort and personnel needed to restrain each animal. It is far easier to simply herd the animals into a truck which is then sealed. Regardless of this belief, the primary concern of APHIS is to move these animals to slaughter without disseminating the diseases they carry to healthy animals. While we are attempting to achieve this in the most humane manner possible, there are circumstances under which we would advise branding over the other alternatives we proposed, such as if the cattle or bison cannot be moved immediately to slaughter. For this reason, we are not promoting the consistent use of one alternative over another. Further, it is likely that most owners of tuberculosis or brucellosis affected herds would not elect to publicize the fact that their animals were slaughtered because of these diseases. We are offering owners several options for moving their animals, and we are available to advise them about which option would be most appropriate, and safe, given the circumstances under which their

animals will be moved. If a private entity wishes to award such certificates of recognition, and they find that cattle and bison owners are willing to accept such recognition, they may feel free to do so.

One commenter pointed out that, although the Supplementary Information in the proposal states that ''(w)e would allow brucellosis reactor and exposed cattle or bison moving directly to slaughter to be moved without branding if they are accompanied directly to slaughter by an APHIS or State representative,'' we do not include this allowance in the regulatory amendments to part 78. Our failure to make the change was an oversight, as it was clearly our intention to allow exposed cattle and bison to be moved directly to slaughter without branding if they are accompanied directly to slaughter by an APHIS or State representative, and we did make the necessary changes to part 51 to allow for that. We are, therefore, in this final rule amending § 78.8(a)(2)(iii)(D) to allow brucellosis exposed cattle and bison to be moved directly to slaughter without branding if they are accompanied directly to slaughter by an APHIS or State representative.

Therefore, based on the rationale set forth in the proposed rule and in this document, we are adopting the provisions of the proposal as a final rule, with the changes discussed in this document.

Executive Order 12866 and Regulatory Flexibility Act

This rule has been reviewed under Executive Order 12866. The rule has been determined to be not significant for the purposes of Executive Order 12866 and, therefore, has not been reviewed by the Office of Management and Budget.

We do not anticipate that this rule will have an economic impact on any entities, large or small. Cattle and bison that have contracted or been exposed to tuberculosis, brucellosis, or paratuberculosis, or that have been immunized against brucellosis, are already required to be identified by a brand; this rule will simply change the location of the brand. Under the tuberculosis, brucellosis, and paratuberculosis eradication programs, the Animal and Plant Health Inspection Service and cooperating States bear the costs of branding cattle and bison, and changing the location of the brand will not result in any change in costs to APHIS or the States. Further, although branding is generally done on the ranch or farm where the cattle or bison are located, no new equipment will be necessary for branding the cattle or bison on the hip, so there will be no new costs to the owner of the animals.

This rule will also allow certain cattle and bison to be moved interstate to slaughter without branding if they are accompanied directly to slaughter by an APHIS or State representative, or if they are moved in vehicles closed with official seals applied and removed by an APHIS representative, State representative, accredited veterinarian, or an individual authorized for this purpose by an APHIS representative. Such movement will be a voluntary alternative to branding, and will not impose any additional costs to owners of cattle or bison that are to be moved interstate.

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

Executive Order 12778

This rule has been reviewed under Executive Order 12778, Civil Justice Reform. This rule: (1) Preempts all State and local laws and regulations that are in conflict with this rule; (2) has no retroactive effect; and (3) does not require administrative proceedings before parties may file suit in court challenging this rule.

Paperwork Reduction Act

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

List of Subjects

9 CFR Part 50

Animal diseases, Bison, Cattle, Hogs, Indemnity payments, Reporting and recordkeeping requirements, Tuberculosis.

9 CFR Part 51

Animal diseases, Cattle, Hogs, Indemnity payments, Reporting and recordkeeping requirements.

9 CFR Part 77

Animal diseases, Bison, Cattle, Reporting and recordkeeping requirements, Transportation, Tuberculosis.

9 CFR Part 78

Animal diseases, Bison, Cattle, Hogs, Quarantine, Reporting and recordkeeping requirements, Transportation.

9 CFR Part 80

Animal diseases, Livestock, Transportation.

Accordingly, 9 CFR parts 50, 51, 77, 78, and 80 are amended as follows:

PART 50—ANIMALS DESTROYED BECAUSE OF TUBERCULOSIS

1. The authority citation for part 50 continues to read as follows:

Authority: 21 U.S.C. 111–113, 114, 114a, 114a–1, 120, 121, 125, and 134b; 7 CFR 2.17, 2.51, and 371.2(d).

2. In § 50.6, paragraphs (a) and (b) are revised to read as follows:

§ 50.6 Identification of animals to be destroyed because of tuberculosis.

* * * * *

(a) *Reactor cattle and bison.* Reactor cattle and bison shall be identified by branding the letter ''T,'' at least 5 by 5 centimeters (2 by 2 inches) in size, high on the left hip near the tailhead and by attaching to the left ear an approved metal eartag bearing a serial number and the inscription ''U.S. Reactor'', or a similar State reactor tag. Reactor cattle and bison may be moved interstate to slaughter without branding if they are permanently identified by the letters ''TB'' tattooed legibly in the left ear, they are sprayed on the left ear with yellow paint, and they are either accompanied by an APHIS or State representative or moved directly to slaughter in vehicles closed with official seals. Such official seals must be applied and removed by an APHIS representative, State representative, accredited veterinarian, or an individual authorized for this purpose by an APHIS representative.

(b) *Exposed cattle and bison.* Exposed cattle and bison shall be identified by branding the letter ''S,'' at least 5 by 5 centimeters (2 by 2 inches) in size, high on the left hip near the tailhead and by attaching to the left ear an approved metal eartag bearing a serial number. Exposed cattle and bison may be moved interstate to slaughter without branding if they are either accompanied by an APHIS or State representative or moved directly to slaughter in vehicles closed with official seals. Such official seals must be applied and removed by an APHIS representative, State representative, accredited veterinarian, or an individual authorized for this purpose by an APHIS representative.

* * * * *

PART 51—ANIMALS DESTROYED BECAUSE OF BRUCELLOSIS

3. The authority citation for part 51 continues to read as follows:

Authority: 21 U.S.C. 111–113, 114, 114a, 114a–1, 120, 121, 125, and 134b; 7 CFR 2.17, 2.51, and 371.2(d).

4. In § 51.5, paragraph (b) is revised to read as follows:

§ 51.5 Identification of animals to be destroyed because of brucellosis.

* * * * *

(b) Except as provided in paragraph (b)(4) of this section, cattle and bison to be destroyed because of brucellosis shall be individually identified prior to moving interstate by attaching to the left ear a metal tag bearing a serial number and the inscription ''U.S. Reactor,'' or a similar State reactor tag, and must be:

(1) ''B'' branded (as defined in § 78.1); or

(2) Accompanied directly to slaughter by an APHIS or State representative; or

(3) Moved in vehicles closed with official seals applied and removed by an APHIS representative, State representative, accredited veterinarian, or an individual authorized for this purpose by an APHIS representative. The official seal numbers must be recorded on the accompanying permit.

(4) Reactor and exposed cattle and bison in herds scheduled for herd depopulation may be moved interstate without eartagging or branding if they are identified by USDA approved backtags and either accompanied directly to slaughter by an APHIS or State representative or moved directly to slaughter in vehicles closed with official seals. Such official seals must be applied and removed by an APHIS representative, State representative, accredited veterinarian, or an individual authorized for this purpose by an APHIS representative.

* * * * *

PART 77—TUBERCULOSIS

5. The authority citation for part 77 continues to read as follows:

Authority: 21 U.S.C. 111, 114, 114a, 115–117, 120, 121, 134b, and 134f; 7 CFR 2.17, 2.51, and 371.2(d).

6. In § 77.5, the heading is amended by removing the word ''comtaining'' and adding the word ''containing'' in its place, and paragraphs (a)(1) and (b)(1) are revised to read as follows:

§ 77.5 Interstate movement of cattle and bison that are exposed, reactors, or suspects, or from herds containing suspects.

(a) *Reactor cattle and bison.* * * *

(1) Reactor cattle and bison must be individually identified by attaching to the left ear an approved metal eartag bearing a serial number and the inscription ''U.S. Reactor'', or a similar State reactor tag, and must be:

(i) Branded with the letter ''T,'' at least 5 by 5 centimeters (2 by 2 inches) in size, high on the left hip near the tailhead; or

(ii) Permanently identified with the letters ''TB'' tattooed legibly in the left ear and sprayed with yellow paint on the left ear, and either accompanied directly to slaughter by an APHIS or State representative or moved directly to slaughter in vehicles closed with official seals. Such official seals must be applied and removed by an APHIS representative, State representative, accredited veterinarian, or an individual authorized for this purpose by an APHIS representative.

* * * * *

(b) *Exposed cattle and bison.* * * *

(1) Exposed cattle and bison must be individually identified by attaching to the left ear an approved metal eartag bearing a serial number, and must be:

(i) Branded with the letter ''S,'' at least 5 by 5 centimeters (2 by 2 inches) in size, high on the left hip near the tailhead; or

(ii) Accompanied directly to slaughter by an APHIS or State representative; or

(iii) Moved directly to slaughter in vehicles closed with official seals. Such official seals must be applied and removed by an APHIS representative, State representative, accredited veterinarian, or an individual authorized for this purpose by an APHIS representative.

* * * * *

PART 78—BRUCELLOSIS

7. The authority citation for part 78 continues to read as follows:

Authority: 21 U.S.C. 111–114a–1, 114g, 115, 117, 120, 121, 123–126, 134b, and 134f; 7 CFR 2.17, 2.51, and 371.2(d).

Subpart A—General Provisions

§ 78.1 [Amended]

8. Section 78.1 is amended as follows:

a. In the definition for *''B'' branded,* the phrase ''at least 5 sq. cm. (2X2 inches) in size on the left jaw'' is removed and ''high on the left hip near the tailhead and at least 5 by 5 centimeters (2 by 2 inches) in size'' is added in its place.

b. In the definition for *Official adult vaccinate,* paragraph (b)(1) is amended by removing ''on the right jaw or'' and by adding ''at least 5 by 5 centimeters (2 by 2 inches) in size'' immediately after ''tailhead''.

c. In the definition for *''S'' branded,* the phrase ''at least 5 sq. cm. (2X2 inches) in size on the left jaw or high on the tailhead (over the fourth to the seventh coccygeal vertebrae)'' is removed and ''high on left hip near the tailhead and at least 5 by 5 centimeters (2 by 2 inches) in size'' is added in its place.

Subpart B—Restrictions on Interstate Movement of Cattle Because of Brucellosis

9. In § 78.7, paragraph (b) is revised to read as follows:

§ 78.7 Brucellosis reactor cattle.

* * * * *

(b) *Identification.* Brucellosis reactor cattle must be individually identified prior to moving interstate by attaching to the left ear a metal tag bearing a serial number and the inscription ''U.S. Reactor,'' or a metal tag bearing a serial number designated by the State animal health official for identifying brucellosis reactors, and must be:

(1) ''B'' branded (as defined in § 78.1); or

(2) Accompanied directly to slaughter by an APHIS or State representative; or

(3) Moved in vehicles closed with official seals applied and removed by an APHIS representative, State representative, accredited veterinarian, or an individual authorized for this purpose by an APHIS representative. The official seal numbers must be recorded on the accompanying permit.

* * * * *

10. Section 78.8 is amended as follows:

a. Paragraph (a)(2)(iii)(D) is redesignated as paragraph (a)(2)(iii)(E); and a new paragraph (a)(2)(iii)(D) is added to read as set forth below.

b. The period at the end of paragraphs (a)(3)(iii)(C), (a)(5)(iii)(C), and (b)(3)(ii) is removed, and ''; or'' is added in its place; and new paragraphs (a)(3)(iii)(D), (a)(5)(iii)(D), and (b)(3)(iii) are added to read as set forth below.

§ 78.8 Brucellosis exposed cattle.

* * * * *

(a) * * *

(2) * * *

(iii) * * *

(D) Accompanied directly to slaughter by an APHIS or State representative; or

* * * * *

(3) * * *

(iii) * * *

(D) Moved in vehicles closed with official seals applied and removed by an APHIS representative, State representative, accredited veterinarian, or an individual authorized for this purpose by an APHIS representative. The official seal numbers must be recorded on the accompanying permit or ''S'' brand permit.

* * * * *

(5) * * *

(iii) * * *

(D) Moved in vehicles closed with official seals applied and removed by an APHIS representative, State representative, accredited veterinarian, or an individual authorized for this purpose by an APHIS representative. The official seal numbers must be recorded on the accompanying permit or ''S'' brand permit.

* * * * *

(b) * * *

(3) * * *

(iii) Moved in vehicles closed with official seals applied and removed by an APHIS representative, State representative, accredited veterinarian, or an individual authorized for this purpose by an APHIS representative. The official seal numbers must be recorded on the accompanying permit or ''S'' brand permit.

* * * * *

11. Section 78.9 is amended by removing the period and adding ''; or'' in its place at the end of the following paragraphs:

a. (c)(1)(v)(C).

b. (c)(1)(vii)(C).

c. (c)(2)(i)(C).

d. (c)(2)(ii)(B).

e. (d)(1)(v)(C).

f. (d)(1)(vii)(C).

g. (d)(2)(i)(C).

h. (d)(2)(ii)(B).

12. Section 78.9 is amended by adding new paragraphs (c)(1)(v)(D), (c)(1)(vii)(D), (c)(2)(i)(D), (c)(2)(ii)(C), (d)(1)(v)(D), (d)(1)(vii)(D), (d)(2)(i)(D), and (d)(2)(ii)(C) to read as follows:

§ 78.9 Cattle from herds not known to be affected.

* * * * *

(c) * * *

(1) * * *

(v) * * *

(D) They are accompanied by an ''S'' brand permit and moved in vehicles closed with official seals applied and removed by an APHIS representative, State representative, accredited veterinarian, or an individual authorized for this purpose by an APHIS representative. The official seal numbers must be recorded on the accompanying ''S'' brand permit.

* * * * *

(vii) * * *

(D) They are accompanied by an ''S'' brand permit and moved in vehicles closed with official seals applied and removed by an APHIS representative, State representative, accredited veterinarian, or an individual authorized for this purpose by an APHIS representative. The official seal numbers must be recorded on the accompanying ''S'' brand permit.

(2) * * *

(i) * * *

(D) A quarantined feedlot, a specifically approved stockyard and then directly to a quarantined feedlot, or an approved intermediate handling facility and then directly to a quarantined feedlot if the cattle are accompanied by an ''S'' brand permit and moved in vehicles closed with official seals applied and removed by an APHIS representative, State representative, accredited veterinarian, or an individual authorized for this purpose by an APHIS representative. The official seal numbers must be recorded on the accompanying ''S'' brand permit.

(ii) * * *

(C) They are accompanied by an ''S'' brand permit and moved in vehicles closed with official seals applied and removed by an APHIS representative, State representative, accredited veterinarian, or an individual authorized for this purpose by an APHIS representative. The official seal numbers must be recorded on the accompanying ''S'' brand permit.

* * * * *

(d) * * *

(1) * * *

(v) * * *

(D) They are accompanied by an ''S'' brand permit and moved in vehicles closed with official seals applied and removed by an APHIS representative, State representative, accredited veterinarian, or an individual authorized for this purpose by an APHIS representative. The official seal numbers must be recorded on the accompanying ''S'' brand permit.

* * * * *

(vii) * * *

(D) They are accompanied by an ''S'' brand permit and moved in vehicles closed with official seals applied and removed by an APHIS representative, State representative, accredited veterinarian, or an individual authorized for this purpose by an APHIS representative. The official seal numbers must be recorded on the accompanying ''S'' brand permit.

(2) * * *

(i) * * *

(D) A quarantined feedlot, a specifically approved stockyard and then directly to a quarantined feedlot, or an approved intermediate handling facility and then directly to a quarantined feedlot if the cattle are accompanied by an ''S'' brand permit and moved in vehicles closed with official seals applied and removed by an APHIS representative, State representative, accredited veterinarian, or an individual authorized for this purpose by an APHIS representative. The official seal numbers must be recorded on the accompanying ''S'' brand permit.

(ii) * * *

(C) They are accompanied by an ''S'' brand permit and moved in vehicles closed with official seals applied and removed by an APHIS representative, State representative, accredited veterinarian, or an individual authorized for this purpose by an APHIS representative. The official seal numbers must be recorded on the accompanying ''S'' brand permit.

* * * * *

Subpart C—Restrictions on Interstate Movement of Bison Because of Brucellosis

13. In § 78.22, paragraph (b) is revised to read as follows:

§ 78.22 Brucellosis reactor bison.

* * * * *

(b) *Identification.* Brucellosis reactor bison must be individually identified prior to moving interstate by attaching to the left ear a metal tag bearing a serial number and the inscription ''U.S. Reactor,'' or a metal tag bearing a serial number designated by the State animal health official for identifying brucellosis reactors, and must be:

(1) ''B'' branded (as defined in § 78.1); or

(2) Accompanied directly to slaughter by an APHIS or State representative; or

(3) Moved in vehicles closed with official seals applied and removed by an APHIS representative, State representative, accredited veterinarian, or an individual authorized for this purpose by an APHIS representative. The official seal numbers must be recorded on the accompanying permit.

* * * * *

PART 80—PARATUBERCULOSIS IN DOMESTIC ANIMALS

14. The authority citation for part 80 is revised to read as follows:

Authority: 21 U.S.C. 111–113, 114a–1, 115, 117, 120, 121, and 125; 7 CFR 2.17, 2.51, and 371.2(d).

15. In § 80.4, paragraph (a) is revised to read as set forth below.

§ 80.4 Movement of paratuberculosis reactors.

* * * * *

(a) Cattle and other domestic animals that have reacted to such a test must be individually identified by attaching to

the left ear an approved metal eartag bearing a serial number and the inscription ''U.S. Reactor'', or a similar State reactor tag. Cattle must also be:

(1) Branded with the letter ''J,'' at least 5 by 5 centimeters (2 by 2 inches) in size, high on the left hip near the tailhead; or

(2) Accompanied directly to slaughter by an APHIS or State representative; or

(3) Moved in vehicles closed with official seals applied and removed by an APHIS representative, State representative, accredited veterinarian, or an individual authorized for this purpose by an APHIS representative.

* * * * *

Done in Washington, DC, this 13th day of September 1995.

Patricia Jensen,

Acting Assistant Secretary, Marketing and Regulatory Programs.

[FR Doc. 95–23191 Filed 9–18–95; 8:45 am]

BILLING CODE 3410–34–P

NUCLEAR REGULATORY COMMISSION

10 CFR Part 21

RIN 3150–AF01

Procurement of Commercial Grade Items by Nuclear Power Plant Licensees

AGENCY: Nuclear Regulatory Commission.

ACTION: Final rule.

SUMMARY: The Nuclear Regulatory Commission (NRC) is amending its regulations to provide added flexibility in procuring commercial grade items for safety-related service by nuclear power plant licensees. This action provides the requirements for the procurement of basic components, which will be procured initially as commercial grade items with subsequent dedication for safety-related service, in a manner that avoids unnecessary delay and expense while maintaining an adequate level of plant safety.

EFFECTIVE DATE: October 19, 1995.

ADDRESSES: Copies of the public record, including the final regulatory analysis and any public comments received on the proposed rule, may be examined and copied for a fee in the Commission's Public Document Room at 2120 L Street, NW, Washington, DC.

FOR FURTHER INFORMATION CONTACT: M. L. Au, P.E., Office of Nuclear Regulatory Research, U.S. Nuclear Regulatory Commission, Washington, DC 20555, telephone (301) 415–6181; E-mail MLA@nrc.gov.

SUPPLEMENTARY INFORMATION:

Background

On October 24, 1994 (59 FR 53372), the NRC published a proposed rule in the Federal Register that would clarify and add flexibility to 10 CFR Part 21 requirements for the procurement of commercial grade items for safety-related service by nuclear power plant licensees. This action was in response to a petition for rulemaking (PRM–21–2) from the Nuclear Management and Resources Council (NUMARC), which has been incorporated into the Nuclear Energy Institute (NEI). The notice of receipt of the petition for rulemaking was published on October 14, 1993 (58 FR 53159). The petitioner contended that many of the manufacturers and suppliers of original equipment no longer maintain programs that meet the requirements of Appendix B, ''Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants,'' to 10 CFR Part 50, ''Domestic Licensing of Production and Utilization Facilities,'' because of the high cost of maintaining and implementing these programs relative to the diminishing demand for plant parts. Thus, according to NEI, an increasing number of safety-related items are being purchased as commercial grade items from manufacturers and suppliers who no longer maintain quality assurance programs required by Appendix B to 10 CFR Part 50. Because this is a relatively small market, the petitioner stated that many vendors are unwilling to develop and maintain evaluation and notification procedures that meet the reporting requirements in 10 CFR Part 21. With fewer vendors agreeing to comply with these requirements, the petitioner claimed that it is becoming increasingly difficult for nuclear power plant licensees to procure items for safety-related applications.

The petitioner believed that the sections in 10 CFR Part 21 that relate to procurement of commercial grade items, the dedication of these items for use in safety-related applications, and the reporting requirements associated with these items are unworkable and ineffective and consequently may adversely affect safety. Furthermore, the petitioner believed that the effect of these provisions has been to discourage vendors from maintaining programs that meet NRC requirements and to even refuse to provide parts to licensees. To alleviate these problems, the petitioner proposed the following three changes to 10 CFR Part 21:

First, the petitioner suggested that the NRC broaden the definition of ''commercial grade item'' in 10 CFR 21.3 to read as follows: ''Commercial grade item means any item that has not been dedicated for use as a basic component.'' Essentially this definition would cover any item obtained on the open market. The petitioner believed that allowing commercially available items to qualify as commercial grade items would result in more reasonable prices and delivery times with no adverse impacts on safe plant operations.

Second, the petitioner suggested a more flexible generic definition of ''dedication'' in 10 CFR 21.3 to read as follows: ''Dedication is the evaluation process undertaken to provide reasonable assurance that a commercial grade item to be used as a basic component will perform its intended function.'' According to the petitioner, dedication methods could include testing, inspection, surveying the commercial grade supplier to determine that the appropriate quality control is in place, observing the manufacturing process, and analyzing the historical record of the item for acceptable performance. The petitioner also proposed that the dedicating entity maintain documentation of the dedication process for an audit or inspection.

The petitioner believed that the benefits of establishing this approach would be that the licensee or third-party performing the dedication:

(1) Understands the safety significance and function of the proposed component;

(2) Is able to identify the characteristics necessary to perform its intended function better than the manufacturer; and

(3) Is responsible for the quality of the commercial grade item.

This would require the party performing the dedication to determine the suitability of the component by analyzing its ability to perform successfully in a safety-related application.

Third, the petitioner suggested that the responsibility for reporting defects and failures to comply for commercial grade items that have been dedicated should reside with the entity responsible for performing the dedication process. The petitioner suggested that the following language be added to 10 CFR 21.21(b): ''The entity that performs the dedication is responsible for identifying, evaluating and reporting the deviations and failures to comply associated with substantial safety hazards of a commercial grade item.'' Since the manufacturers, suppliers, and sub-tier suppliers of commercial grade items do

not necessarily know whether the item is destined for a safety-related application, the petitioner believes it is appropriate to clarify that the responsibility for reporting defects and failures to comply found in commercial grade items falls on the entity performing the dedication process.

To sum up, the petitioner requested that 10 CFR Part 21 be amended to:

(1) Replace the existing definition of commercial grade item with a more inclusive definition;

(2) Include a flexible generic process for dedication of commercial grade items for safety-related use; and

(3) Clarify that the entity performing the dedication of a commercial grade item is responsible for discovering and evaluating deviations and for reporting defects and failures to comply as required by 10 CFR Part 21.

The rule grants in part and denies in part the petition for rulemaking (PRM–21–2) from the NEI and completes action on the petition.

Public Comment

The NRC received 23 letters of public comments in response to the Federal Register notice announcing the receipt of the petition for rulemaking. All but one letter supported the petition and called for a revision of the NRC's regulations consistent with the proposal set forth in the petition. The NRC considered these comments in the development of the proposed rule that was published in October 1994.

The NRC received 19 letters of comment in response to the proposed rule. The NRC considered these comments in developing the final rule, the objective of which is to provide requirements for the procurement of basic components, initially procured as commercial grade items and subsequently dedicated for safety-related service, in a timely and cost effective manner that avoids unnecessary delay and expense to the licensee while maintaining an adequate level of plant safety.

The 19 letters of comment received in response to the proposed rule can be categorized as follows: 1 from an interested individual, 1 from an individual in a citizen's group, 1 from the Nuclear Energy Institute (NEI) with a supplemental letter re-emphasizing comments important to NEI, 1 from a law firm, 14 from nuclear power plant licensees, and 1 from a nuclear power plant supplier. Many of the letters contained comments that were similar in nature. The majority of the commenters were supportive of the proposed rule. Only one commenter, an individual from a citizens group, objected to the proposed rule. The following section summarizes the public comments received and provides NRC's responses to the concerns expressed.

Comment. The proposed rule contains changes developed by NRC staff which differ from the proposal originally submitted by NEI (formerly NUMARC), and in addition, codifies new prescriptive requirements for the dedication process.

Response. Part 21 currently does not contain a regulatory definition of ''dedication,'' indicating only the time when dedication occurs; however, the NEI petition sought, among other matters, to define and establish by rulemaking a standard for the dedication process. As such, it was appropriate for the Commission to consider the elements of a dedication process for commercial grade items which assure the protection of the health and safety of the public rather than limit this standard to the industry's proposal. Therefore, it is not inappropriate for the NRC to consider ''provisions not sought by the petitioner.'' The NRC has never interpreted, nor has it implemented, the 10 CFR 2.802 rulemaking petition process in a manner which requires either the wholesale acceptance or rejection of specific rulemaking proposals contained in a 10 CFR 2.802 petition.

Comment. Amendments to the definitions are ambiguous and do not provide a clear demarcation between basic components and commercial grade items. The definition of ''basic component'' raises two problems involving wording. The definition states that it ''includes'' two categories of items, i.e., those designed ''or'' manufactured under Appendix B to 10 CFR Part 50 quality assurance programs, and commercial grade items successfully dedicated as basic components. The first problem is the use of the term ''includes'' in the definition of basic component. This opens the possibility that other categories of items could also exist which is not the intent. The second problem is the use of the word ''or'' between ''design'' and ''manufactured.'' An item designed under an Appendix B quality assurance program, but manufactured commercial grade should not be categorized as a basic component. It requires dedication to be categorized as a basic component.

Response. The NRC agrees with the commenter's observation that the Commission's intent was for the definition of basic component to be limited to only two categories of items: (1) those designed and manufactured under 10 CFR Part 50, Appendix B quality assurance programs, and (2) those commercial grade items successfully dedicated as basic components. The definition of ''basic component'' has been revised to address the commenter's concern.

Comment. The proposed definition of ''Commercial Grade Items'' appears to be unnecessarily restrictive and could give rise to interpretational difficulties that could limit or preclude options available to the licensee, rather than enhance the flexibility of licensees or utilities in dedicating commercial grade items for safety-related applications. The difficulty with the proposed definition of commercial grade item is that it would force utilities to always purchase a product as nuclear grade if a manufacturer with an Appendix B to 10 CFR Part 50 quality assurance program exists, which would result in a monopoly or a ''captive market.''

Response. The new definition is not intended to restrict the licensee from purchasing commercial grade items for subsequent dedication for safety-related applications even though a basic component designed and manufactured under an Appendix B to 10 CFR Part 50 quality assurance program is currently available. The commercial grade item, when properly and successfully dedicated, is deemed by the NRC to be equivalent in its safety function performance to the same or a similar item designed and manufactured under an Appendix B to Part 50 quality assurance program.

Comment. The phrase ''or part of a basic component'' should be deleted from the definition of commercial grade items because it could be interpreted to mean that all commercial grade items used in basic components are required to be dedicated for safety-related use.

Response. To address this comment, the NRC has modified the definition of ''commercial grade item'' to clarify that a commercial grade item that is part of a basic component but does not affect a safety-related function need not be dedicated. Therefore, a commercial grade item which is part of a basic component is considered to be a basic component after it has been dedicated prior to installation only if it affects a safety function.

Comment. The proposed new definition of ''commercial grade item'' and other changes to Part 21 should not be limited to only nuclear power plant licensees under Part 50, and their vendors, since these entities hold other licenses and would benefit from changes to Part 21.

Response. Proposed changes to Part 21 regulatory requirements for

nonreactor licensees are currently being considered.

Comment. The definition of the term ''dedication'' needs to be clarified as it lacks flexibility for dedication of a commercial grade item for safety-related applications. The graded approach should be used for applying Appendix B to 10 CFR Part 50.

Response. The dedication process must be performed using the applicable quality assurance criteria of Appendix B to 10 CFR Part 50. Appendix B already allows the level of quality assurance implemented to be consistent with the item's importance to safety (i.e., the graded approach).

Comment. The complexity of an item's design or manufacturing process should not be a criterion for excluding commercial grade items from eligibility to undergo a dedication process.

Response. To the extent the term ''complexity'' has caused confusion, the language of the rule has been modified to remove that term. The NRC maintains that if the design of an item and its manufacturing process are such that the dedication process cannot reasonably ensure the absence of a defect or failure to comply that affects one or more critical characteristics of the item, then the item cannot be dedicated, and must be designed and manufactured as a basic component. Included are items for which the manufacturing process requires in-process inspections and verifications to ensure that defects are identified and corrected. Typical examples include, but are not limited to, fuel assemblies, control rod assemblies, and reactor coolant pressure boundary components.

Comment. In the definition of term ''dedication,'' the example of ''pressure vessels'' does not meet the specific nuclear-unique requirement since pressure vessels are used widely outside the nuclear industry and should be considered a potential candidate for dedication.

Response. The example is no longer included in the definition. In the Statement of Considerations, ''pressure vessel'' has been replaced with ''reactor coolant pressure boundary components'' since the NRC believes such components, due to their importance to safety, should continue to be designed and manufactured as basic components under an Appendix B quality assurance program.

Comment. In the definition of ''dedicating entity,'' the word ''qualify'' should be replaced with the word ''accept'' to ensure that the dedication process is differentiated from equipment qualification.

Response. The NRC agrees that the word ''qualify'' could lead to misinterpretation. The definition of ''dedicating entity'' has been revised.

Comment. The proposed definition of ''critical characteristics'' should not be codified for two reasons. First, it is not necessary or beneficial to codify the processes. Second, the term was originally developed by industry to support improved dedication and procurement programs under NUMARC procurement initiatives. There are fundamental differences in the interpretation of the term ''critical characteristics'' between the NRC and much of the nuclear industry.

Response. The NRC believes it is important to define and codify ''critical characteristics'' because this term represents a subject of importance in the dedication process for commercial grade items. The Commission is aware that in the Electric Power Research Institute's (EPRI) ''Guideline for the Utilization of Commercial Grade Items in Nuclear Safety Related Applications,'' EPRI NP–5652, ''critical characteristics'' is defined primarily in procurement terms, i.e., that the item received is the item specified as verified by part number. However, in the Commission's view, this is an appropriate term by which to convey the intent of this rulemaking that the dedication process specify those characteristics important to the design, material, and performance of an item so that the verification of those characteristics will provide reasonable assurance that the item will perform its intended safety function.

Comment. One utility commented that a backfit analysis should be required because new requirements for dedication are being specified.

Response: The current Part 21 regulation already provides for the dedication of commercial grade items to be used in safety-related applications. The final rule provides for a broadening of the definition of commercial grade items and their subsequent dedication for safety-related service. The rule does not impose a more restrictive requirement upon any licensee or dedicating entity; therefore, it does not constitute a backfit as defined in 10 CFR 50.109(a)(1), and no backfit analysis is necessary.

Comment. Part 21 does not clearly address the responsibilities for reporting defects and failures to comply associated with the purchase and subsequent transfer of a basic component by one utility to another. A provision should be included in the rulemaking allowing one utility to accept an item as a basic component when the utility supplying the item is unwilling to accept the Part 21 responsibilities associated with this kind of transaction. The utility purchasing the item should document the qualification of the vendor during the time of original manufacture and sale of the item.

Response: The NRC does not agree with the position set forth in this comment. The Part 21 regulation specifies the responsibilities of any individual or corporation and each director and responsible officer of such organization that supplies basic components. Those responsibilities are also applicable to utilities which supply basic components to other utilities. Nothing in the regulation prevents a utility from contacting the original supplier or manufacturer for the direct transfer of information regarding the item.

Basis for Commission's Decision

The NRC has reviewed the public comments that were submitted on the proposed rule. The final rule has taken into consideration many of the suggested changes as indicated in this Statement of Considerations.

When Part 21 was first issued in 1977, the suppliers of all parts making up a basic component were subject to the reporting requirements under Part 21. However, recognizing that the Commission lacked experience in implementing a reporting program of this scope, the Commission also pointed out in the Statement of Considerations accompanying this part that it would examine closely the implementation of Part 21 as the Commission gained experience. Following the issuance of Part 21, the NRC received many requests for clarification of the regulations. The NRC examined the issue of how far down the procurement chain Part 21 should be applicable and on October 19, 1978 (43 FR 4862), amended Part 21 to exempt commercial grade items from the reporting requirements of Part 21 until the items were dedicated for use as a basic component. The NRC held that the October 1978 rule was needed for safety reasons. Problems such as the inability to obtain needed parts and services were all cited as detriments to safety. The NRC was challenged on this amendment and the court of appeals upheld the Commission's interpretation of section 206 of the ERA requiring the Commission to ''draw a line somewhere to demarcate the outer boundaries of the duty to report'' (*Natural Resources Council* v. *NRC,* 666 F.2d 595 (D.C. Cir. 1981)).

Problems such as the inability to obtain parts and services from the most qualified suppliers and excessive delays

in procurements were all cited as detriments to safety. With the development of increased confidence in licensee implementation of dedication activities through NRC inspection and experience, and because the availability of basic components has further declined, the NRC believes that the current definition of commercial grade items has become unnecessarily restrictive.

The petitioner proposed that a commercial grade item be defined as any item that has not been dedicated for use as a basic component. Thus, any commercial grade item could be subject to a dedication process to verify its qualification as a basic component. The Commission maintains that not all commercial grade items can be properly dedicated for safety-related use after the manufacturing process is completed. In fact several commenters agreed that there is a limited category of components for which quality assurance is an integral part of the manufacturing process and that their critical characteristics cannot be attested to after-the-fact. The Commission believes that if the design or manufacturing process of an item is such that dedication cannot reasonably assure the absence of a defect that could affect one or more critical characteristics of the item, the item must be designed and manufactured as a basic component in accordance with 10 CFR Part 50, Appendix B requirements. There are components in this limited category that generally have requirements and applications in which the design and manufacturing processes require in-process inspections and verifications to ensure that defects and failures to comply are identified and corrected. Thus, the NRC believes that commercial grade items cannot encompass the full spectrum of items envisioned by the petitioner.

Part 21 currently defines a commercial grade item as an item that is (1) Not subject to nuclear-unique design or specification requirements; (2) used in applications outside the nuclear industry; and (3) ordered on the basis of specifications set forth in the manufacturer's published product description. This set of conditions resulted in very limited use of the commercial grade item designation. To provide added flexibility in using commercial grade items for safety-related service by nuclear power plant licensees, the NRC is replacing the set of conditions and adopted a new definition for commercial grade item. Under this new definition, a ''commercial grade item,'' when applied to nuclear power plants, means a structure, system, or component, or part thereof that affects its safety function, that was not designed and manufactured as a basic component. The definition makes clear that a commercial grade item that is part of a basic component but does not affect a safety-related function need not be dedicated and that item is not considered a basic component. Commercial grade items do not include items in which their design and manufacturing process require in-process inspections and verifications to ensure that defects or failures to comply are identified and corrected (i.e., one or more critical characteristics of the item cannot be verified). Typical examples include, but are not limited to, fuel assemblies, control rod assemblies, and reactor coolant pressure boundary components. Thus the definition of ''commercial grade item'' does not include items whose quality assurance is an integral part of the manufacturing process and whose acceptance is based primarily on the vendor's certification of compliance with specific design requirements. For facilities and activities licensed pursuant to 10 CFR Parts 30, 40, 50 (other than nuclear power plants), 60, 61, 70, 71, or 72, the existing definition is retained, although proposed revisions to Part 21 for application to these facilities and activities (including those certified under 10 CFR Part 76) are under consideration in a separate rulemaking.

The new definition is not intended to restrict the licensee from purchasing commercial grade items for subsequent dedication for safety-related applications even though a basic component designed and manufactured under an Appendix B to 10 CFR Part 50 quality assurance program is currently available. The commercial grade item, when properly and successfully dedicated, is deemed by the NRC to be equivalent in its safety function performance to the same or a similar item designed and manufactured under an Appendix B to Part 50 quality assurance program.

Sections 21.6, 21.21, 21.31, 21.41, and 21.51 contain the NRC's requirements for posting, notification, inspection, records, and maintenance and inspection of records, respectively. The NRC is clarifying these sections to point out that dedicating entities are subject to the regulations in these sections. In addition, minor editorial changes have been made in § 21.51(b).

Section 21.61 has been amended to clarify the scope of this section. NRC licensees and their employees subject to Part 21 are also subject to the normal enforcement process and sanctions. In addition, Section 206 of the Energy Reorganization Act of 1974, as amended, and implemented by 10 CFR Part 21, imposes an obligation on firms and organizations that are involved in the nuclear industry, and further, imposes these obligations as a direct liability on certain individuals in these firms and organizations. The ''knowingly and consciously'' standard specified in § 21.61 applies only to non-licensees.

Environmental Impact: Categorical Exclusion

The NRC has determined that this regulation is the type of action described in the categorical exclusion in 10 CFR 51.22(c)(1). Therefore, neither an environmental impact statement nor an environmental assessment has been prepared for this regulation.

Paperwork Reduction Act Statement

This rule does not contain a new information collection requirement subject to the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 et seq.). Existing requirements were approved by the Office of Management and Budget approval number 3150–0035.

Regulatory Analysis

The Commission has prepared a regulatory analysis on this regulation. The analysis examines the costs and benefits of the alternatives considered by the Commission. The analysis is available for inspection in the NRC Public Document Room, 2120 L Street NW. (Lower Level), Washington, DC. Single copies may be obtained from (See **FOR FURTHER INFORMATION CONTACT.**)

Regulatory Flexibility Certification

In accordance with the Regulatory Flexibility Act of 1980 (5 U.S.C. 605(b)), the Commission certifies that this rule, if promulgated, will not have a significant economic impact on a substantial number of small entities. The rule primarily impacts nuclear power plant licensees because they are expected to assume a greater role in the dedication process. The companies that own these plants do not fall within the scope of the definition of ''small entities'' set forth in the Regulatory Flexibility Act or the size standards established by the NRC (10 CFR 2.810). In addition, the rule, when promulgated, will allow small entities to more effectively compete in providing components and services to nuclear power plants, and to the extent this occurs, the rule is advantageous to them.

Backfit Analysis

The Commission has determined that the backfit rule, 10 CFR 50.109, does not apply to this rule. These amendments do not involve any provision that would impose additional requirements requiring a backfit analysis as defined in 10 CFR 50.109(a)(1).

List of Subjects in 10 CFR Part 21

Nuclear power plants and reactors, Penalties, Radiation protection, Reporting and recordkeeping requirements.

For the reasons set out in the preamble and under the authority of the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974 as amended, and 5 U.S.C. 552 and 553, the NRC is adopting the following amendments to 10 CFR Part 21.

PART 21—REPORTING OF DEFECTS AND NONCOMPLIANCE

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

Authority: Sec. 161, 68 Stat. 948, as amended; sec. 234, 83 Stat. 444, as amended; sec. 1701, 106 Stat. 2951, 2953 (42 U.S.C. 2201, 2282, 2297f); secs. 201, as amended, 206, 88 Stat. 1242, as amended, 1246 (42 U.S.C. 5841, 5846).

Section 21.2 also issued under secs. 135, 141, Pub. L. 97–425, 96 Stat. 2232, 2241 (42 U.S.C. 10155, 10161).

§ 21.2 [Amended]

2. Section 21.2 (d) is amended by revising the reference reading ''(see § 21.3(a–1)'' to read ''(as defined in § 21.3),'' and in the third sentence of this section, change the word ''five'' to ''four.''

3. Section 21.3 is amended by removing the paragraph designations from each of the defined terms and arranging the definitions in alphabetical order, removing the words ''paragraph (d)(1) of'' in paragraph (2) of the term *Defect,* removing the parenthetical references in the terms *Defect* and *Deviation,* revising the terms *Basic component, Commercial grade item,* and *Dedication,* and adding the terms *Critical characteristics* and *Dedication entity* to read as follows:

§ 21.3 Definitions.

Basic component. (1)(i) When applied to nuclear power plants licensed pursuant to 10 CFR Part 50 of this chapter, basic component means a structure, system, or component, or part thereof that affects its safety function necessary to assure:

(A) The integrity of the reactor coolant pressure boundary;

(B) The capability to shut down the reactor and maintain it in a safe shutdown condition; or

(C) The capability to prevent or mitigate the consequences of accidents which could result in potential offsite exposures comparable to those referred to in § 100.11 of this chapter.

(ii) Basic components are items designed and manufactured under a quality assurance program complying with 10 CFR Part 50, Appendix B, or commercial grade items which have successfully completed the dedication process.

(2) When applied to other facilities and when applied to other activities licensed pursuant to 10 CFR Parts 30, 40, 50 (other than nuclear power plants), 60, 61, 70, 71, or 72 of this chapter, basic component means a structure, system, or component, or part thereof that affects their safety function, that is directly procured by the licensee of a facility or activity subject to the regulations in this part and in which a defect or failure to comply with any applicable regulation in this chapter, order, or license issued by the Commission could create a substantial safety hazard.

(3) In all cases, basic component includes safety-related design, analysis, inspection, testing, fabrication, replacement of parts, or consulting services that are associated with the component hardware whether these services are performed by the component supplier or others.

Commercial grade item. (1) When applied to nuclear power plants licensed pursuant to 10 CFR Part 50, commercial grade item means a structure, system, or component, or part thereof that affects its safety function, that was not designed and manufactured as a basic component. Commercial grade items do not include items where the design and manufacturing process require in-process inspections and verifications to ensure that defects or failures to comply are identified and corrected (i.e., one or more critical characteristics of the item cannot be verified).

(2) When applied to facilities and activities licensed pursuant to 10 CFR Parts 30, 40, 50 (other than nuclear power plants), 60, 61, 70, 71, or 72, commercial grade item means an item that is:

(i) Not subject to design or specification requirements that are unique to those facilities or activities;

(ii) Used in applications other than those facilities or activities; and

(iii) To be ordered from the manufacturer/supplier on the basis of specifications set forth in the manufacturer's published product description (for example, a catalog).

* * * * *

Critical characteristics. When applied to nuclear power plants licensed pursuant to 10 CFR Part 50, critical characteristics are those important design, material, and performance characteristics of a commercial grade item that, once verified, will provide reasonable assurance that the item will perform its intended safety function.

Dedication. (1) When applied to nuclear power plants licensed pursuant to 10 CFR Part 50, dedication is an acceptance process undertaken to provide reasonable assurance that a commercial grade item to be used as a basic component will perform its intended safety function and, in this respect, is deemed equivalent to an item designed and manufactured under a 10 CFR Part 50, Appendix B, quality assurance program. This assurance is achieved by identifying the critical characteristics of the item and verifying their acceptability by inspections, tests, or analyses performed by the purchaser or third-party dedicating entity after delivery, supplemented as necessary by one or more of the following: commercial grade surveys; product inspections or witness at holdpoints at the manufacturer's facility, and analysis of historical records for acceptable performance. In all cases, the dedication process must be conducted in accordance with the applicable provisions of 10 CFR Part 50, Appendix B. The process is considered complete when the item is designated for use as a basic component.

(2) When applied to facilities and activities licensed pursuant to 10 CFR Parts 30, 40, 50 (other than nuclear power plants), 60, 61, 70, 71, or 72, dedication occurs after receipt when that item is designated for use as a basic component.

Dedicating entity. When applied to nuclear power plants licensed pursuant to 10 CFR Part 50, dedicating entity means the organization that performs the dedication process. Dedication may be performed by the manufacturer of the item, a third-party dedicating entity, or the licensee itself. The dedicating entity, pursuant to § 21.21(c) of this part, is responsible for identifying and evaluating deviations, reporting defects and failures to comply for the dedicated item, and maintaining auditable records of the dedication process.

* * * * *

3. In § 21.6, paragraph (a) is revised to read as follows:

§ 21.6 Posting requirements.

(a) (1) Each individual, partnership, corporation, dedicating entity, or other entity subject to the regulations in this part shall post current copies of—

(i) The regulations in this part;

(ii) Section 206 of the Energy Reorganization Act of 1974; and

(iii) Procedures adopted pursuant to the regulations in this part.

(2) These documents must be posted in a conspicuous position on any premises within the United States where the activities subject to this part are conducted.

* * * * *

4. In § 21.21, the introductory text of paragraph (a) is revised, paragraphs (c) and (d) are redesignated as paragraphs (d) and (e), and a new paragraph (c) is added to read as follows:

§ 21.21 Notification of failure to comply or existence of a defect and its evaluation.

(a) Each individual, corporation, partnership, dedicating entity, or other entity subject to the regulations in this part shall adopt appropriate procedures to—

* * * * *

(c) A dedicating entity is responsible for—

(1) Identifying and evaluating deviations and reporting defects and failures to comply associated with substantial safety hazards for dedicated items; and

(2) Maintaining auditable records for the dedication process.

* * * * *

5. Section 21.31 is revised to read as follows:

§ 21.31 Procurement documents.

Each individual, corporation, partnership, dedicating entity, or other entity subject to the regulations in this part shall ensure that each procurement document for a facility, or a basic component issued by him, her or it on or after January 6, 1978, specifies, when applicable, that the provisions of 10 CFR Part 21 apply.

6. Section 21.41 is revised to read as follows:

§ 21.41 Inspections.

Each individual, corporation, partnership, dedicating entity, or other entity subject to the regulations in this part shall permit the Commission to inspect records, premises, activities, and basic components as necessary to accomplish the purposes of this part.

7. In § 21.51 the introductory text of paragraph (a) and paragraph (b) are revised to read as follows:

§ 21.51 Maintenance and inspection of records.

(a) Each individual, corporation, partnership, dedicating entity, or other entity subject to the regulations in this part shall prepare and maintain records necessary to accomplish the purposes of this part, specifically—

* * * * *

(b) Each individual, corporation, partnership, dedicating entity, or other entity subject to the regulations in this part shall permit the Commission the opportunity to inspect records pertaining to basic components that relate to the identification and evaluation of deviations, and the reporting of defects and failures to comply, including any advice given to purchasers or licensees on the placement, erection, installation, operation, maintenance, modification, or inspection of a basic component.

8. Section 21.61 is revised to read as follows:

§ 21.61 Failure to notify.

(a) Any director or responsible officer of an entity (including dedicating entity) that is not otherwise subject to the deliberate misconduct provisions of this chapter but is subject to the regulations in this part who knowingly and consciously fails to provide the notice required as by § 21.21 shall be subject to a civil penalty equal to the amount provided by section 234 of the Atomic Energy Act of 1954, as amended.

(b) Any NRC licensee subject to the regulations in this part who fails to provide the notice required by § 21.21 or otherwise fails to comply with the applicable requirements of this part shall be subject to a civil penalty as provided by section 234 of the Atomic Energy Act of 1954, as amended.

(c) The dedicating entity, pursuant to § 21.21(c) of this part, is responsible for identifying and evaluating deviations, reporting defects and failures to comply for the dedicated item, and maintaining auditable records of the dedication process. NRC enforcement action can be taken for failure to identify and evaluate deviations, failure to report defects and failures to comply, or failure to maintain auditable records.

Dated at Rockville, Maryland, this 8th day of September 1995.

For the Nuclear Regulatory Commission.

James M. Taylor,

Executive Director for Operations.

[FR Doc. 95–23179 Filed 9–18–95; 8:45 am]

BILLING CODE 7590–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 1000 and 1002

[Docket No. 82N–0273]

RIN 0905–AD78

Records and Reports Regulations for Radiation Emitting Electronic Products

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending its regulations regarding the requirements for recordkeeping and reporting of adverse experiences and other information relating to radiation emitting electronic products. This rule reduces recordkeeping and reporting requirements for some products, requires only abbreviated reporting for other products, and clarifies certain requirements. The timing and content of certain reports will be revised to enhance the usefulness of the information. These amendments will improve protection of the public health while reducing regulatory burdens on manufacturers, dealers, and distributors of radiation emitting electronic products.

EFFECTIVE DATE: October 19, 1995.

FOR FURTHER INFORMATION CONTACT: Joanne Barron, Center for Devices and Radiological Health (HFZ–300), Food and Drug Administration, 2094 Gaither Rd., Rockville, MD 20850, 301–594–4654.

SUPPLEMENTARY INFORMATION:

I. Background

The Regulatory Flexibility Act (5 U.S.C. 601) and Executive Order 12866 require FDA to periodically conduct a comprehensive review of existing regulations. This review is to analyze alternative regulatory approaches and to identify regulations that need to be revised or revoked because they impose an unnecessary burden on specific segments of the public, such as manufacturers, dealers, small businesses, or the general public. In the Federal Register of July 2, 1982 (47 FR 29004), FDA announced its plan to review the records and reports regulations in part 1002 (21 CFR part 1002). FDA recognized that, although part 1002 does not appear to have a major impact on the overall radiation emitting electronic products industry, its impact on small manufacturers

should not be overly burdensome and should be determined.

FDA recognizes that, for some products, meeting the full recordkeeping and reporting requirements is not necessary to protect the public health. Therefore, in the final rule, FDA has reduced the recordkeeping and reporting requirements for some products and determined that an abbreviated report is sufficient regulatory monitoring for other products. FDA also recognizes that some sections of the regulations need additional clarification to be more meaningful and reduce regulatory burdens. Thus, FDA has adopted certain amendments to clarify its regulations.

On October 25, 1990, FDA published in the Federal Register (55 FR 43066) a proposed rule amending its regulations regarding the requirements for recordkeeping, reporting, and other information relating to radiation emitting electronic products. FDA invited interested parties to comment on the proposed rule by January 22, 1991. The comment period was later extended until March 25, 1991 (56 FR 7316). FDA received 11 comments. A summary of these comments and FDA's responses to them are set forth below. FDA is finalizing the proposed rule at this time and incorporating changes that are the result of the agency's review of the comments.

FDA is also amending references to statutory citations to reflect changes in the law. On November 28, 1990, the President signed into law the Safe Medical Devices Act of 1990 (the SMDA), which amended the Federal Food, Drug, and Cosmetic Act (the act). Section 19 of the SMDA transferred the Radiation Control for Health and Safety Act of 1968 from the Public Health Service Act (the PHS Act) into the act as subchapter C. Thus, all references to the PHS Act in parts 1000 and 1002 (21 CFR parts 1000 and 1002) are being revised to reflect this change. Additionally, the agency is changing all references to the ''Office of Compliance and Surveillance'' throughout parts 1000 and 1002 to the ''Office of Compliance'' to reflect an organizational change within the Center for Devices and Radiological Health (CDRH). The agency is also changing references to ''the Secretary'' and to ''the Director'' of CDRH in order to reflect the delegation of the Secretary's authority in accordance with 21 CFR 5.90.

II. Highlights of the Final Rule

To reduce the regulatory burden on the industry, FDA is amending regulations regarding the recordkeeping and reporting requirements for certain radiation emitting electronic products.

First, the reporting requirements in § 1002.12 (reports of model changes) have been consolidated with the requirements of § 1002.10 (initial reports), and the name ''initial report'' has been changed to ''product report.''

Second, FDA has developed two new categories of reports, ''supplemental reports'' in § 1002.11, and ''abbreviated reports'' in § 1002.12. New § 1002.11 (supplemental reports), which requires manufacturers to provide information on product safety and testing, applies to a smaller subset of manufacturers, and reduces the number of required reports by approximately 40 percent. New § 1002.12 (abbreviated reports) requires manufacturers to report abbreviated information on product safety and testing and replaces the existing requirements for many initial reports and model change reports. Although the total combined number of product reports and abbreviated reports will remain about the same as the former initial reports and model change reports, the time necessary to complete the reports will be reduced by approximately 60 percent.

Finally, FDA has limited the applicability of the records requirements in §§ 1002.30 and 1002.40. These changes have reduced the number of records to be maintained by manufacturers and by dealers/distributors by 50 percent and 99 percent, respectively.

Overall, this final rule will reduce the annual reporting and recordkeeping burden hours on the industry by 81 percent, without reducing public health protection.

III. Comments

The following is a summary of the comments and the agency's responses to them.

A. Reporting Requirements

1. One comment stated that there are no relevant changes in the content or format of the initial report to warrant a name change to ''product report.'' The comment states that the name change would result in unnecessary additional costs because personnel, particularly nonregulatory staff, who are familiar with the term initial report, would need to be reeducated.

FDA recognizes that, as with any new requirement, the affected parties may need some training in order to appreciate and understand the changes. In this case, the change is intended to lessen the burden of this requirement by clearly describing the reports that are required, and the filing and content requirements of such reports. For example, FDA has deleted the reference to a 90-day due date for filing an initial report (see revised § 1002.10) because that requirement was applicable only to newly listed products. FDA believes that the long-term benefits of such changes—clearer regulatory requirements, a reduced regulatory burden on industry, and improved cost effectiveness and efficiency—outweigh its short-term training costs. Because FDA and the industry have used the previous term for 20 years, it is expected that there will be a period of transition to the new term over the next year for both the industry and FDA personnel.

2. One comment stated that industrial x-ray systems should not be included in the list of products for which abbreviated reports, rather than initial reports (to be called ''product reports''), are required. The comment expressed the belief that industrial x-ray systems should follow the same reporting requirements as diagnostic x-ray and other x-ray systems.

FDA included analytical and industrial x-ray equipment in the list of products for which abbreviated reports are required because there is no FDA radiation performance standard for these products and, unlike diagnostic x-ray systems, any exposure of people to radiation would be unintentional. In addition, the users of such equipment are trained to be more aware of precautions necessary to reduce or eliminate exposures. In the event that a public health concern arises, however, the regulation would permit FDA to request additional safety information from the manufacturer.

3. One comment asked whether FDA will exempt linear accelerators and low-energy therapy x-ray devices from annual reporting requirements.

Linear accelerators and low-energy therapy x-ray equipment are included in § 1002.1, Table 1, under the category of ''Products Intended to Produce Particulate Radiation or X-rays Other Than Diagnostic or Cabinet X-ray.'' The format of Table 1 has been modified to make clear that the requirements are the same for all medical, analytical, and industrial systems that fall within this product category. Specifically, manufacturers are required to submit abbreviated and annual reports and to maintain test and distribution records for these products.

4. One comment expressed the concern that, unlike television receivers, video display terminals (VDT's) are not specifically delineated by FDA under the reporting and recordkeeping provisions of the regulations. The comment stated that there is little

difference between television receivers and VDT screens and monitors and, therefore, these products should be treated similarly in these provisions. The comment stated that recent investigations of VDT use have shown that low levels of electromagnetic radiation are emitted from certain brands and models. The comment stated that the health and safety effects of these emissions are unknown, but the nature of most VDT work suggests that the effects may be detrimental. Given the health concerns, and the fact that such emissions have generally not been examined, the comment recommended that manufacturers be required to provide product reports, supplemental reports, annual reports, and test records to VDT purchasers, who in turn should be required to relay such information to their employees and representatives. The comment suggested that the hazard communication standard under the Occupational Safety and Health Act (29 CFR 1910.1200) would provide a model for FDA in constructing radiation recordkeeping requirements for VDT's.

FDA has used the designation ''television products'' in § 1002.1, Table 1, to reflect the scope of the product category that is the subject of the performance standard for television receivers at 21 CFR 1020.10. The intent of that standard has been to reduce unnecessary x-ray exposure to persons from any electronic product that can display a viewable picture on a cathode ray tube (CRT). FDA agrees that there are a number of clarifications that need to be made regarding this category of products. FDA anticipates issuing a notice of proposed rulemaking to amend the television receiver standard to address the issues raised in this comment and other issues concerning VDT's. FDA will propose the appropriate changes to part 1002 when the performance standard for television receivers is amended.

With respect to the suggestion that manufacturers be required to provide reports and records to users of VDT's, amended § 1002.3 will provide the mechanism for FDA to require manufacturers to provide the ultimate purchaser of the product with necessary performance and technical data.

5. One comment stated that a 25 kilovolt (kV) criterion should be established for television receivers to differentiate between television receivers that will be subject to relatively moderate reporting requirements (abbreviated reports and annual reports) and those that will be subject to more substantial reporting requirements (product reports, supplemental reports, and annual reports).

FDA agrees with this comment and adopted a 25 kV criterion in the rule. See § 1002.1, Table 1.

6. One comment stated that television receivers with less than 25 kV and less than 0.1 milliroentgen per hour (mR/hr) should be relieved of the annual report requirement of 1002.13 and the preservation and inspection of records provisions of § 1002.31. The comment asserted that exemptions from these provisions already apply to receivers with less than 25 kV pursuant to a 1987 letter to industry which stated that only status identification is required for annual reports on these products.

Consistent with the November 16, 1987, letter to manufacturers of television receiver products from the Director of CDRH (Ref. 1), television receivers which, when tested under phase III conditions, will not equal or exceed 25 kV and for which the chassis power curve will not reach or exceed the 0.1 mR/hr isoexposure rate limit curve (IRLC) are relieved of the annual report requirement of § 1002.13 and the preservation and inspection of records provisions of § 1002.31. Section 1002.1, Table 1, has been revised accordingly.

7. One comment noted discrepancies between the preamble language and Table 1 of the proposed rule. The preamble states that abbreviated reports will replace initial and supplemental reports for ''certain television products.'' The text further states that product reports, but not supplemental reports, will be required for television receivers emitting less than 0.1 mR/hr. However, Table 1 of the proposed rule states that television receivers with less than 25 kV and less than 0.1 mR/hr will require abbreviated reports and television receivers emitting greater than 0.1 mR/hr will require only product reports (not supplemental reports). The comment supports the requirements as set forth in Table 1, but recommends, consistent with the preamble, that the requirement for supplemental reports be deleted for television receivers with greater than 25 kV and less than 0.1 mR/hr.

FDA has corrected the errors appearing in Table 1. Since November 16, 1987, the policy at CDRH has been that certain categories of television products may be exempt from some of the reporting and recordkeeping requirements, depending on the maximum high voltage on the picture tube and the possibility of emission of x-rays at or above 0.1 mR/hr. Manufacturers were given the responsibility to conduct phase III tests and inform CDRH, through annual reports, which models qualify for such exemptions. The agency's intention was to maintain the same level of requirements under the amended reporting and recordkeeping regulations that has previously been in effect for products that may operate at or above 25 kV and products that may emit x-rays at a rate of 0.1 mR/hr or above. The agency believes that these products represent different levels of risks and that different levels of recordkeeping and reporting requirements continue to be appropriate for each category.

Therefore, any television product that contains a CRT or other component capable of producing x-rays, and which, when tested under phase III conditions, will not equal or exceed 25 kV and for which the chassis power curve will not reach or exceed the 0.1 mR/hr IRLC, will require only abbreviated reports. A television product containing a CRT, which, when tested under phase III conditions, may equal or exceed 25 kV but for which the chassis power curve does not reach or exceed the 0.1 mR/hr IRLC, will require product reports, supplemental reports, and annual reports. A television product containing a CRT, for which, when tested under phase III conditions, the chassis power curve reaches or exceeds the 0.1 mR/hr IRLC, will require product reports, supplemental reports, annual reports, and maintenance of the records of test results and distribution of products for 5 years.

Manufacturers must continue to conduct an adequate quality control and testing program to ensure continued compliance of all models with the performance standard. Products for which there is no requirement that test results be kept for 5 years must, nevertheless, be tested adequately and the results should be reviewed by a quality control manager. These products should be rejected at a maximum limit of 0.1 mR/hr when tested under phase III conditions.

The agency retains the authority to inspect all documents supporting the adequacy of the manufacturer's quality control and testing program, including programs for these products for which it is not necessary to retain test results for 5 years. The final rule has added a footnote to Table 1 (footnote 1) to clarify this point.

8. One comment stated that FDA should codify its existing practice concerning importation of products for compliance testing and other related purposes to reduce the potential for confusion about the precise terms and conditions surrounding these activities. The comment stated that bulletins sent by FDA to the industry have stated, at

least with respect to television receivers and laser products, that FDA performance standards do not apply to products ''that are imported for purpose of research, investigations, studies, demonstrations, or training, and that consist of 10 or fewer units per shipment,'' so long as certain administrative safeguards are observed.

The scope of this rule is limited to the reporting andrecordkeeping requirements in part 1002 and is not intended to amend FDA practices and regulations regarding the scope of the applicability of performance standards. Under current policies, FDA allows exemptions from performance standards for 10 or fewer units of certain products (i.e., television products, microwave ovens, and certain laser products), that are imported for test and evaluation and remain under the importer's control, if such products are properly labeled. These exemptions are referenced in FDA Compliance Program 7382.007 which is available from the Division of Small Manufacturers Assistance, Center for Devices and Radiological Health (HFZ–220), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 800–638–2041 or 301–443–6597. These policies will be continued but this rule does not expand the scope of that exemption to all products. However, the rule codifies procedures that allow manufacturers to apply for special exemptions from the reporting and recordkeeping requirements of part 1002 or the Director of CDRH to grant such exemptions on his or her own. See §§ 1002.50(a)(3) and 1002.50(b).

9. One comment requested that FDA clarify the distinctionbetween television receivers and CRT's and explain whether there are differences in the regulations that apply to the products that fall within these two categories. The comment noted that the majority of television receivers use CRT's to display video images (a small minority of receivers use liquid crystal displays), and the comment was uncertain why television receivers remain subject to various reporting requirements while CRT's will be generally exempt from reporting requirements, with the exception of § 1002.20. The comment further stated that FDA's distinction apparently depends on whether a device is limited by design to display only alphanumeric characters (CRT) or whether it can also display other video images (television receiver). The comment stated that FDA's distinction does not appear to be based on public health considerations, and that confusion and potential compliance problems would be avoided by adopting a definition of television that is more consistent with that of the affected industry. The comment suggests that FDA consider adopting the definition used by the FCC, which defines television receiver as a ''device designed to receive television pictures that are broadcast simultaneously with sound on the television channels authorized under part 73 of the FCC's rules.'' (See 47 CFR 15.3(w)(1990)).

Previously, the regulations required manufacturers to submit initial, model change, and annual reports for television receivers and to submit initial and model change reports for CRT's. A CRT is an electronic product component and, as such, is subject to the general radiation safety requirements, but not subject to a performance standard. FDA has determined that the Joint Electron Device Engineering Council/Tube Engineering Panel Advisory Council (JEDEC/TEPAC) data on CRT's that is available from the Electronic Industries Association is sufficient for FDA to assess the potential radiation hazards for CRT's; therefore, any additional reports on the CRT's are not necessary. However, the monitors and video display products that contain the CRT's and associated electronics are subject to the television receiver standard. Accordingly, manufacturers are required to demonstrate that these products, including the CRT's contained in them, meet the standard and to report how the products are tested for compliance. FDA currently is reviewing whether to change the performance standard for television receivers to clarify the definitions of products to which the standard is applicable. This comment will be included in that review.

B. Exemptions

10. One comment proposed that manufacturers of products forwhich there is no applicable performance standard under 21 CFR part 1020 and for which a 510(k) premarket notification (510(k)) has been submitted and cleared in accordance with part 807, subpart E, be exempt from submitting all reports listed in Table 1 of proposed § 1002.1. The comment believes it would be appropriate to include manufacturers of these products in the exemption under proposed § 1002.50(e), because sufficient information regarding safety and effectiveness has been obtained through FDA review of the 510(k) submission. Alternatively, the comment suggests that the fact that any particular electronic product is also a medical device subject to 510(k) notifications should be included among the criteria for considering a special exemption under proposed § 1002.50(a).

Generally, a 510(k) notice on a medical device is submitted to FDA to demonstrate that a design specification is substantially equivalent to the specifications of a predicate device. The radiation safety reporting required by this part of the regulations is intended to provide information on actual production testing and quality control and on the actual product design as produced. If the two are redundant in any particular circumstance, the Director of CDRH can issue exemptions from the reporting and recordkeeping requirements in accordance with § 1002.50(b). FDA does not believe a general exemption from the reporting requirement is in the interest of public health.

11. One comment objected to the exemption of distributors and dealers from the recordkeeping requirement for microwave ovens. The comment states that if such an exemption is granted, these products would be much more difficult to locate to ensure their safety. The comment notes that customer warranty registrations are not sufficient to locate products because such registrations are returned by the customers at such a low rate. The comment states that if the dealer/distributor records are no longer required, the burden of locating the microwave oven shifts to the manufacturer who would have no other alternative but to launch an advertising campaign that would be more expensive, less effective, and slower than any recordkeeping on the part of distributors or dealers.

It has been FDA's experience that dealer and distributor records are rarely needed for the intended purpose of notifying purchasers of product noncompliance. In light of the fact that there have been limited recalls of microwave ovens in the past 10 years (due in part to prototype examinations by FDA), FDA believes that it would be overly burdensome to require distributors and dealers to comply with the recordkeeping requirement. When recalls are necessary, FDA believes that purchasers can be notified by other means, such as general media announcements.

12. One comment recommended that FDA exempt televisionreceivers whose voltage on the CRT is less than 5 kV at zero beam current from the recordkeeping and reporting requirements of part 1002, with the exception of § 1002.20. The comment stated that there is no evidence to suggest that products with such a low voltage (generally, videocamera

viewfinders and televisions with 2 or 3 inch screens) are capable of generating x-rays, which is the primary concern in part 1002. Another comment contended that it would be inappropriate to impose testing and reporting requirements on television receivers with less than 5 kV on the CRT, while CRT's with comparable or even greater voltages are exempted.

Under the amended reporting and recordkeeping requirements, television products whose voltage on the CRT is less than 5 kV will require only abbreviated reports and annual reports, and manufacturers may apply for special exemption from these requirements under the new regulations in § 1002.50. FDA will include these comments in the agency's review of possible amendments to the television performance standard.

13. One comment noted that the preamble to the proposed rule states that television receivers emitting less than 0.1 mR/hr will be exempt from the requirements of maintaining manufacturer's testing and distribution records. The preamble also notes that other products, including ''television receivers,'' are already exempt from these requirements. In comparison, Table 1 of the proposed rule exempts all television receivers from the requirements to maintain manufacturer testing and distribution records. The comment supports the exemption for all television receivers as reflected in Table 1.

A similar concern about the discrepancy between the preamble and Table 1 was addressed above in comment 7. There was an error in the printing of Table 1 of the proposed rule. For television receivers for which the chassis power curve reaches or exceeds the 0.1 mR/hr IRLC, there should have been an X in the following columns: Supplemental reports, Test records, and Manufacturer distribution records. These reports and records are important for FDA to monitor the safety of those products which, by design, can emit radiation levels above background. Table 1 has been amended accordingly.

14. One comment noted an inadvertent error with respect tomanufacturer distribution recordkeeping requirements under § 1002.30(b). The comment stated that FDA has eliminated these requirements for class I lasers and products containing such lasers. Proposed Table 1 to § 1002.1, however, appears to state that class I lasers and products containing class I lasers will be subject to manufacturer distribution recordkeeping requirements under § 1002.30(b). The comment requested FDA to clarify, by amendment of proposed Table 1, that class I lasers and products containing such lasers will retain the exemptions that already apply, including the exemption for manufacturer's distribution records.

Table 1 has been amended to clarify that the exemption for these products from certain reporting requirements remains in effect. FDA has added to Table 1 a category for ''Class I lasers and laser products containing such lasers,'' that will have X's in the columns for Product Reports, Annual Reports, Manufacturer's Test Records, but not for Supplemental Reports, Abbreviated Reports, Manufacturer's Distribution Records, or Dealer/Distributor Distribution Records.

FDA will determine which reporting category is applicable to a product that may have more than one class of laser on the basis of the worst-case hazard in the product. Thus, a class I laser product containing a class IV laser and a class II alignment laser will fall in the category ''Class IIIb and IV lasers and products containing such lasers,'' because this represents the worst-case hazard within the product. Table 1 has been supplemented with a footnote to explain this policy (footnote 7).

15. One set of comments supported the agency's efforts to minimize the reporting and recordkeeping requirements for radiation emitting electronic products. Another comment disagreed with the intent to eliminate initial reports for diagnostic ultrasound equipment. Instead, that comment proposed that diagnostic ultrasound equipment be added to the category of products for which an abbreviated report is required, and that such products be exempt from annual reports. The comment stated that this proposal would reduce the burden on the industry from the medical device premarket clearance process.

Currently, diagnostic ultrasound devices are subject to initial reports but not annual reports. However, in a letter to all manufacturers of diagnostic ultrasound products from the CDRH Director dated February 24, 1986 (Ref. 2), these devices were exempted from the initial reports as long as a 510(k) was filed. CDRH issued this letter to reduce the burden and duplication of paperwork on the industry. The agency recognizes the increase in the timeframe necessary to gather all the information that must be submitted in the 510(k) notification, including production test information that otherwise would be contained in the initial report. Therefore, FDA has amended Table 1 to include abbreviated reports for diagnostic ultrasound equipment in order to retain its ability to obtain production test information about these products. However, CDRH intends to continue to exempt these products from the abbreviated (formerly initial) report requirement until documentation submitted for premarket clearance or for special controls is no longer duplicative of information that would be contained in the abbreviated report.

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 final 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. Because the provisions of the final rule reduce or simplify the records and reporting requirements for manufacturers, dealers, and distributors of radiation emitting electronic products, 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. A copy of the document supporting this determination, ''Report of the CDRH Task Force for Retrospective Review of the Recordkeeping and Reporting Requirements of 21 CFR 1002,'' is on file at the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857, and may be seen by interested persons in

that office between 9 a.m. and 4 p.m., Monday through Friday.

VI. Paperwork Reduction Act of 1980

This final rule contains information collections which are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1980 (44 U.S.C. Chapter 35). 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: Reporting and Recordkeeping Requirements for Electronic Products Under Pub. L. 90–602—General Requirements.

Description: The Food and Drug Administration is amending its regulations regarding the requirements for recordkeeping, reporting, and other information relating to radiation emitting electronic products. The timing and content of certain reports will be revised to enhance the usefulness of the information. The purpose of these changes is to improve the protection of the public health while also reducing the regulatory burden on manufacturers, dealers, and distributors of radiation emitting electronic products.

Description of Respondents: Businesses or other for profit organizations.

Estimated annual reporting and recordkeeping burden

Section	Annual number of reports and records	Average burden per response (hours)	Annual burden (hours)
1002.10, 1002.12			
Existing:			
Initial	320	34	10,880
Model Change	725	42	30,450
Supplements	2,520	0.5	1,260
Subtotal	3,565	avg 11.9	42,590
Amended:			
Product	850	24	20,400
Supplements	1,500	0.5	750
Abbreviated	150	5	750
Subtotal	2,500	avg 8.8	21,900
Total Reports Reduction			20,690
1002.30			
Existing:	4,000,000	0.12	480,000
Amended:	1,904,000	0.12	480,000
Reduction:			251,520
1002.40			
Existing:	17,000,000	0.048	816,000
Amended:	145,000	0.048	6,960
Reduction:			809,040
Total Records Reduction			1,060,560
Total existing annual burden hours			1,338,590
Total amended annual burden hours			257,340
Total difference in annual burden hours			1,081,250
			(81% reduction)

As required by section 3504(h) of the Paperwork Reduction Act of 1980, FDA has submitted a copy of this rule to OMB for its review of these information collection requirements. Other organizations and individuals desiring to submit comments regarding this 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. and 4 p.m., Monday through Friday.

1. Director, CDRH, FDA, letter to manufacturers of television receiver products, dated November 16, 1987.

2. Director, CDRH, FDA, letter to manufacturers of ultrasound products, dated February 24, 1986.

List of Subjects

21 CFR Part 1000

Electronic products, Radiation protection, Reporting and recordkeeping requirements, X-rays.

21 CFR Part 1002

Electronic products, Radiation protection, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act, the Radiation Control for Health and Safety Act, and under authority delegated to the Commissioner of Food and Drugs, 21 CFR parts 1000 and 1002 are amended as follows:

PART 1000—GENERAL

1. The authority citation for 21 CFR part 1000 is revised to read as follows:

Authority: Secs. 530–542 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360hh–360ss).

2. Section 1000.3 is revised to read as follows:

§ 1000.3 Definitions.

As used in this Subchapter J:

(a) Accidental radiation occurrence means a single event or series of events that has/have resulted in injurious or potentially injurious exposure of any person to electronic product radiation as a result of the manufacturing, testing, or use of an electronic product.

(b) Act means the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360hh–360ss).

(c) Chassis family means a group of one or more models with all of the following common characteristics:

(1) The same circuitry in the high voltage, horizontal oscillator, and power supply sections;

(2) The same worst component failures;

(3) The same type of high voltage hold-down or safety circuits; and

(4) The same design and installation.

(d) Commerce means:

(1) Commerce between any place in any State and any place outside thereof, and

(2) Commerce wholly within the District of Columbia.

(e) Component, for the purposes of this part, means an essential functional part of a subassembly or of an assembled electronic product, and which may affect the quantity, quality, direction, or radiation emission of the finished product.

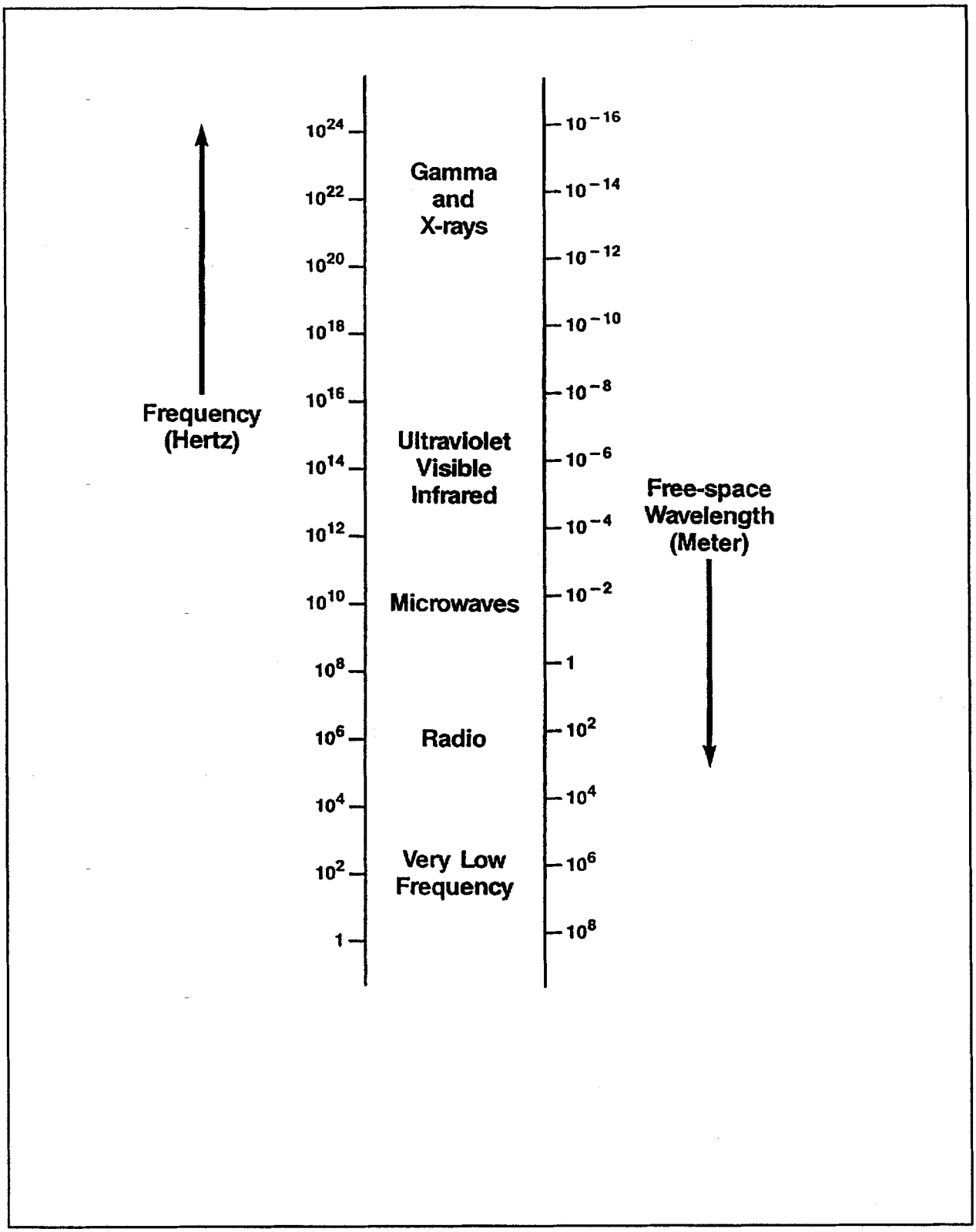
(f) Dealer means a person engaged in the business of offering electronic products for sale to purchasers, without regard to whether such person is or has been primarily engaged in such business, and includes persons who offer such products for lease or as prizes or awards.

(g) Director means the Director of the Center for Devices and Radioloical Health.

(h) Distributor means a person engaged in the business of offering electronic products for sale to dealers, without regard to whether such person is or has been primarily or customarily engaged in such business.

(i) Electromagnetic radiation includes the entire electromagnetic spectrum of radiation of any wavelength. The electromagnetic spectrum illustrated in Figure 1 includes, but is not limited to, gamma rays, x-rays, ultra-violet, visible, infrared, microwave, radiowave, and low frequency radiation.

Figure 1



BILLING CODE 4160–01–C

(j) Electronic product means:

(1) Any manufactured or assembled product which, when in operation:

(i) Contains or acts as part of an electronic circuit and

(ii) Emits (or in the absence of effective shielding or other controls would emit) electronic product radiation, or

(2) Any manufactured or assembled article that is intended for use as a component, part, or accessory of a product described in paragraph (j)(1) of this section and which, when in operation, emits (or in the absence of effective shielding or other controls would emit) such radiation.

(k) Electronic product radiation means:

(1) Any ionizing or nonionizing electromagnetic or particulate radiation, or

(2) Any sonic, infrasonic, or ultrasonic wave that is emitted from an electronic product as the result of the operation of an electronic circuit in such product.

(l) Federal standard means a performance standard issued pursuant to section 534 of the Federal Food, Drug, and Cosmetic Act.

(m) Infrasonic, sonic (or audible) and ultrasonic waves refer to energy transmitted as an alteration (pressure, particle displacement or density) in a property of an elastic medium (gas, liquid or solid) that can be detected by an instrument or listener.

(n) Manufacturer means any person engaged in the business of manufacturing, assembling, or importing electronic products.

(o) Model means any identifiable, unique electronic product design, and refers to products having the same structural and electrical design characteristics and to which the manufacturer has assigned a specific designation to differentiate between it and other products produced by that manufacturer.

(p) Model family means products having similar design and radiation characteristics but different manufacturer model numbers.

(q) Modified model means a product that is redesigned so that actual or potential radiation emission, the manner of compliance with a standard, or the manner of radiation safety testing is affected.

(r) Particulate radiation is defined as:

(1) Charged particles, such as protons, electrons, alpha particles, or heavy particles, which have sufficient kinetic energy to produce ionization or atomic or electron excitation by collision, electrical attractions or electrical repulsion; or

(2) Uncharged particles, such as neutrons, which can initiate a nuclear transformation or liberate charged particles having sufficient kinetic energy to produce ionization or atomic or electron excitation.

(s) Phototherapy product means any ultraviolet lamp, or product containing such lamp, that is intended for irradiation of any part of the living human body by light in the wavelength range of 200 to 400 nanometers, in order to perform a therapeutic function.

(t) Purchaser means the first person who, for value, or as an award or prize, acquires an electronic product for purposes other than resale, and includes a person who leases an electronic product for purposes other than subleasing.

(u) State means a State, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, Guam, and American Samoa.

PART 1002—RECORDS AND REPORTS

3. The authority citation for 21 CFR part 1002 is revised to read as follows:

Authority: Secs. 502, 510, 519, 520, 531–542, 701, 704 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 352, 360, 360i, 360j, 360hh–360ss, 371, 374).

4. Section 1002.1 is revised to read as follows:

§ 1002.1 Applicability.

The provisions of this part are applicable as follows:

(a) All manufacturers of electronic products are subject to § 1002.20.

(b) Manufacturers, dealers, and distributors of electronic products are subject to the provisions of part 1002 as set forth in Table 1 of this section, unless excluded by paragraph (c) of this section, or unless an exemption has been granted under § 1002.50 or § 1002.51.

(c) The requirements of part 1002 as specified in Table 1 of this section are not applicable to:

(1) Manufacturers of electronic products intended solely for export if such product is labeled or tagged to show that the product meets all the applicable requirements of the country to which such product is intended for export.

(2) Manufacturers of electronic products listed in Table 1of this section if such product is sold exclusively to other manufacturers for use as components of electronic products to be sold to purchasers, with the exception that the provisions are applicable to those manufacturers certifying components of diagnostic x-ray systems pursuant to provisions of § 1020.30(c) of this chapter.

(3) Manufacturers of electronic products that are intended for use by the U.S. Government and whose function or design cannot be divulged by the manufacturer for reasons of national security, as evidenced by government security classification.

(4) Assemblers of diagnostic x-ray equipment subject to the provisions of § 1020.30(d) of this chapter, provided the assembler has submitted the report required by § 1020.30(d)(1) or (d)(2) of this chapter and retains a copy of such report for a period of 5 years from its date.

Table 1.—Record and Reporting Requirements By Product

	Manufacturer						
Products	Product reports § 1002.10	Supplemental reports § 1002.11	Abbreviated reports § 1002.12	Annual reports § 1002.13	Test records § 1002.30(a)[1]	Distribution records § 1002.309(b)[2]	Dealer Distributor—Distribution records §§ 1002.40 and 1002.41
DIAGNOSTIC X RAY[3] (1020,30, 1020,31, 1020.32, 1020.33)							
Computed tomography	X	X		X	X	X	X
X-ray system[4]	X	X		X	X	X	X
Tube housing assembly	X	X		X	X	X	
X-ray control	X	X		X	X	X	X
X-ray high voltage generator	X	X			X	X	X
X-ray table or cradle			X		X	X	X
X-ray film changer			X		X	X	X
Vertical cassette holders mounted in a fixed location and cassette holders with front panels			X		X	X	X
Beam-limiting devices	X	X		X	X	X	X
Spot-film devices and image intensifiers manufactured after April 26, 1977	X	X		X	X	X	X
Cephalometric devices manufactured after February 25, 1978			X		X	X	
Image receptor support devices for mammographic x-ray systems manufactured after September 5, 1978			X		X	X	
CABINET X RAY (§ 1020.40)							
Baggage inspection	X	X		X	X	X	X
Other	X	X		X	X	X	

Table 1.—Record and Reporting Requirements By Product

	Manufacturer						
Products	Product reports § 1002.10	Supplemental reports § 1002.11	Abbreviated reports § 1002.12	Annual reports § 1002.13	Test records § 1002.30(a)[1]	Distribution records § 1002.309(b)[2]	Dealer Distributor—Distribution records §§ 1002.40 and 1002.41
PRODUCTS INTENDED TO PRODUCE PARTICULATE RADIATION OR X-RAYS OTHER THAN DIAGNOSTIC OR CABINET X-RAY							
Medical			X	X	X	X	
Analytical			X	X	X	X	
Industrial			X	X	X	X	
TELEVISION PRODUCTS (§ 1020.10)							
<25 kilovolt (kV) and <0.1 millroentgen per hour (mR/hr IRLC[1,2]			X	X[6]			
≤=24kV and <0.1mR/hr IRLC[5]	X	X		X	X	X	
≤=0.1mR/hr IRLC[5]	X	X		X	X	X	
MICROWAVE/RF							
MW ovens (§ 1030.10)	X	X		X	X	X	
MW diathermy			X				
MW heating, drying, security systems			X				
RF sealers, electromagnetic induction and heating equipment, dielectric heaters (2–500 megahertz)			X				
OPTICAL							
Phototherapy products	X	X					
Laser products (§§ 1040.10, 1040.11)							
Class I lasers and products containing such lasers[2]	X			X	X		
Class I laser products containing class IIa, II, IIIa, lasers[7]	X			X	X	X	

Table 1.—Record and Reporting Requirements By Product

Products	Manufacturer						
	Product reports § 1002.10	Supplemental reports § 1002.11	Abbreviated reports § 1002.12	Annual reports § 1002.13	Test records § 1002.30(a)[1]	Distribution records § 1002.309(b)[2]	Dealer Distributor—Distribution records §§ 1002.40 and 1002.41
Class IIa, II, IIIa lasers and products other than class I products containing such lasers[7]DX	X		X	X	X	X	
Class IIIb and IV lasers and products containg such lasers[7]	X	X		X	X	X	X
Sunlamp products (§ 1040.20)							
Lamp only	X						
Sunlamp products	X	X		X	X	X	X
Mercury vapor lamps (§ 1040.30)							
T lamps	X	X		X			
R lamps			X				
ACOUSTIC							
Ultrasonic therapy (1050.10)	X	X		X	X	X	X
Diagnostic ultrasound			X				
Medical ultrasound othe than therapy or diagnostic	X	X					
Nonmedical ultrasound			X				

[1]However, authority to inspect all appropriate documents supporting the adequacy of a manufacturer's compliance testing program is retained.
[2]The requirement includes §§ 1002.31 and 1002.42, if applicable.
[3]Report of Assembly (Form FDA 2579) is required for diagnostic x-ray components; see 21 CFR 1020.30(d)(1) through (d)(3).
[4]Systems records and reports are required if a manufacturer exercises the option and certifies the system as permitted in 21 CFR 1020.30(c).
[5]Determined using the isoexposure rate limit curve (IRLC) under phase III test conditions (1020.10(c)(3)(iii)).
[6]Annual report is for production status information only.
[7]Determination of the applicable reporting category for a laser product shall be based on the worst-case hazard present within the laser product.

§ 1002.2 [Removed]

5. Section 1002.2 Definitions is removed from subpart A.

6. Section 1002.3 is revised to read as follows:

§ 1002.3 Notification to user of performance and technical data.

As authorized by § 5.90 of this chapter, the Director and Deputy Director of the Center for Devices and Radiological Health may require a manufacturer of a radiation emitting electronic product, to provide to the ultimate purchaser at the time of original purchase, such performance data and other technical data related to safety of the product as the Director or Deputy Director finds necessary.

7. Section 1002.7 is amended by adding a new sentenceto the end of the introductory text, by revising the first sentence in paragraph (b), and by adding new paragraph (c) to read as follows:

§ 1002.7 Submission of data and reports.

* * * The submissions required by this part shall be addressed to the Center for Devices and Radiological Health, Electronic Product Reports, Office of Compliance (HFZ–307), 2098 Gaither Rd., Rockville, MD 20850.

* * * * *

(b) Where guides or instructions have been issued by the Director for the submission of material required by this part, such as test data, product reports, abbreviated reports, supplemental reports, and annual reports, the material submitted shall conform to the applicable reporting guides or instructions.

* * *

(c) Where the submission of quality control and testing information is common to more than one model, or model family of the same product

category, a ''common aspects report'' consolidating similar information may be provided, if applicable.

8. Subpart B, consisting of §§ 1002.10 through 1002.13, is revised to read as follows:

Subpart B—Required Manufacturers' Reports for Listed Electronic Products

Sec.
1002.10 Product reports.
1002.11 Supplemental reports.
1002.12 Abbreviated reports.
1002.13 Annual reports.

Subpart B—Required Manufacturers' Reports for Listed Electronic Products

§ 1002.10 Product reports.

Every manufacturer of a product or component requiring aproduct report as set forth in Table 1 of § 1002.1 shall submit a product report to the Center for Devices and Radiological Health, Electronic Product Reports, Office of Compliance (HFZ–307), 2098 Gaither Rd., Rockville, MD 20850, prior to the introduction of such product into commerce. The report shall be distinctly marked ''Radiation Safety Product Report of (name of manufacturer)'' and shall:

(a) Identify which listed product is being reported.

(b) Identify each model of the listed product together with sufficient information concerning the manufacturer's code or other system of labeling to enable the Director to determine the place of manufacture.

(c) Include information on all components and accessories provided in, on, or with the listed product that may affect the quantity, quality, or direction of the radiation emissions.

(d) Describe the function, operational characteristics affecting radiation emissions, and intended and known uses of each model of the listed product.

(e) State the standard or design specifications, if any, for each model with respect to electronic product radiation safety. Reference may be made to a Federal standard, if applicable.

(f) For each model, describe the physical or electrical characteristics, such as shielding or electronic circuitry, incorporated into the product in order to meet the standards or specifications reported pursuant to paragraph (e) of this section.

(g) Describe the methods and procedures employed, if any, in testing and measuring each model with respect to electronic product radiation safety, including the control of unnecessary, secondary, or leakage electronic product radiation, the applicable quality control procedures used for each model, and the basis for selecting such testing and quality control procedures.

(h) For those products which may produce increased radiation with aging, describe the methods and procedures used, and frequency of testing of each model for durability and stability with respect to electronic product radiation safety. Include the basis for selecting such methods and procedures, or for determining that such testing and quality control procedures are not necessary.

(i) Provide sufficient results of the testing, measuring, and quality control procedures described in accordance with paragraphs (g) and (h) of this section to enable the Director to determine the effectiveness of those test methods and procedures.

(j) Report for each model all warning signs, labels, and instructions for installation, operation, and use that relate to electronic product radiation safety.

(k) Provide, upon request, such other information as the Director may reasonably require to enable him/her to determine whether the manufacturer has acted or is acting in compliance with the Act and any standards prescribed thereunder, and to enable the Director to carry out the purposes of the Act.

§ 1002.11 Supplemental reports.

Prior to the introduction into commerce of a new or modified model within a model or chassis family of a product listed in Table 1 of § 1002.1 for which a report under § 1002.10 is required, each manufacturer shall submit a report with respect to such new or modified model describing any changes in the information previously submitted in the product report. Reports will be required for changes that:

(a) Affect actual or potential radiation emission.

(b) Affect the manner of compliance with a standard or manner of testing for radiation safety.

§ 1002.12 Abbreviated reports.

Manufacturers of products requiring abbreviated reports as specified in Table 1 of § 1002.1 shall submit, prior to the introduction of such product, a report distinctly marked ''Radiation Safety Abbreviated Report'' which shall include:

(a) Firm and model identification.

(b) A brief description of operational characteristics that affect radiation emissions, transmission, or leakage or that control exposure.

(c) A list of applications or uses.

(d) Radiation emission, transmission, or leakage levels.

(e) If necessary, additional information as may be requested to determine compliance with the Act and this part.

§ 1002.13 Annual reports.

(a) Every manufacturer of products requiring an annual report as specified in Table 1 of § 1002.1 shall submit an annual report summarizing the contents of the records required to be maintained by § 1002.30(a) and providing the volume of products produced, sold, or installed.

(b) Reports are due annually by September 1. Such reports shall cover the 12-month period ending on June 30 preceding the due date of the report.

(c) New models of a model family that do not involve changes in radiation emission or requirements of a performance standard do not require supplemental reports prior to introduction into commerce. These model numbers should be reported in quarterly updates to the annual report.

9. Section 1002.20 is amended by adding a sentence at the end of paragraph (c) to read as follows:

§ 1002.20 Reporting of accidental radiation occurrences.

* * * * *

(c) * * * A manufacturer need not file a separate report under this section if an incident involving an accidental radiation occurrence is associated with a defect or noncompliance and is reported pursuant to § 1003.10 of this chapter.

10. Section 1002.30 is amended in the first sentence of paragraph (a) introductory text, by removing ''paragraphs (b) and (c) of § 1002.61'' and adding in its place ''Table 1 of § 1002.1''; and adding new paragraph (a)(5) to read as follows:

§ 1002.30 Records to be maintained by manufacturers.

(a) * * *

(5) Data on production and sales volume levels if available.

* * * * *

§ 1002.31 [Amended]

11. Section 1002.31 Preservation and inspection of records is amended in paragraph (c) by removing ''paragraph (c) of § 1002.61'' and adding in its place ''Table 1 of § 1002.1''.

12. Section 1002.40 is amended by revising paragraph (a) to read as follows:

§ 1002.40 Records to be obtained by dealers and distributors.

(a) Dealers and distributors of electronic products for which there are performance standards and for which

the retail price is $50 or more shall obtain such information as is necessary to identify and locate first purchasers if the product is subject to this section by virtue of Table 1 of § 1002.1.

* * * * *

13. Section 1002.50 is revised to read as follows:

§ 1002.50 Special exemptions.

(a) Manufacturers of electronic products may submit to the Director a request, together with accompanying justification, for exemption from any requirements listed in Table 1 of § 1002.1. The request must specify each requirement from which an exemption is requested. In addition to other information that is required, the justification must contain documented evidence showing that the product or product type for which the exemption is requested does not pose a public health risk and meets at least one of the following criteria:

(1) The products cannot emit electronic product radiation in sufficient intensity or of such quality, under any conditions of operation, maintenance, service, or product failure, to be hazardous;

(2) The products are produced in small quantities;

(3) The products are used by trained individuals and are to be used by the same manufacturing corporation or for research, investigation, or training.

(4) The products are custom designed and used by trained individuals knowledgeable of the hazards; or

(5) The products are produced in such a way that the requirements are inappropriate or unnecessary.

(b) The Director may, subject to any conditions that the Director deems necessary to protect the public health, exempt manufacturers from all or part of the record and reporting requirements of this part on the basis of information submitted in accordance with paragraph (a) of this section or such other information which the Director may possess if the Director determines that such exemption is in keeping with the purposes of the Act.

(c) The Director will provide written notification of the reason for any denial. If the exemption is granted, the Director will provide written notification of:

(1) The electronic product or products for which the exemption has been granted;

(2) The requirements from which the product is exempted; and

(3) Such conditions as are deemed necessary to protect the public health and safety. Copies of exemptions shall be available upon request from the Office of Compliance (HFZ–307), Center for Devices and Radiological Health, 2098 Gaither Rd., Rockville, MD 20850.

(d) The Director may, on the Director's own motion, exempt certain classes of products from the reporting requirements listed in Table 1 of § 1002.1, provided that the Director finds that such exemption is in keeping with the purposes of the act.

(e) Manufacturers of products for which there is no applicable performance standard under parts 1020 through 1050 of this chapter and for which an investigational device exemption has been approved under § 812.30 of this chapter or for which a premarket approval application has been approved in accordance with § 814.44(d) of this chapter are exempt from submitting all reports listed in Table 1 of § 1002.1.

Subpart G—[Removed]

14. Subpart G, consisting of § 1002.61 *List of specific product groups*, is removed.

Dated: September 11, 1995.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 95–23130 Filed 9–18–95; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF VETERANS AFFAIRS

38 CFR Part 1

RIN 2900–AG75

Organizational Contact for Missing Children Official Mail Program

AGENCY: Department of Veterans Affairs.

ACTION: Final rule.

SUMMARY: This final rule amends the Department of Veterans Affairs (VA) regulations concerning the use of official mail in the location and recovery of missing children. This rule updates the Departmental contact person and organizational units, reflects current practices, and clarifies provisions.

EFFECTIVE DATE: This amendment is effective September 19, 1995.

FOR FURTHER INFORMATION CONTACT: Mrs. Roslynd R. Stewart, Information Management Service (045A4), Office of Policy and Program Assistance, Office of Information Resources Management, Office of Management, Department of Veterans Affairs, 810 Vermont Avenue, NW., Washington, DC 20420–0001, (202) 565–8949.

SUPPLEMENTARY INFORMATION:

Administrative Procedure Act

The changes made by this final rule constitute rules of agency organization. The remainder of the changes made by this final rule are nonsubstantive and there is good cause for concluding that notice and public procedure thereon are unnecessary and contrary to the public interest. Accordingly, pursuant to 5 U.S.C. 553, we are dispensing with prior notice and comment and with a 30-day delay of the effective date.

Regulatory Flexibility Act

The Secretary certifies that this final rule will not have a significant economic impact on a substantial number of small entities as they are defined in the Regulatory Flexibility Act, 5 U.S.C. 601–612. The amendments made by this final rule will not have a substantial effect on any individuals or entities. Therefore, pursuant to 5 U.S.C. 605(b), this amendment is exempt from the initial and final regulatory flexibility analysis requirements of sections 603 and 604.

The Catalog of Federal Domestic Assistance number is 16.543.

List of Subjects in 38 CFR Part 1

Administrative practice and procedure, Archives and records, Cemeteries, Claims, Courts, Flags, Freedom of information, Government contracts, Government employees, Government property, Infants and children, Inventions and patents, Investigations, Parking, Penalties, Postal Service, Privacy, Reporting and recordkeeping requirements, Seals and insignia, Security measures, Veterans Affairs Department, Wages.

Approved: September 8, 1995.

Jesse Brown,

Secretary of Veterans Affairs.

For the reasons set out in the preamble, 38 CFR part 1 is amended as follows:

PART 1—GENERAL PROVISIONS

1. The authority citation following the table of contents for part 1 is revised to read as follows:

Authority: 38 U.S.C. 501, except as otherwise noted.

2. Section 1.700 is revised to read as follows:

§ 1.700 Purpose.

Sections 1.700 through 1.705 of this title provide a Missing Children Official Mail Program in the Department of Veterans Affairs.

(Authority: 39 U.S.C. 3220(a)(2), 5 U.S.C. 301)

3. Section 1.701 is revised to read as follows:

§ 1.701 Contact person for missing children official mail program.

The Department of Veterans Affairs contact person for the Missing Children Official Mail Program is: Mrs. Roslynd R. Stewart, Information Management Service (045A4), Office of Policy and Program Assistance, Office of Information Resources Management, Office of Management, Department of Veterans Affairs, 810 Vermont Avenue, NW., Washington, DC 20420–0001. Telephone: (202) 565–8949.

(Authority: 39 U.S.C. 3220(a)(2), 5 U.S.C. 301)

§ 1.702 [Amended]

4. In § 1.702, paragraph (b) is amended by removing ''If doing so would be cost effective, the Department of Veterans Affairs shall insert via automated insertion equipment'' and adding, in its place, ''The Department of Veterans Affairs will insert''; by removing ''types of''; by removing ''data processing'' and adding, in its place, ''automation''; and by removing ''may be'' and adding, in its place, ''are''.

5. In § 1.702, paragraph (c) is amended by removing ''will be'' in both places and adding, in its place in both places, ''is''; and by removing ''the Mail and Travel Policy Division'' and adding, in its place, ''Information Management Service''.

6. In § 1.702, paragraph (d) is amended by removing ''(i.e. use or destroy)''; by removing ''will be'' and adding, in its place, ''is''; by removing ''contract'' and adding, in its place, ''contact''; by removing ''envelopes''; and by removing ''as to'' and adding, in its place, ''as of''.

7. In § 1.702, paragraph (h) is amended by removing ''reguations'' and adding, in its place, ''regulations''.

8. Section 1.703 is revised to read as follows:

§ 1.703 Percentage estimate.

It is the Department of Veterans Affairs objective that 20 percent of its first class official mail addressed to the public contain missing children photographs and information.

(Authority: 39 U.S.C. 3220(a)(2), 5 U.S.C. 301)

§ 1.705 [Amended]

9. In § 1.705, paragraph (a) is amended by removing ''which are ordered and/or stocked in quantities which'' and adding, in its place, ''ordered and stocked in quantities that''.

10. In § 1.705, paragraph (c) is amended by removing ''and/or'' and adding, in its place, ''or''.

11. In § 1.705, paragraph (e) is amended by removing ''return, address areas'' and adding, in its place, ''return address area''; and by removing ''OJJDP'' and adding, in its place, ''Office of Juvenile Justice and Delinquency Prevention''.

[FR Doc. 95–23146 Filed 9–18–95; 8:45 am]

BILLING CODE 8320–01–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 9 and 63

[AD-FRL–5272–8]

RIN 2060–AD02

Federal Standards for Marine Tank Vessel Loading Operations and National Emission Standards for Hazardous Air Pollutants for Marine Tank Vessel Loading Operations

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This action promulgates standards under section 183(f) of the Clean Air Act (the Act) and requires reasonably available control technology (RACT) to limit air emissions of volatile organic compounds (VOC) and hazardous air pollutants (HAP) from new and existing marine tank vessel loading operations. VOC emissions, together with nitrogen oxides are precursors to the formation of tropospheric ozone, which can impair lung capacity, cause eye, nose and throat irritation, timber and other valuable crops such as soybeans and cotton. The health effects of exposure to HAPs can include cancer, respiratory irritation and damage to the nervous system. An additional set of standards promulgate national emission standards for hazardous air pollutants (NESHAP) under section 112 of the Act for marine tank vessel loading operations and require existing and new major sources to control emissions using maximum achievable control technology (MACT) to control HAP.

EFFECTIVE DATE: This regulation is effective September 19, 1995. See **SUPPLEMENTARY INFORMATION** section concerning judicial review.

ADDRESSES: *Technical Support Document.* The Technical Support Document (TSD) for the promulgated standards may be obtained from the U.S. Department of Commerce, National Technical Information Service (NTIS), Springfield, Virginia 22161, telephone number (703) 487–4650. Please refer to ''Federal Standards for Marine Tank Vessel Loading Operations and National Emission Standards For Hazardous Air Pollutants For Marine Tank Vessel Loading Operations—Technical Support Document for Final Standards,'' Document Number PB95–234514. The TSD contains, (1) a summary of public comments made on the proposed standards and the Administrator's response to the comments and (2) a summary of the changes made to the standards since proposal.

Electronic versions of the promulgation TSD as well as this final rule are available for download from the EPA's Technology Transfer Network (TTN), a network of electronic bulletin boards developed and operated by the Office of Air Quality Planning and Standards (select ''CAAA'' ''Title III''). The TTN provides information and technology exchange in various areas of air pollution control. The service is free, except for the cost of a phone call. Dial (919) 541–5742 for data transfer of up to a 14,400 bits per second (bps). If more information on TTN is needed, contact the systems operator at (919) 541–5384. A copy of the TSD has also been placed in the Docket at the address given below.

Docket. Docket No. A–90–44, containing supporting information used in developing the promulgated standards, is available for public inspection and copying from 8 a.m. to 4 p.m., Monday through Friday, at the EPA's Air and Radiation Docket and Information Center, Waterside Mall, Room M–1500, Ground Floor, 401 M Street SW., Washington, DC 20460. A reasonable fee may be charged for copying.

FOR FURTHER INFORMATION CONTACT: For information concerning the standards or technical aspects, contact Mr. David Markwordt at (919) 541–0837, Emission Standards Division (MD–13), U.S. Environmental Protection Agency, Research Triangle Park, North Carolina 27711.

SUPPLEMENTARY INFORMATION: Under section 307(b)(1) of the Act, judicial review of NESHAP is available only by the filing of a petition for review in the U.S. Court of Appeals for the District of Columbia Circuit within 60 days of today's publication of this rule. Under section 307(b)(2) of the Act, the requirements that are the subject of today's notice may not be challenged later in civil or criminal proceedings

brought by the EPA to enforce these requirements.

The information presented in this preamble is organized as follows:

I. The Standards
II. Summary of Impacts
III. Significant Changes to the Proposed Standards
A. Public Participation
B. Comments on the Proposed Standards
C. Significant Changes
D. Minor Changes
E. Other Significant Issues
IV. Administrative Requirements
A. Docket
B. Paperwork Reduction Act
C. Administrative Designation and Regulatory Analysis
D. Regulatory Flexibility Act
E. Unfunded Mandates Act

I. The Standards

A summary of today's final standards is listed in Table 1. Included in this table are applicability cutoffs based on annual throughput (under section 183(f)) and HAP emissions (under section 112), separation of marine tank vessel loading operations at petroleum refineries (which are now included under the petroleum refineries source category), and emission standards based on subcategory determinations for offshore terminals and the Alyeska Pipeline Service Company's (APSC's) Valdez Marine Terminal (VMT). The promulgated regulations allow for several alternative compliance technologies to allow owners or operators maximum compliance flexibility.

TABLE 1.—FINAL STANDARDS, NATIONAL COSTS, AND EMISSION REDUCTIONS

Section of act	Subcategory	Standard	Emission reduction, Mg/yr	Annual cost, $MM
183(f)	New and existing terminals having throughput of ≥1.6 billion liters per year (10 million barrels per year) of gasoline or ≥32 billion liters per year (200 million barrels per year) of crude oil.	98 percent reduction in emissions if using combustion techniques; 95 percent reduction in emissions if using recovery techniques.	13,000 (VOC), 900 (HAP).	20–40.
112	Existing major source terminals having emissions of hazardous air pollutants (HAP) of 10/25 tons per year or more from loading of marine tank vessels.	97 percent reduction in HAP emissions	7,000 (VOC), 750 (HAP).	20–40.
112	Existing major source terminals collocated at petroleum refineries having HAP emissions of 10/25 tons per year or more from loading of marine tank vessels; new major source terminals regardless of HAP emissions from marine tank vessel loading (both existing and new sources are regulated under the Gasoline Refineries NESHAP).	97 percent reduction in HAP emissions for existing sources, 98 percent reduction in HAP emissions for new sources; emissions averaging with petroleum refinery emissions points is allowed.	Impacts included in previous subcategory data.	Impacts included in previous subcategory data.
112	Existing major source terminals having HAP emissions of less than 10/25 tons per year from loading of marine tank vessels.	No control	None	None.
112	New major source terminals regardless of HAP emissions from marine tank vessel loading.	98 percent reduction in HAP emissions	None	None.
112 and 183(f)	Existing major source terminals located more than 0.8 kilometers (0.5 miles) offshore.	No control	None	None.
112	New major source terminals located more than 0.8 kilometers (0.5 miles) offshore.	95 percent reduction in HAP emissions	None	None.
112 and 183(f)	Alyeska Pipeline Service Company's Valdez Marine Terminal.	98 percent reduction in emissions with maximum throughput limits.	19,000 (VOC), 2,500 (HAP).	20.

Sources required to reduce emissions are also required to monitor the performance of control technology installed to achieve the required emissions reductions. Baseline parameters may be established by owners or operators during initial performance tests, or continuous emissions monitoring devices may be used to provide indicators of performance. The baseline parameters may be based on manufacturer's recommended operating parameters or other parameters selected by the source and approved by the Administrator. Sources are also required to develop and implement an operation and maintenance plan that describes a program of corrective action for varying (i.e., exceeding baseline parameters) air pollution control equipment and monitoring equipment used to comply with these emissions standards. This plan includes operating parameters that shall be monitored and recorded as indicators of proper operation of the air pollution control devices.

In developing these final monitoring requirements and compliance provisions, the Agency has provided significant flexibility to owners or operators of sources required to reduce emissions in regard to selecting monitoring protocols, yet has assured compliance with the standards. Compliance is assured through reporting and recordkeeping requirements that specify annual reports of system performance. This reporting interval is compressed to semi-annual for sources that experience excess emissions.

Owners or operators of all marine tank vessel loading operations subject to the federal standards promulgated

under section 183(f) of the Act (RACT sources) are required to commence construction of its vapor collection system and air pollution control device(s) within 2 years from September 19, 1995. These RACT sources are required to complete the installation of the control technology needed to comply with the standards within 3 years from September 19, 1995. Owners or operators of new RACT sources with an initial startup after September 21, 1998 are required to comply with all requirements upon startup. A RACT source may request a waiver of final compliance for up to 1 year if it can prove that the additional time is necessary for the installation of controls.

Owners or operators of marine tank vessel loading operations subject only to the requirements promulgated under section 112(d) of the Act (MACT standards) are required to install the control technology needed to comply with the standards within 4 years from September 19, 1995. Owners or operators of new MACT-only sources with initial startup after September 20, 1999 are required to comply with all requirements upon startup.

The VMT owners or operators are required to install the control technology needed to comply with the standards within 30 months from September 19, 1995.

II. Summary of Impacts

These standards will reduce nationwide emissions of hazardous air pollutants (HAP) from marine tank vessel loading operations by approximately 4,150 Mg (4,565 tons) after 1999 compared to the emissions that would result in the absence of the standards. These standards will reduce emissions of volatile organic compounds (VOC) from marine tank vessel loading operations by approximately 39,000 Mg (42,900 tons) after 1999 compared to the emissions that would result in the absence of the standards. No significant adverse secondary air, water, solid waste, or energy impacts are anticipated from the promulgation of these standards.

The implementation of this regulation is expected to result in nationwide annualized costs for existing marine tank vessel loading operations of $60 million to $100 million beyond baseline based on an analysis of applying controls to all existing facilities not currently controlled to the level of the standards. Nationwide capital costs expected to result from these regulations are approximately $266 million to $440 million.

As discussed in this preamble under Regulatory Flexibility Act Compliance, the economic impact analysis performed for this rulemaking showed that the estimated maximum price increases for the affected products varied, but were not large (less than 1%). These price-increase estimates reflect the control cost increases for transporting crude and products. Because these increases are small and because the elasticities of demand for petroleum products are small, estimated percent output reductions were minimal. Correspondingly, estimated employment reductions were also relatively small.

Potentially significant economic impacts on some of the smaller affected terminal operations were identified, although the decision not to require emission controls for existing smaller operations greatly reduces the potential for adverse economic impacts on small terminal operations. These potential impacts would result from the high per barrel control cost differential between the smaller and larger terminal operations that would need to control emissions. Some of these smaller terminal operations, to the extent that they are competing with nearby larger or unaffected terminal operations, could have had difficulty raising prices to cover cost increases and could have been significantly adversely impacted by this rule.

The potential economic impact on marine tank vessel owners was substantially reduced because of the decision not to require emission controls on small existing terminals in this rulemaking. Because only a small percentage of U.S. marine transported volume of products will be impacted by the standard, only a relatively small percentage of U.S. marine tank vessels will need to retrofit. Thus, only the vessels that will need the least cost to retrofit (most likely the larger, newer, double-skin vessels) will do so, leading to some degree of dedicated service. It is expected that vessel owners that do retrofit will be able to pass most retrofit costs forward in terms of higher prices.

III. Significant Changes to the Proposed Standards

Proposed standards for marine tank vessel loading operations were published in the Federal Register on May 13, 1994 (59 FR 25004). Under section 183(f) of the Act, the proposed rule would have required a 98 percent reduction in emissions (or a 95 percent reduction, if recovery techniques were used) from marine tank vessel loading and unloading operations that load either 100 million barrels per year of crude oil or 5 million barrels per year of gasoline. Sources would have had 2 years to comply with these RACT standards. Under section 112(d) of the Act, the proposed rule also would have required owners or operators of major sources that emit 1 ton per year or more of HAP from marine tank vessel loading and unloading operations to reduce total HAP emissions by at least 93 percent. Sources would have had 3 years to comply with these MACT standards. The control devices used to meet these standards were required to be operated at 98 and 95 percent efficiencies for combustion and recovery control technologies respectively. The EPA also proposed to regulate emissions from ballasting.

Three alternatives were proposed to ensure vessel tightness: (1) Pressure test the vessel, (2) perform a leak test on all components using Method 21 of appendix A of 40 CFR part 60, or (3) load the vessel at less than atmospheric pressure.

Proposed monitoring requirements required owners or operators to monitor any valves that could divert flow from a control device if those bypass valves could not be secured. Monitoring criteria were also proposed for combustion devices, carbon adsorbers, condensers, absorbers, and flares. Owners or operators were generally required to establish operating parameters during an initial performance test and then monitor combustion temperature for combustion devices, VOC concentration in the exhaust stream for carbon adsorbers, exhaust stream temperature for condensers, VOC outlet concentration for absorbers, and continuous presence of a flame and the vent stream flow for flares. Criteria to apply for and obtain approval for alternative monitoring criteria (and for alternative monitoring devices) were also specified in the proposed rule.

Under the proposed rule, owners or operators of sources required to install controls would have had to fulfill the reporting and recordkeeping requirements of the part 63 General Provisions, including submittal of the following reports: (1) Initial notification that the source is subject to the standards, (2) notification of initial performance test, (3) initial notification of compliance status, (4) annual excess emissions and monitoring system performance report and/or summary report, and (5) an annual emissions estimation report. These sources would also have been required to maintain documentation that vessels loaded at the facility were vapor tight. All information was to have been made readily available to the Administrator or

delegated State authority for a minimum of 5 years.

In addition, the Agency requested comment on several issues, including the subcategorization of certain types of terminals. On August 31, 1994, the Agency published a notice reopening the comment period to request comment on amending the Marine Tank Vessel Loading and the Petroleum Refinery source categories to move marine terminals collocated at petroleum refineries to the Petroleum Refineries source category (59 FR 44955). On March 8, 1995, the Agency reopened the comment period to request comment on extending the proposed compliance dates (60 FR 12703).

A. Public Participation

Prior to proposal of the standards, interested parties were advised by public notice in the Federal Register (56 FR 1186) of a meeting of the National Air Pollution Control Techniques Advisory Committee to discuss the regulation of this source category. This meeting was held on January 31, 1991. The meeting was open to the public, and each attendee was given an opportunity to comment on the standards recommended for proposal.

The standards were proposed, and the preamble was published in the Federal Register on May 13, 1994 (59 FR 25004). The preamble to the proposed standards discussed the availability of the regulatory text and proposal TSD, which described the regulatory alternatives considered and the impacts of those alternatives. Public comments were solicited at the time of proposal, and copies of the regulatory text and TSD were distributed to interested parties. Electronic versions of the preamble, regulation, and TSD were made available to interested parties via the TTN (see **ADDRESSES** section of this preamble).

To provide interested persons the opportunity for oral presentation of data, views, or arguments concerning the proposed standards, a public hearing was held on June 15, 1994 in Research Triangle Park, North Carolina. The public comment period was from May 13 to July 18, 1994. The Agency also reopened the public comment period for specific comments on two occasions—August 31, 1994 (59 FR 44955) and March 8, 1995 (60 FR 12723). In all, over 150 comment letters were received (including seven duplicates). Additional information received from interested parties but not submitted directly to the docket was included in the docket as additional comments on the proposed regulation. Information submitted after the close of the comment period is also included in the docket and may appear on the docket index as public comments in docket category IV–D. The comments have been carefully considered, and changes have been made to the proposed standards when determined by the Administrator to be appropriate.

B. Comments on the Proposed Standards

Comments on the proposed standards were received from 143 commenters composed mainly of States, environmental groups, private citizens, control device vendors, industry, and trade associations. A detailed discussion of these comments and responses can be found in the promulgation TSD, which is referred to in the **ADDRESSES** section of this preamble. The summary of comments and responses in the TSD serves as the basis for the revisions that have been made to the regulations between proposal and promulgation. Most of the comment letters contained multiple comments. A summary of the revisions to the regulations along with discussion of the comments on the major issues is provided below. In the TSD, the comments have been divided into the following areas:

(1) Applicability of standards.
(2) Inclusion of certain terminals with the petroleum refinery source category.
(3) Subcategorization issues.
(4) RACT/MACT.
(5) Compliance schedule for Titles I and III standards.
(6) Compliance, performance testing, and monitoring requirements.
(7) Vapor tightness requirements.
(8) Leak detection and repair.
(9) Reporting and recordkeeping requirements.
(10) General provisions interaction.
(11) Wording of regulation.
(12) Administrative record/sources of information.
(13) Cost effectiveness/impacts.
(14) Miscellaneous.
(15) Comments on proposed appendices to 40 CFR part 64.

C. Significant Changes

Several changes have been made since the proposal of these standards. The majority of the changes have been made to clarify portions of the rule that were unclear to the commenters. A summary of the major changes is presented below.

(1) *Removal of unloading operations (ballasting) from the source category.* In the proposed rule, the Agency included regulations proscribing emissions from ballasting of vessels following unloading of vessels. Comments asserted that ballasting operations are performed by vessel operators, not by the regulated terminal sources. The Agency agrees with this interpretation of the affected source. The Agency also agrees that regulating ballasting operations would be difficult to enforce. The Agency's intent in prohibiting ballasting emissions in the proposed regulation was to provide a cross-reference with existing Coast Guard regulations addressing ballasting in vessels. The Coast Guard rules require vessels to have segregated ballast tanks for crude oil loadings. The Agency sees no benefit to restating Coast Guard requirements for ballasting. Moreover, EPA agrees that the relatively low amount of actual emissions associated with ballasting does not justify dual regulation of ballasting. As discussed in the proposal TSD, the total VOC emissions from crude oil tankship ballasting were estimated to be approximately 950 Mg/yr. Based on the portion of HAP in crude oil vapor, total HAP emissions from ballasting are less than 120 Mg/yr. Ballasting emissions will diminish in the future because tankships built since 1980 are required by domestic law and international agreement to use segregated ballast tanks that do not emit vapors during ballasting. Therefore, in order to prevent confusion in the regulated community, the Agency does not address ballasting or bunkering emissions in the final regulation. The Agency defers to the U.S. Coast Guard's existing standards (33 CFR parts 155 and 157; and 46 CFR parts 30 et al.).

(2) *Extension of the compliance schedule for section 183(f) (''Title I'') and section 112 (''Title III'') standards.* In the proposed rule, EPA proposed to establish compliance deadlines of 2 years for the section 183(f) standards, and 3 years for the section 112 standards. The Agency received numerous comments regarding these schedules that stated the length of the compliance periods was insufficient to comply with the standards. Commenters noted that facilities' abilities to install pollution control devices are constrained by several factors, including the following: (1) The limited number of contractors experienced in installing control equipment in marine loading facilities; (2) the numerous facilities that will need to meet the standards at the same time; and (3) the lead time needed to meet permitting and safety requirements from permitting authorities and the U.S. Coast Guard.

Commenters stated that EPA had discretion to extend the compliance period under section 183(f), noting the ambiguity of the term ''effective date'' and that the evidence indicated that the proposed emission control technologies

would not be ''reasonably available, considering costs, nonair-quality benefits, environmental impacts, energy requirements, and safety factors'' within 2 years. Commenters also noted that EPA had the authority to provide for a waiver of compliance with MACT standards under section 112 for up to 1 year if certain findings were made.

On March 8, 1995, EPA reopened the comment period to receive more comments on the issue of whether the compliance periods for the RACT and MACT regulations should be extended. Numerous commenters indicated support for extending the compliance periods, generally reiterating the views expressed in earlier comments. Some commenters also pointed out that greater environmental benefits can sometimes be obtained by granting longer compliance periods, which can allow for better designed, more robust, safer and more advanced technologies, and in this instance, could result in greater use of recovery technologies (rather than incineration). Commenters also noted that previous attempts by States to regulate tank vessel loading in less than 3 years resulted in the need for numerous waivers as it became clear that the deadlines could not be met. One commenter provided a list of several marine loading terminals in California that had installed emission control equipment and indicated that almost all of these installation projects took at least 3 years to complete.

The Agency agrees with the commenters that permitting and safety approvals from permitting authorities and the Coast Guard, the dearth of skilled engineering and construction firms, and the history of facilities being unable to comply with existing regulations compels the Agency to extend the date for full compliance with the RACT and MACT rules. In these final standards, EPA allows sources regulated under section 183(f) 3 years to be in full compliance with the emission control requirements promulgated under section 183(f). In addition, RACT sources may request a waiver of up to 1 year to achieve full compliance with the requirements if they can show that the additional period is necessary for the installation of controls. The Agency believes that this result is consistent with section 183(f). Section 183(f) requires the application of ''reasonably available'' control technology, considering costs, any non-air quality benefits, environmental impacts, energy requirements, and safety factors. The overwhelming evidence received by the Agency indicates that most, if not all, sources that must install emission control devices cannot do so within 2 years. States that have attempted to enforce such a requirement have been forced to provide waivers to the regulated sources. Given the relative scarcity of qualified contractors and the permitting and other requirements necessary for such construction, it is clear that the emission control technologies required by this rule will not be ''reasonably available'' within 2 years of the promulgation of this rule. Moreover, the information provided to the Agency indicates that a 2-year deadline may force regulated sources to install equipment that is less reliable and that may cause safety concerns. Given the emphasis that Congress put on safety in these regulations and the fact that the Coast Guard will need to review such installations prior to operation, a 2-year deadline seems contrary to Congress' broad intent and may result in conflicts with Coast Guard requirements. The Agency has in the past provided sources with reasonable time to complete actions required by the Clean Air Act. *See* EPA rulemaking on fuel/fuel additives published on June 27, 1994 (59 FR 33042).

Moreover, EPA believes that the imprecision of the term ''effective date'' could also provide EPA with the ability to allow compliance after 2 years. The distinction between ''effective dates'' of regulations and ''compliance dates'' is important and has been a clear part of administrative procedure for many years. *See, e.g.,* section 112(i)(3); *Natural Resources Defense Council* v. *Environmental Protection Agency,* 22 F. 3d 1125, 1138 (D.C. Cir. 1994).

The Agency is requiring regulated RACT sources to provide proof that they have commenced construction of vapor collection systems and air pollution control devices within 2 years after promulgation of the final standards. The Agency believes that these actions can reasonably be achieved within 2 years of promulgation.

The Agency believes that most RACT terminals will be able to meet the emissions reduction requirements contained in the final standards within the 3 years following the promulgation date. The Agency estimates that only 8 terminals subject to the RACT requirements are not presently controlling emissions to the level specified in the standards. These terminals are among the largest terminals in the U.S., and can reasonably be expected to have in-house staff capable of assisting in the design and installation of control technology. Furthermore, the Agency is aware that some of these terminals are already designing control equipment in anticipation of these final RACT requirements.

The EPA shall allow existing sources regulated solely under section 112 four years to be in full compliance with the emission control requirements promulgated under section 112. Sources must generally comply with MACT standards under section 112 within 3 years of promulgation. However, section 112(i) of the Act specifically allows EPA to provide sources with a waiver of up to 1 year to achieve full compliance with the requirements if they can show that the additional period is necessary for installing the controls. Commenters stated that standards containing similar compliance dates for a large number of sources would result in numerous facilities competing for a limited number of experienced contractors in order to meet the standards at the same time. Commenters suggested a staggered compliance schedule for the sources affected by the standards. Commenters also stated that many sources would require more than 3 years to install the required control equipment given the limited number of contractors experienced in installing control equipment in marine loading facilities and the lead time needed to meet permitting and safety requirements from permitting authorities and the U.S. Coast Guard.

The Agency agrees with the commenters that many MACT sources would probably require 1-year waivers if there was a 3-year compliance date for MACT sources in the final rule. The Agency notes that these sources are typically smaller than the sources regulated under RACT, and would not be as likely to have in-house staff capable of assisting in the design and installation of control technology. Therefore, the Agency believes that the sources controlled under section 112 that are not controlled under section 183(f) should automatically receive a waiver of 1 year that will allow a total of four years from September 19, 1995 to comply with the MACT emission reduction requirements. The Agency believes that this total of 4 years is sufficient time for the estimated 20 sources presently uncontrolled to design and install control technologies sufficient to meet the MACT standards. The Agency believes that the staggered compliance schedule (i.e., 3 years for RACT terminals and 4 years for MACT terminals) coupled with the reduced number of terminals required to control emissions under the final rule should alleviate commenters' concerns about the scarcity of qualified installation consultants and vendors. This extended

schedule is also expected to address concerns regarding permitting delays.

The Agency is providing the VMT with 30 months to be in full compliance with these regulations. The Agency believes, per its discussions with APSC, that this extension provides sufficient time to comply with the promulgated rule.

(3) *Addition of new subcategories under the section 112 regulations for offshore terminals and for the Alyeska Pipeline Service Corporation's Valdez Marine Terminal.* In the proposed rule, the Agency established two subcategories based on size for the section 112 MACT regulations. The Agency also solicited comments on whether additional subcategories should be established under the MACT regulations for specific types of terminals based on particular characteristics of those types of terminals of which the Agency had no information at that time. Based on information received in the public comments, the Agency has determined that two additional subcategories exist within the marine tank vessel loading operation source category.

(a) Subcategory for offshore terminals. As stated in the solicitation of comments in the proposed rule, the Agency does not believe that a facility at least one-half mile offshore is part of a land-based contiguous site. The Agency also stated that such offshore terminals present unique regulatory challenges such as costs, environmental impacts, and/or size constraints. The Agency requested information regarding the feasibility and costs of controlling emissions from offshore terminals. The Agency also requested comments on whether offshore terminals should be grouped into a separate subcategory and what the control status of terminals in such a subcategory should be. Comments in response to this request indicated that these types of vessel loading operations face significant challenges in controlling emissions that were different from land-based, contiguous loading operations. These challenges include high costs, technical complications, and permitting requirements that would result from requirements to construct new platforms to locate control equipment adjacent to the offshore terminal or additional subsea or surface lines to route loading vapors to onshore control equipment. Commenters noted that these challenges are either non-existent or not as pronounced for onshore, contiguous terminals. The Agency has therefore determined that a subcategory for these types of terminals is justified and has based its definition for offshore terminals on a minimum distance of one-half mile from the terminal's furthest loading point to the shore, regardless of the existence of subsea lines. [See the discussion in section 2.3.2 of the TSD for the rationale supporting the one-half mile limit].

Once the Agency determined that offshore terminals should be placed in a subcategory for the MACT standards, the MACT floor was determined (see Docket A–90–44, Item Number IV–B–2). Based on information received from commenters, (see Docket A–90–44, Item Number IV–D–136) the Agency estimates that there are fewer than 20 offshore terminals having subsea lines. None of these terminals presently control emissions from marine tank vessel loading. The Agency is also aware of additional offshore terminals that do not have subsea lines. Two of these terminals are known to presently control emissions (see Docket A–90–44, Item Number IV–D–80). Based on the information available to the Agency, the MACT floor for this subcategory is no control of HAP emissions (see MACT floor memorandum in Docket A–90–44, Item Number IV–B–2). Data submitted by commenters showed that the costs associated with the control of offshore terminals are between two and five times more expensive than comparable onshore control techniques (see Docket A–90–44, Item numbers IV–D–108 and IV–D–136). Because of the poor cost effectiveness resulting from these significantly higher costs, as well as the environmental, safety, and technical challenges associated with requiring control more efficient than the MACT floor, the Agency has selected the MACT floor level of no control for offshore marine tank vessel loading operations.

The Agency also determined that offshore terminals loading 10 million barrels or more per year of gasoline or 200 million barrels or more of crude oil should not be required to control VOC or HAP emissions under section 183(f) RACT requirements. Although one commenter (see Docket A–90–44, Item Number IV–D–80) noted two controlled offshore terminals, no information was submitted regarding the specific control techniques used at these two terminals. Since most of the other comments noted that the significantly higher costs and poor cost effectiveness shown by these sources (see previous paragraph) would make control requirements unreasonable for these offshore terminals, the Agency determined that requirement for controls at offshore RACT terminals would not be consistent with the requirements for the technology to be ''reasonable.''

(b) Subcategory for Alyeska Pipeline Service Company's Valdez Marine Terminal. In the proposed rule, the Agency solicited comment on the possibility of placing the VMT in a separate subcategory. Comments from APSC and several other commenters representing State and local governments, industry, private citizens, and environmental groups were considered by the Agency in developing this final rule.

The Agency has determined that the VMT should be placed in a separate subcategory for the following reasons: (1) The VMT is the largest (by a significant amount) crude oil loading operation in the U.S.; (2) special circumstances, including climatic and economic conditions, require keeping the oil moving through the pipeline; (3) severe meteorological conditions result in increased loading irregularity; (4) the VMT throughput projections show declining throughput over the next several years. Several comments from environmental groups, State and local agencies, and private citizens in the Valdez area did not object to placing VMT in a separate subcategory provided that emissions were controlled. Based on all of these factors, the Agency determined that APSC's VMT should be placed in a separate subcategory.

Once the subcategory for VMT was established, the Agency determined the MACT floor for the subcategory (see Docket A–90–44, Item Number IV–B–2). The VMT presently does not control emissions, therefore the MACT floor is no control. However, the Agency noted that in all of the comments received concerning the establishment of this subcategory, the cost effectiveness associated with requiring controls more stringent than the MACT floor is not prohibitive. The annual emissions reductions anticipated from controlling VMT are expected to be approximately 19,000 Mg (20,900 tons) of VOC and approximately 2,500 Mg (2,750 tons) of HAP. The annual costs anticipated with today's regulation of VMT are expected to be $20 million. The resulting cost effectiveness is approximately $1,050 per megagram based on VOC or approximately $8,000 per megagram based on HAP. The Agency therefore selected a strategy for both MACT and RACT standards for VMT that requires a reduction in emissions by 98 percent efficiency of all throughput loaded from at least two of the terminal's loading berths. Maximum limits for total throughput and throughput at uncontrolled berths (above which all VMT loading berths would be required to reduce emissions by 98 percent) are included as part of these standards.

These throughput limits address the projected decreasing throughput that would necessitate the use of only two berths for routine loading after 2001. Provisions to allow for scheduled maintenance of the controlled berths are also established in the VMT standards.

Some commenters initially noted that the cost of controlling VOC may be high relative to the benefits of controlling VOC at a remote site in an Arctic ozone attainment area. Additionally, some commenters initially stated that the benefits of controlling HAP would not appear to justify the costs. However, the Agency has also considered later comments from the APSC, the State of Alaska, the Prince William Sound Regional Citizens Advisory Committee (a local citizens group) and private citizens in determining MACT/RACT for the VMT. These commenters agreed that a Federal rule mandating control of primary emissions at the APSC was acceptable. After careful consideration of the costs, the environmental impacts and the comments, the Agency decided that MACT for this subcategory was control beyond the level of the MACT floor (see Docket A–44–90, Item Number IV–B–2).

(4) *Expansion of the petroleum refineries source category to include marine tank vessel loading operations collocated at petroleum refinery operations.* The preamble to the proposed petroleum refinery NESHAP published in the Federal Register on July 15, 1994 (59 FR 36130) requested comments on whether marine tank vessel loading operations at refineries should be included in emissions averaging. On August 31, 1994, the EPA also reopened the comment period for the proposed NESHAP for Marine Tank Vessel Loading Operations (59 FR 44955) to request comment on whether marine terminals collocated at refineries should be moved to the petroleum refinery source category. During the comment period for the gasoline distribution NESHAP, commenters requested that bulk gasoline terminals contiguous to a refinery be regulated by the petroleum refinery NESHAP.

Several commenters responding to the marine tank vessel loading operations proposed NESHAP supported averaging of refinery process unit emissions with emissions from marine terminals and gasoline distribution operations that are located at refineries. The commenters cited more cost effective emission reduction as the advantage of including these emission points in emissions averaging and specifically commented that the costs per Mg emission reduction of the marine tank vessel loading emission controls are high. These commenters also claimed that emission calculation procedures for loading are well established and that adding marine loading to the averaging provisions will not appreciably increase the complexity of enforcement. Other commenters opposed including marine tank vessel loading and gasoline distribution in emissions averaging. Some commenters claimed that these are separate source categories, and the Act does not permit averaging across source categories. Others were concerned that including marine loading in averages could result in uncontrolled peak emissions.

In the final rules, emissions from marine tank vessel loading operations, bulk gasoline terminal or pipeline breakout station storage vessels, and bulk gasoline terminal loading racks at petroleum refineries are allowed to be included in emissions averages. The petroleum refinery source category and source definitions have been changed to include marine tank vessel loading operations, bulk gasoline terminal and pipeline breakout station storage vessels, equipment leaks, and bulk gasoline terminal loading racks classified under SIC codes 5171 (Petroleum Bulk Stations and Terminals) and 4613 (Refined Petroleum Pipelines) that are located at refinery plant sites. Note that these operations are closely connected with refinery process unit operations since they transfer products of the refinery process units.

A marine tank vessel loading operation or gasoline terminal or pipeline breakout station that is collocated at a petroleum refinery can be considered part of the same source as the refinery subject to this rule. Because these operations are redefined to be part of the source subject to the rule, the prohibition against intersource averaging is not violated. However, all terminals subject to section 183(f) regardless of location will not be allowed to average emissions with petroleum refinery sources.

In keeping with EPA's stated goal of increasing flexibility in rulemakings, this decision has been made to provide more opportunities to average. This decision optimizes the opportunities for refiners to find cost-effective emission reductions from overall facility operations on-site. Costs and cost effectiveness of controlling a particular kind of emission point, such as marine tank vessel loading, will vary depending on many site-specific factors. Emissions averaging allows the owner and operator to find the optimal control strategy for their particular situation.

Including emissions from marine tank vessel loading operations, bulk gasoline terminal or pipeline breakout station storage vessels, and bulk gasoline terminal loading racks in emissions averages will result in equivalent or greater overall HAP emission reduction at each refinery. The averaging provisions are structured such that ''debits'' generated by not controlling an emission point that otherwise would require control must be balanced by achieving extra control at other refinery emission points covered by the NESHAP.

With regard to commenter's concerns about peak emissions, the quarterly cap on the ratio of debits to credits is intended to limit the possibility of exposure peaks. Furthermore, because loading operations occur fairly frequently and emissions from an individual vessel filling or loading event are relatively small, such emissions are not expected to cause significant exposure peaks. Moreover, no evidence has been presented that emissions averaging would permit a very different mix of emissions to occur than would point-by-point compliance. That is, peaks of exposures from batch streams, storage, and loading operations should be equally likely under point-by-point compliance as under emissions averaging; therefore, emissions averaging does not represent a less effective control strategy. Furthermore, in order to receive approval for an emissions average, the owner or operator is required to demonstrate that the emissions average does not increase the risk or hazard relative to compliance without averaging.

(5) *Revision to the subcategories established based on annual HAP emissions from 1 ton per year to 10 tons per year of any single HAP or 25 tons per year of total HAP.* The proposed standards grouped major source terminals into two subcategories based on HAP emissions: Terminals with HAP emissions of 1 ton per year or more and terminals having HAP emissions of less than 1 ton per year. In the preamble of the proposed rule, the Agency requested comment on establishing these subcategories based on size (i.e., HAP emissions). In the public comments, the Agency found general, though not universal, agreement on establishing subcategories based on size for this source category. However, some of the comments encouraged the Agency to raise the HAP emissions level of the controlled subcategory. The final standards continue to group major source terminals into subcategories based on HAP emissions; however, these subcategories were changed to terminals with emissions of 10 tons per year or more of any single HAP or 25

tons per year or more of total HAP and terminals having HAP emissions of less than 10 tons per year of all single HAP or less than 25 tons per year of total HAP. The Agency based this decision on information found in the comments received. Commenters noted that prior state regulations generally (though not invariably) distinguished between large tank vessel loading facilities that are responsible for the vast majority of emissions and small tank vessel loading facilities that are substantially less cost effective to regulate. (As discussed below, the incremental cost effectiveness of moving from the 10/25 ton per year distinction to the 1-ton delineation is between $80,000 and $112,000 per megagram, while the cost effectiveness of the 10/25 ton delineation is between $14,500 and $24,000 per megagram.)

Though section 112 does not provide any language indicating the criteria for subcategorization, section 112(d)(1) of the Act states that EPA may distinguish among classes, types, and sizes of sources in establishing standards. EPA believes that division of this source category into two subcategories based on size is appropriate in this instance. (See section 2.3.1 of the promulgation TSD for additional discussion of the subcategories based on size.)

(6) *Incorporation of minimum vapor pressure limit.* The Agency received several comments regarding HAP having low vapor pressures. Most of these commenters stated that these low vapor pressure HAPs are not presently controlled under existing State regulations and that the control of these low vapor pressure compounds presents technical challenges and imposes significantly greater costs to the affected industry. The proposed rule enabled individual facilities to determine which products to control to achieve the 93 percent mass limit. Therefore, facilities would not have had to control low vapor pressure liquids under the proposed rule if higher vapor pressure liquids were available for control. Based on the comments received, the Agency altered the format of the MACT standards to explicitly exempt low vapor pressure liquids consistent with State requirements and recalculated the control requirement for liquids above the vapor pressure limit. Therefore, the MACT floor for existing sources is no control for liquids having a vapor pressure below 1.5 psia and 97 percent control for liquids having a vapor pressure 1.5 psia or greater. Because no low vapor pressure liquids are required to be controlled at any of the known existing sources, the MACT floor for new sources is also no control for liquids having a vapor pressure below 1.5 psia and 98 percent control for liquids having a vapor pressure 1.5 psia or greater. The format of the standard was changed to an efficiency format to reflect the new approach.

The issue of cost effectiveness to control emission streams from the loading of these low vapor pressure materials was also a realistic concern of the commenters. As the MACT floor for regulation of such activities is no control, EPA has discretion, based on section 112(d)'s criteria used for going beyond the floor, to institute a vapor pressure limit. Because of the high costs cited by commenters, the Agency elected not to require controls more stringent than the MACT floor for these low vapor pressure HAP. The Agency therefore selected a vapor pressure limit of 1.5 psia for determining the HAP emissions reduction for the final standards. Control of HAP having vapor pressures below this limit is not required to meet the standards.

(7) *Recalculation of the MACT floors.* The MACT floors determined for this final rulemaking are different than those in the proposed rule. These final rule MACT floors reflect changes in the Agency's regulation of marine tank vessel loading including: (1) The establishment of subcategories for offshore terminals and the VMT terminal; (2) the incorporation of a 1.5 psia minimum vapor pressure limit instead of the weighted average as was proposed; and (3) the increase of the levels of the subcategories based on size (i.e., HAP emissions) from 1 ton per year to 10/25 tons per year. The MACT floors for the final rule also reflect comments on the proposed rule. However, the Agency has not changed the way in which the MACT floors for the final rule have been calculated. With the exception of the MACT floor for VMT, the MACT floors for existing and new sources in the marine tank vessel loading source category are shown in Table 1.

Using the criteria established in section 112(d)(3) of the Act, and after inclusion of information supplied in the public comments, the MACT floors for existing source marine terminal subcategories subject to regulation under Title III of the Clean Air Act were determined. Additional information on the determination of these MACT floors is in the docket (Docket Number A–90–44, Item Number IV-A–2). There are approximately 44 major source terminals (not including the VMT) that emit 10 tons per year or more of any one hazardous air pollutant (HAP) or 25 tons per year or more of any combination of HAP. Twenty-three of these terminals are controlled. The resulting MACT floor level of control is a 97 percent reduction of HAP emissions. There are approximately 1,435 terminals that emit less than 10 tons per year of all individual HAP and less than 25 tons per year of combined HAP. Seventy-nine of these terminals reduce emissions from marine tank vessel loading. The resulting MACT floor level of control is no reduction in HAP emissions. The Agency estimated that there are less than 30 offshore terminals (i.e., loading terminals located 0.5 miles or more from shore). The Agency is aware of only 2 controlled offshore terminals. Therefore the resulting MACT floor level of control is no reduction in HAP emissions. The VMT is presently uncontrolled. Since this is the only terminal in the VMT source category, the MACT floor level of control is no control.

The MACT floors for new source marine terminal subcategories subject to regulation under Title III of the Act were also calculated following the criteria in section 112(d)(3) of the Act. For new major source onshore terminals (not including the VMT) regardless of the marine tank vessel loading HAP emissions, the best performing source achieves a 98 percent reduction of controlled emissions. Therefore, the resulting MACT floor for these sources is 98 percent reduction of HAP emissions. For new major source offshore terminals whose marine tank vessel loading HAP emissions exceed the limits for a major source (i.e., 10 tons of any one HAP, or 25 tons of total HAP), the best controlled similar source achieves a 95 percent reduction of controlled emissions. The resulting MACT floor for new offshore major sources is therefore a 95 percent reduction in HAP emissions. Since the VMT subcategory only contains a single source, and it is not possible for an additional source to be added to this subcategory, no new source MACT floor was calculated for the VMT subcategory.

(8) *Incorporation of additional flexibility to the monitoring requirements and compliance provisions.* The proposed rule required parametric monitoring or continuous emissions monitoring (CEM) as a means of showing compliance with the standards. Any exceedance of the parameters or concentration limits established during a performance test would have resulted in a violation of the standard. Comments indicated that this approach was too severe and warranted additional flexibility. Although the Agency continues to believe that parametric monitoring can be used to determine compliance given availability

of sufficient test data to establish the relationship between control performance and associated parameters, in consideration of the lack of test data establishing the relationship between marine tank vessel loading emissions control efficiency and parametric monitoring and because of the batch nature of marine tank vessel loading operations, the Agency has thoroughly revised the monitoring requirements and compliance provisions of the final rule. A requirement for an operation and maintenance (O & M) plan has been added to the final regulation to ensure proper operation of the air pollution control and monitoring equipment. The O & M plan contains an inspection schedule for each component of the control and monitoring equipment. The ''compliance'' language that appeared in § 63.563 of the proposed rule has been removed. In its place, the final rule contains provisions that require an unscheduled inspection and corrective actions when operating parameters exceed the applicable baseline parameters.

Flexibility has also been added to the methods for determining baseline parameters. Owners or operators of a source required to reduce emissions may establish baseline parameters during a performance test or may choose to set the applicable baseline based on a manufacturer's recommended baseline operating parameter.

Commenters on the proposed rule also requested that additional operating parameters be added to the regulation and that sources be allowed to apply for alternatives to the Administrator. Additional operating parameters have been added to the final regulation for several control devices. A cross reference to the general provisions found in 40 CFR part 63 (containing requirements for establishing alternative monitoring procedures) has been provided to assist sources seeking approval of alternative monitoring procedures. Commenters also requested that time intervals of the monitoring requirements be made consistent for each of the operating parameters. In the final rule, sources are required to monitor and record data points every 15 minutes for each operating parameter.

D. Minor Changes

(1) Revisions to definitions and phrasing have been made to clarify the regulation.

(2) Based on comments received and on changes to the monitoring and compliance provision requirements, the reporting requirements have been changed. Under today's final rule, the Agency is requiring the following one-time reports as specified in the general provisions found in 40 CFR part 63, subpart A: report of startup, construction or modification; notification and report of emissions tests and results and/or initial notification of compliance status; notification and report of physical/operational changes; notification and report of waiver applications; and an engineering report describing the vent system used to vent each vent stream to a control device.

The final rule also requires owners or operators to submit yearly summary reports and yearly reports of excess emissions and monitoring system performance reports. However, in order to provide relief from the reporting requirements to well-controlled sources while assuring compliance with the standards, the Agency has provided that sources whose exceedances have durations that total less than 5 percent of the total reporting time for that reporting period and whose CMS downtime for the reporting period is less than 10 percent of the total operating time for that reporting period may submit only the summary report found in 40 CFR part 63 subpart A instead of both the summary report and the full excess emissions and continuous monitoring system performance report found in § 63.567(d)(2).

The final rule does not require quarterly reports of excess emissions or monitoring parameter exceedances. The Agency agreed with commenters that quarterly reporting did not add sufficient compliance assurance to warrant the high costs associated with the quarterly reporting. Quarterly reporting also did not agree with the revised monitoring and compliance determination requirements found in the final rule (see section 3(c)(5) of this preamble and section 2.6 of the promulgation TSD for additional discussion of the revised monitoring requirements contained in the final rule).

(3) Several commenters requested clarification of the general provisions found in 40 CFR part 63 as they relate to this rule. A table identifying the relationship of the final General Provisions requirements has been added to the final regulation. Language similar to that in the General Provisions has been added to subpart Y in cases where a direct reference to the General Provisions was not appropriate.

(4) References to the proposed Performance Specifications 101 and 102 have been updated to incorporate the Agency's promulgation of Performance Specifications 8 and 9.

E. Other Significant Issues

(1) Regulation Under Sections 183(f) and 112

The EPA proposed to regulate tank vessel loading operations under both sections 183(f) and 112 of the Act. Some commenters suggested that regulation under section 112 was inappropriate because section 183(f) specifically provides for regulation of tank vessel loading operations, whereas section 112 is a more general standard. On the other hand, one commenter believed that regulation was more appropriate, at least for certain facilities, under section 112.

The Agency believes that the best interpretation of the Clean Air Act requires that standards be issued under both sections 183(f) and 112. The language of section 112 of the Act is clear. ''[T]he Administrator shall publish * * * a list of *all* categories and subcategories of major sources and area sources of [HAP].'' Clean Air Act section 112(c)(1), 42 U.S.C. § 7412(c)(1) [emphasis added]. Further, the Administrator ''shall promulgate regulations establishing emission standards for each category or subcategory of major sources and area sources of hazardous air pollutants listed for regulation pursuant to subsection (c).'' Clean Air Act section 112(d)(1), 42 U.S.C. § 7412(d)(1). The marine tank vessel loading operations source category is clearly a category of major sources, as defined in the Act. The Act is thus clear on its face that this source category should be regulated under section 112.

The fact that two separate sections of the Act regulate the same source category does not necessitate that one of the sections should be ignored. In fact, unless the regulations promulgated under one section would create an inescapable conflict with regulations promulgated under the other section, both must be followed. The regulations promulgated under section 112 are not in conflict with those promulgated under section 183(f). EPA believes that any source regulated under both sections would have no problem meeting the requirements of both standards at the same time.

Congress often provides for regulation of sources under two separate sections. The legislative history indicates that Congress was well aware that sources could be subject to dual regulation under section 112 and other sections of the Act. *See* page 167 of the Senate Committee Report (Report 101–228). In addition, where Congress wanted one section of the Clean Air Act to be exclusive of further regulation under

section 112(d), they said so explicitly; *see* sections 129(h)(2), 112(d)(9). Thus, Congress could have added specific language to section 183(f) preventing the Agency from regulating this source category under section 112; however, it did not do so.

In addition, neither the statute nor the legislative history indicates that Congress intended EPA regulations under section 183(f) to be the exclusive regulation of these sources. In fact, section 183(f) explicitly provides that states may regulate tank vessel loading processes and, in fact, *requires* that any such regulations be as stringent or *more* stringent than the Agency's regulations under section 183(f).

IV. Administrative Requirements

A. Docket

The Docket is an organized and complete file of all the information considered by the EPA in the development of this rulemaking. The Docket is a dynamic file, since material is added throughout the rulemaking development. The docketing system allows members of the public and industries to readily identify and locate documents so that they can effectively participate in the rulemaking process. Along with the statement of basis and purpose of the proposed and promulgated standards and the EPA responses to significant comments, the contents of the Docket will serve as the record in case of judicial review [section 307(d)(7)(A)].

B. Paperwork Reduction Act

The information collection requirements in this rule have been approved by the Office of Management and Budget (OMB) under the provisions of the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq.*, and have been assigned OMB control number (2060–0289). An Information Collection Request (ICR) document has been prepared by the EPA (ICR No. 1679.02) to reflect the changed information requirements of the final rule.

This collection of information has an estimated burden per affected facility of about 685 hours for the first year. In subsequent years, the burden is approximately 280 hours per affected facility. These burden estimates include 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 Director, Regulatory Information Division, EPA, 401 M St., S.W. (Mail Code 2136), Washington, DC 20460, and to the Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, DC 20503, marked ''Attention: Desk Officer for EPA.''

C. Administrative Designation and Regulatory Analysis

Under Executive Order 12866 [58 FR 51735 (October 4, 1993)], the EPA is required to judge whether a regulation is ''significant'' and therefore subject to Office of Management and Budget (OMB) review and the requirements of this Executive Order to prepare a regulatory impact analysis (RIA). The Order defines ''significant regulatory action'' as one that is likely to result in a rule that may: (1) Have an annual effect on the economy of $100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities; (2) create a serious inconsistency or otherwise interfere with an action taken or planned by another agency; (3) materially alter the budgetary impact of entitlements, grants, user fees, or loan programs, or the rights and obligations of recipients thereof; or (4) raise novel legal or policy issues arising from legal mandates, the President's priorities, or the principles set forth in the Executive Order.

Pursuant to the terms of Executive Order 12866, it has been determined that this rule is a ''significant regulatory action'' because it will have an annual effect on the economy of $100 million or more. As such, this action was submitted to OMB for review. Changes made in response to OMB suggestions or recommendations are documented in the public record (see Docket A–90–44, Item Number IV–H–2).

D. Regulatory Flexibility Act

The Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) requires the EPA to consider potential impacts of proposed regulations on small business ''entities,'' which are small businesses, small organizations, and small governments. It is EPA's current policy to perform a regulatory flexibility analysis whenever a regulation is anticipated to adversely affect any small entities. An economic impact and regulatory flexibility analysis for this regulation was performed and included within the regulatory impact analysis that has been submitted to the public docket (Docket Number A–90–44, Item Number IV–A–2).

The regulatory flexibility analysis identified two types of businesses that could incur adverse economic impacts from this standard, marine terminal operations and marine vessel operations. With regard to marine terminal operations, only the very largest terminal operations are expected to be affected by this standard. The decision not to require controls at existing smaller operations greatly reduces the potential for adverse economic impacts on small terminal operations. Nevertheless, some of the smaller terminal operations that will be affected by this regulation could be put under increased competitive pressure as a result of this rule. Of these terminals, however, it is expected that few or none are independently owned. The rest are part of large integrated petroleum operations. The number of small business terminal operations affected by this regulation is expected to be minimal.

With regard to marine vessel operations, the economic impact analysis considered the majority of these operations to be small businesses. However, the number of vessel operations significantly impacted from the proposed standard is not expected to be substantial. Only a relatively small percentage of U.S. marine transported throughput will be impacted by the standard. Excluding crude oil volume shipped by large tankers from the VMT, no more than one-third of the remaining U.S. marine transported throughput is expected be impacted by the standard. It is expected that an even smaller percentage of U.S. vessels will need to be retrofitted to accommodate the volume of affected products. Only the largest and newest vessels (i.e., those that will cost least to retrofit) will therefore need to be retrofitted. Moreover, it is expected that vessel owners will be able to pass forward most retrofit costs in the form of higher prices. Vessels that cannot retrofit cost effectively and that cannot pass through costs can be dedicated to transporting unregulated products.

Economic Impacts

The EPA performed an economic impact analysis of the regulatory requirements in this regulation. Potential price, output, and employment impacts for affected products and for the marine transport industry were examined. Detailed results from the analysis are included in the regulatory impact analysis for this rule that has been submitted to the public docket.

Estimated maximum price increases for the affected products varied but were not large (less than 1%). These price-increase estimates reflect the control cost increases for transporting crude and products. Because these increases are small and because the elasticities of demand for petroleum products are small, estimated percent output reductions were minimal. Correspondingly, estimated employment reductions were also relatively small.

Potentially significant economic impacts on some of the smaller affected terminal operations were identified, although the decision not to require emission controls for existing smaller operations greatly reduces the potential for adverse impacts on small terminal operations. These potential impacts would result from the high per barrel control cost differential between the smaller and larger terminal operations that would need to control emissions. Some of these smaller terminal operations, to the extent that they are competing with nearby larger or unaffected terminal operations, could have had difficulty raising prices sufficiently to cover cost increases and could have been significantly and adversely impacted by this rule if the rule were applicable to such operations.

The potential economic impact on marine vessel owners was substantially reduced because of the decision not to require emission controls for small terminals in this rulemaking. Because only a relatively small percentage of U.S. marine transported volume of products will be impacted by the standard, only a relatively small percentage of U.S. marine vessels will need to retrofit. Thus only the vessels that will cost least to retrofit (most likely the larger, newer, double-skin vessels) will do so, leading to some degree of dedicated service. Vessel owners that do retrofit probably will be able to pass most retrofit costs forward in terms of higher prices.

E. Unfunded Mandates Act

Under section 202 of the Unfunded Mandates Reform Act of 1995 (Unfunded Mandates Act), signed into law on March 22, 1995, the EPA must prepare a budgetary impact statement to accompany any proposed or final rule that includes a Federal mandate that may result in estimated costs to State, local, or tribal governments in the aggregate; or to the private sector of $100 million or more. The budgetary impact statement must include: (1) An identification of the Federal law under which the rule is promulgated; (2) a qualitative and quantitative assessment of anticipated costs and benefits of the Federal mandate and an analysis of the extent to which such costs to State, local, and tribal governments may be paid with Federal financial assistance; (3) if feasible, estimates of the future compliance costs and any disproportionate budgetary effects of the mandate; (4) if feasible, estimates of the effect on the national economy; and (5) a description of the Agency's prior consultation with elected representatives of State, local, and tribal governments and a summary and evaluation of the comments and concerns presented. Section 203 provides that if any small governments may be significantly or uniquely impacted by the rule, the Agency must establish a plan for obtaining input from and informing, educating, and advising any such potentially affected small governments.

Under section 205 of the Unfunded Mandates Act, the Agency must identify and consider a reasonable number of regulatory alternatives before promulgating a rule for which a budgetary impact statement must be prepared. The Agency must select from those alternatives the least costly, most cost-effective, or least burdensome alternative for State, local, and tribal governments and the private sector, that achieves the objectives of the rule, unless the Agency explains why this alternative is not selected or unless the selection of this alternative is inconsistent with law.

Because this final rule is estimated to result in the expenditure by State, local, and tribal governments in aggregate or by the private sector of $60 million to $100 million per year starting in 2000, EPA has prepared a supplement to the Regulatory Impact Analysis (RIA) in compliance with the Unfunded Mandates Act. The EPA summarizes that supplement as follows:

This final rule is promulgated under section 112 and section 183(f) of the Clean Air Act. The analysis in the RIA developed in preparation of the proposed rule and revised in preparation of the final rule contains the information to be considered in response to the requirements of the Unfunded Mandates Act.

Total expenditures resulting from the final rule are estimated at between $60 million and $100 million (of which less than $75,000 is by State, local, and tribal governments) per year in 1997–2000; and $550,000 (of which $38,000 is by State, local, and tribal governments) per year starting in 2001. There are no federal funds available to assist State, local, and tribal governments in meeting these costs. There are important benefits from VOC and HAP emission reductions because these compounds have significant, adverse impacts on human health and welfare and on the environment. The rule does not have any disproportionate budgetary effects on any particular region of the nation, any State, local, or tribal government, or urban or rural or other type of community. On the contrary, the rule will result in only a minimal increase in the average product rates (less than 1 percent). Moreover, the rule will not have a material effect on the national economy.

Prior to issuing this rule, the EPA provided numerous opportunities (e.g., National Air Pollution Control Techniques Advisory Committee proceedings; public comment period; public hearing; meetings with industry, trade associations, state and local air pollution representatives; State, local, and tribal governments; and concerned citizens) for consultation with interested parties. In general, State and local environmental agencies advocated that EPA adopt more stringent environmental controls. The Agency evaluated the comments and concerns expressed, and the final rule reflects, to the extent consistent with sections 112 and 183(f) of the Act, those comments and concerns. While small governments are not significantly or uniquely affected by the rule, these procedures, as well as additional public conferences and meetings, gave small governments an opportunity to give meaningful and timely input and obtain information, education, and advice on compliance.

The Agency considered several regulatory options in developing the rule. As discussed above, the Agency has found that regulation solely under section 183(f) of the Act would not be consistent with the law. The options selected in the final rule for all subcategories of sources except the VMT subcategory are the least costly and least burdensome alternatives currently available for achieving the objectives of sections 112 and 183(f) of the Act. Regarding regulation of the VMT, the Agency notes that the cost effectiveness of controlling VOC at this terminal is approximately $1,050 per Mg and the cost effectiveness of controlling HAP is approximately $8,000 per Mg. The Agency initially received comments stating that the cost of controlling VOC at this terminal is high relative to the benefits of controlling VOC at a remote site in an Arctic ozone attainment area. Additionally, some commenters initially stated that the benefits of controlling HAP would not appear to justify the costs. However, the Agency has also considered later comments from the

APSC, the State of Alaska, the Prince William Sound Regional Citizens Advisory Committee (a local citizens group) and private citizens in determining MACT/RACT for the VMT. These commenters agreed that a Federal rule mandating control of the primary emissions at the APSC was acceptable. After careful consideration of the costs, the environmental impacts and the comments, the Agency decided that MACT for this subcategory was control beyond the level of the MACT floor (see Docket A–44–90, Item Number IV–B–2).

List of Subjects in 40 CFR Parts 9 and 63

Environmental protection, Air pollution control, Intergovernmental relations, Reporting and recordkeeping requirements, Tank vessel standards.

Dated: July 28, 1995.

Carol M. Browner,

Administrator.

For reasons set out in the preamble, title 40, chapter I of the Code of Federal Regulations is amended as follows:

PART 9—[AMENDED]

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

Authority: 7 U.S.C. 135 *et seq.*, 135–136y; 15 U.S.C. 2001, 2003, 2005, 2006, 2601–2671; 21 U.S.C. 331j, 346a, 348; 31 U.S.C. 9701; 33 U.S.C. 1251 *et seq.*, 1311, 1313d, 1314, 1321, 1326, 1330, 1344, 1345(d) and (e), 1361; E.O. 11735, 38 FR 21243, 3 CFR, 1971–1975 Comp. p. 973; 42 U.S.C. 241, 242b, 243, 246, 300f, 300g, 300g-1, 300g-2, 300g-3, 300g-4, 300g-5, 300g-6, 300j-1, 300j-2, 300j-3, 300j-4, 300j-9, 1857 *et seq.*, 6901–6992k, 7401–7671q, 7542, 9601–9657, 11023, 11048.

2. Section 9.1 is amended by adding a new entry to the table under the indicated heading in numerical order to read as follows:

§ 9.1 OMB approvals under the Paperwork Reduction Act.

* * * * *

40 CFR citation	OMB control No.
* * * * * * *	
National Emissions Standards for Hazardous Air Pollutants for Source Categories.	
* * * * * * *	
63.563–63.567	2060–0289
* * * * * * *	

PART 63—[AMENDED]

1. The authority citation for part 63 continues to read as follows:

Authority: 42 U.S.C. 7401 et seq.

2. By adding a new subpart Y consisting of §§ 63.560 through 63.567 to read as follows:

Subpart Y—National Emission Standards for Marine Tank Vessel Loading Operations

Sec.
63.560 Applicability and designation of affected source.
63.561 Definitions.
63.562 Standards.
63.563 Compliance and performance testing.
63.564 Monitoring requirements.
63.565 Test methods and procedures.
63.566 Construction and reconstruction.
63.567 Recordkeeping and reporting requirements.

Subpart Y—National Emission Standards for Marine Tank Vessel Tank Loading Operations

§ 63.560 Applicability and designation of affected source.

(a) *Maximum achievable control technology (MACT) standards.*

(1) The provisions of this subpart pertaining to the MACT standards in § 63.562(b) and (d) of this subpart are applicable to existing and new sources with emissions of 10 or 25 tons, as that term is defined in § 63.561, except as specified in paragraph (d) of this section, and are applicable to new sources with emissions less than 10 and 25 tons, as that term is defined in § 63.561, except as specified in paragraph (d) of this section.

(2) Existing sources with emissions less than 10 and 25 tons are not subject to the emissions standards in § 63.562(b) and (d).

(3) The recordkeeping requirements of § 63.567(j)(4) and the emission estimation requirements of § 63.565(l) apply to existing sources with emissions less than 10 and 25 tons.

(b) *Reasonably available control technology (RACT) standards.*

(1) The provisions of this subpart pertaining to RACT standards in § 63.562(c) and (d) of this subpart are applicable to sources with throughput of 10 M barrels or 200 M barrels, as that term is defined in § 63.561, except as specified in paragraph (d) of this section.

(2) Sources with throughput less than 10 M barrels and 200 M barrels, as that term is defined in § 63.561, are not subject to the emissions standards in § 63.562(c) and (d).

(c) *General Provisions applicability.* Owners or operators of affected sources, as that term is defined in § 63.561, of this subpart must comply with the requirements of subpart A of this part in accordance with the provisions for applicability of subpart A to this subpart in Table 1 of this section.

(d) *Exemptions from MACT and RACT standards.*

(1) This subpart does not apply to emissions resulting from marine tank vessel loading operations, as that term is defined in § 63.561, of commodities with vapor pressures less than 10.3 kilopascals (kPa) (1.5 pounds per square inch, absolute) (psia) at standard conditions, 20°C and 760 millimeters Hg (mm Hg).

(2) The provisions of this subpart pertaining to the MACT standards in § 63.562(b)(2), (3) and (4) and to the RACT standards in § 63.562(c)(3) and (4) do not apply to marine tank vessel loading operations where emissions are reduced by using a vapor balancing system, as that term is defined in § 63.561. The provisions pertaining to the vapor collection system, ship-to-shore compatibility, and vapor tightness of marine tank vessels in § 63.562(b)(1) and (c)(2) do apply.

(3) The provisions of this subpart pertaining to the MACT standards in § 63.562(b)(2), (3), and (4) do not apply to marine tank vessel loading operations that are contiguous with refinery operations at sources subject to and complying with subpart CC of this part, National Emissions Standards for Organic Hazardous Air Pollutants from Petroleum Refineries, except to the extent that any such provisions of this subpart are made applicable by subpart CC of this part.

(4) The provisions of this subpart pertaining to the MACT standards in § 63.562(b) and (d) do not apply to benzene emissions from marine tank vessel loading operations that are subject to and complying with 40 CFR part 61, subpart BB, National Emissions Standards for Benzene Emissions from Benzene Transfer Operations, except that benzene emissions or other HAP emissions (i.e., nonbenzene HAP emissions) from marine tank vessel loading operations that are not subject to subpart BB are subject to the provisions of this subpart.

(5) The provisions of this subpart pertaining to the MACT standards in § 63.562(b) and (d) do not apply to marine tank vessel loading operations at loading berths that only transfer liquids containing organic HAP as impurities, as that term is defined in § 63.561.

(6) The provisions of this subpart do not apply to marine tank vessel loading operations at existing offshore loading terminals, as that term is defined in § 63.561.

(7) The provisions of this subpart do not apply to ballasting operations, as that term is defined in § 63.561.

(e) *Compliance dates.*

(1) *MACT standards compliance dates, except the Valdez Marine Terminal (VMT) source.*

(i) A new or existing source with emissions of 10 or 25 tons, except the VMT source, and a new source with emissions less than 10 and 25 tons, except the VMT source, that has an initial startup date on or before September 20, 1999 shall comply with the provisions of this subpart pertaining to the MACT standards in § 63.562(b) no later than 4 years after the effective date.

(ii) A new source with emissions of 10 or 25 tons, except the VMT source, and a new source with emissions less than 10 and 25 tons, except the VMT source, that has an initial startup date after September 20, 1999 shall comply with provisions of this subpart pertaining to the MACT standards in § 63.562(b) immediately upon startup.

(iii) A source with emissions less than 10 and 25 tons that increases its emissions subsequent to September 20, 1999 such that it becomes a source with emissions of 10 or 25 tons shall comply with the provisions of this subpart pertaining to the MACT standards in § 63.562(b) within 3 years following the exceedance of the threshold level.

(2) *RACT standards compliance dates, except the VMT source.*

(i) A source with throughput of 10 M barrels or 200 M barrels, except the VMT source, with an initial startup date on or before September 21, 1998 shall comply with § 63.562(c)(1) no later than 2 years after the effective date.

(ii) A source with throughput of 10 M barrels or 200 M barrels, except the VMT source, with an initial startup date on or before September 21, 1998 shall comply with the provisions of this subpart pertaining to the RACT standards in § 63.562(c) other than § 63.562(c)(1), no later than 3 years after the effective date.

(iii) A source with throughput of 10 M barrels or 200 M barrels, except the VMT source, with an initial startup date after September 21, 1998 shall comply with the provisions of this subpart pertaining to the RACT standards in § 63.562(c) immediately upon startup.

(iv) A source with throughput less than 10 M barrels and 200 M barrels that increases its throughput subsequent to September 21, 1998 such that it becomes a source with throughput of 10 M barrels or 200 M barrels shall comply with the provisions of this subpart pertaining to the RACT standards in § 63.562(c) within 3 years following the exceedance of the threshold levels.

(v) A source with throughput of 10 M barrels or 200 M barrels may apply for approval from the Administrator for an extension of the compliance date of up to 1 year if it can demonstrate that the additional time is necessary for installation of the control device.

(3) *MACT and RACT compliance dates for the VMT source.*

The VMT source, as that term is defined in § 63.561, shall comply with the provisions of this subpart pertaining to the MACT and RACT standards in § 63.562(d) no later than 30 months after the effective date.

TABLE 1 OF § 63.560.—GENERAL PROVISIONS APPLICABILITY TO SUBPART Y

Reference	Applies to affected sources in subpart Y	Comment
63.1(a)(1)	Yes	Additional terms are defined in § 63.561; when overlap between subparts A and Y occurs, subpart Y takes precedence.
63.1(a)(2)	Yes	
63.1(a)(3)	Yes	
63.1(a)(4)	Yes	Subpart Y clarifies the applicability of each paragraph in subpart A to sources subject to subpart Y in this table.
.63.1(a)(5)	No	Reserved.
63.1(a)(6)	Yes	
63.1(a)(7)	Yes	
63.1(a)(8)	Yes	
63.1(a)(9)	No	Reserved.
63.1(a)(10)	Yes	
63.1(a)(11)	Yes	§ 63.567(a) also allows report submissions via facsimile and on electronic media.
63.1(a)(12)	Yes	
63.1(a)(13)	Yes	
63.1(a)(14)	Yes	
63.1(b)(1)	Yes	
63.1(b)(2)	Yes	
63.1(b)(3)	No	§ 63.560 specifies applicability.
63.1(c)(1)	Yes	Subpart Y clarifies the applicability of each paragraph in subpart A to sources subject to subpart Y in this table.
63.1(c)(2)	Yes	Subpart Y is not applicable to area sources.
63.1(c)(3)	No	Reserved.
63.1(c)(4)	Yes	

TABLE 1 OF § 63.560.—GENERAL PROVISIONS APPLICABILITY TO SUBPART Y—Continued

Reference	Applies to affected sources in subpart Y	Comment
63.1(c)(5)	No	§ 63.560 specifies applicability.
63.1(d)	No	Reserved.
63.1(e)	Yes	
63.2	Yes	Additional terms are defined in § 63.561; when overlap between subparts A and Y occurs, subpart Y takes precedence.
63.3	Yes	Other units used in subpart Y are defined in the text of subpart Y.
63.4(a)(1)	Yes	
63.4(a)(2)	Yes	
63.4(a)(3)	Yes	
63.4(a)(4)	No	Reserved.
63.4(a)(5)	Yes	
63.4(b)	Yes	
63.4(c)	Yes	
63.5(a)	Yes	
63.5(b)(1)(i)	Yes	
63.5(b)(1)(ii)	No	
63.5(b)(2)	No	Reserved.
63.5(b)(3)	Yes	
63.5(b)(4)–(5)	No	
63.5(b)(6)	Yes	
63.5(c)	No	Reserved.
63.5(d)(1)(i)	No	See § 63.566(b)(2).
63.5(d)(1)(ii)(A)(H)	Yes	
63.5(d)(1)(ii)(I)	No	Reserved.
63.5(d)(1)(ii)(J)	Yes	
63.5(d)(1)(iii)	Yes	
63.5(d)(2)–(4)	Yes	
63.5(e)	Yes	
63.5(f)(1)(i) and (ii)	Yes	
63.5(f)(1)(iii) and (iv)	No	
63.5(f)(2)	No	See § 63.566(c).
63.6(a)(1)	Yes	
63.6(a)(2)	No	§ 63.560 specifies applicability.
63.6(b)(1)–(5)	No	§ 63.560(e) specifies compliance dates for sources.
63.6(b)(6)	No	Reserved.
63.6(b)(7)	No	§ 63.560(e) specifies compliance dates for sources.
63.6(c)(1)	No	§ 63.560(e) specifies compliance dates for sources.
63.6(c)(2)	No	
63.6(c)(3)–(4)	No	Reserved.
63.6(c)(5)	No	§ 63.560(e) specifies compliance dates for sources.
63.6(d)	No	Reserved.
63.6(e)	No	See § 63.562(e).
63.6(f)(1)	Yes	
63.6(f)(2)(i)	Yes	
63.6(f)(2)(ii)	No	
63.6(f)(2)(iii)	Yes	
63.6(f)(2)(iv)	Yes	
63.6(f)(2)(v)	No	See § 63.562(e)(1).
63.6(f)(3)	Yes	
63.6(g)	Yes	
63.6(h)	No	No opacity monitoring is required under subpart Y.
63.6(i)(1)–(3)	Yes	
63.6(i)(4)(i)(A)	No	
63.6(i)(4)(i)(B)	Yes	
63.6(i)(4)(ii)	No	
63.6(i)(5)–(12)	Yes	
63.6(i)(13)	No	
63.6(i)(14)	Yes	
63.6(i)(15)	No	Reserved.
63.6(i)(16)	Yes	
63.6(j)	Yes	
63.7(a)(1)	Yes	
63.7(a)(2)(i)–(iv)	No	See § 63.563(b)(1).
63.7(a)(2)(v)	Yes	
63.7(a)(2)(vi)	No	
63.7(a)(2)(vii)–(viii)	No	Reserved.
63.7(a)(2)(ix)	No	
63.7(a)(3)	Yes	

TABLE 1 OF § 63.560.—GENERAL PROVISIONS APPLICABILITY TO SUBPART Y—Continued

Reference	Applies to affected sources in subpart Y	Comment
63.7(b)	Yes	
63.7(c)(1)–(2)	Yes	The site-specific test plan must be submitted only if requested by the Administrator.
63.7(c)(3)(i)–(ii)(A)	Yes	
63.7(c)(3)(ii)(B)	No	See § 63.565(m)(2).
63.7(c)(3)(iii)	Yes	
63.7(c)(4)	Yes	
63.7(d)	Yes	
63.7(e)	Yes	
63.7(f)	Yes	
63.7(g)(1)	Yes	
63.7(g)(2)	No	Reserved.
63.7(g)(3)	Yes	
63.7(h)	Yes	
63.8(a)(1)–(2)	Yes	
63.8(a)(3)	No	Reserved.
63.8(a)(4)	Yes	
63.8(b)(1)	Yes	
63.8(b)(2)	No	
63.8(b)(3)	Yes	
63.8(c)(1)(i)	Yes	
63.8(c)(1)(ii)	No	
63.8(c)(1)(iii)	Yes	
63.8(c)(2)	Yes	
63.8(c)(3)	Yes	
63.8(c)(4)	No	See § 63.564(a)(3).
63.8(c)(5)	No	
63.8(c)(6)	Yes	See also performance specifications for continuous monitoring systems § 63.564(a)(4).
63.8(c)(7)(i)(A)–(B)	Yes	See also § 63.564(a)(5).
63.8(c)(7)(i)(C)	No	
63.8(c)(7)(ii)	Yes	
63.8(c)(8)	No	See § 63.564(a)(5).
63.8(d)	No	See § 63.562(e)(2)(iv).
63.8(e)(1)–(4)	Yes	
63.8(e)(5)(i)	Yes	
63.8(e)(5)(ii)	No	
63.8(f)(1)	Yes	
63.8(f)(2)(i)–(vii)	Yes	
63.8(f)(2)(viii)	No	
63.8(f)(2)(ix)	Yes	
63.8(f)(3)–(6)	Yes	
63.8(g)	Yes	
63.9(a)(1)	Yes	
63.9(a)(2)	Yes	
63.9(a)(3)	Yes	
63.9(a)(4)	Yes	
63.9(b)(1)(i)	Yes	
63.9(b)(1)(ii)	No	See § 63.567(b)(1)
63.9(b)(1)(iii)	Yes	
63.9(b)(2)	No	See § 63.567(b)(2).
63.9(b)(3)	No	See § 63.567(b)(3).
63.9(b)(4)	No	See § 63.567(b)(4).
63.9(b)(5)	No	See § 63.567(b)(4).
63.9(c)	No	See § 63.567(c).
63.9(d)	No	
63.9(e)	Yes	
63.9(f)	No	
63.9(g)(1)	Yes	
63.9(g)(2)	No	
63.9(g)(3)	Yes	
63.9(h)(1)–(3)	Yes	
63.9(h)(4)	No	Reserved.
63.9(h)(5)–(6)	Yes	
63.9(i)	Yes	
63.9(j)	Yes	
63.10(a)	Yes	
63.10(b)(1)	Yes	
63.10(b)(2)(i)	No	
63.10(b)(2) (ii)–(iii)	Yes	

TABLE 1 OF § 63.560.—GENERAL PROVISIONS APPLICABILITY TO SUBPART Y—Continued

Reference	Applies to affected sources in subpart Y	Comment
63.10(b)(2)(iv)	No	
63.10(b)(2)(v)	No	
63.10(b)(2)(vi)–(xiv)	Yes	
63.10(b)(3)	No	See § 63.567(j)(4).
63.10(c)(1)	Yes	
63.10(c)(2)–(4)	No	Reserved.
63.10(c)(5)	Yes	
63.10(c)(6)	No	See § 63.564(a)(5).
63.10(c)(7)	No	
63.10(c)(8)	Yes	
63.10(c)(9)	No	Reserved.
63.10(c)(10)–(13)	Yes	
63.10(c)(14)	No	See § 63.562(d)(2)(iv).
63.10(c)(15)	No	
63.10(d)(1)–(2)	Yes	
63.10(d)(3)	No	See § 63.567(d).
63.10(d)(4)	Yes	
63.10(d)(5)	No	
63.(10)(e)(1)	Yes	
63.10(e)(2)(i)	Yes	
63.10(e)(2)(ii)	No	
63.10(e)(3)(i)–(v)	No	See § 63.567(e)
63.10(e)(3)(vi).	Yes	
63.10(e)(3)(vii)–(viii)	No	See § 63.567(e)
63.10(e)(4)	No	
63.10(f)	Yes	
63.11	Yes	
63.12–63.15	Yes	

§ 63.561 Definitions.

As used in this subpart, all terms not defined herein shall have the meaning given them in the Clean Air Act or in subpart A of this part.

Affected source means a source with emissions of 10 or 25 tons, a new source with emissions less than 10 and 25 tons, a new major source offshore loading terminal, a source with throughput of 10 M barrels or 200 M barrels, or the VMT source, that is subject to the emissions standards in § 63.562.

Air pollution control device or *control device* means a combustion device or vapor recovery device.

Ballasting operations means the introduction of ballast water into a cargo tank of a tankship or oceangoing barge.

Baseline operating parameter means a minimum or maximum value of a process parameter, established for a control device during a performance test where the control device is meeting the required emissions reduction or established as the manufacturer recommended operating parameter, that, if achieved by itself or in combination with one or more other operating parameters, determines if a control device is operating properly.

Boiler means a device that combusts any fuel and produces steam or heats water or any other heat transfer medium. This term includes any duct burner that combusts fuel and is part of a combined cycle system.

Car-seal means a seal that is placed on a device used to change the position of a valve (e.g., from open to closed) in such a way that the position of the valve cannot be changed without breaking the seal.

Combustion device means all equipment, including, but not limited to, thermal incinerators, catalytic incinerators, flares, boilers, and process heaters used for combustion or destruction of organic vapors.

Commenced means, with respect to construction of an air pollution control device, that an owner or operator has undertaken a continuous program of construction or that an owner or operator has entered into a contractual obligation to undertake and complete, within a reasonable time, a continuous program of construction.

Commodity means a distinct product that a source loads onto marine tank vessels.

Continuous means, with respect to monitoring, reading and recording (either in hard copy or computer readable form) of data values measured at least once every 15 minutes.

Crude oil means a naturally occurring mixture consisting predominantly of hydrocarbons and/or sulfur, nitrogen, and oxygen derivatives of hydrocarbons that is removed from the earth in a liquid state or is capable of being so removed.

Exceedance or *Variance* means, with respect to parametric monitoring, the operating parameter of the air pollution control device that is monitored as an indication of proper operation of the control device is outside the acceptable range or limits for the baseline parameter given in § 63.563(b)(4) through (9).

Excess emissions means, with respect to emissions monitoring, the concentration of the outlet stream of the air pollution control device is outside the acceptable range or limits for the baseline concentration given in § 63.563(b)(4) through (9).

Flow indicator means a device that indicates whether gas flow is present in a line or vent system.

Gasoline means any petroleum distillate or petroleum distillate/alcohol blend having a Reid vapor pressure of 27.6 kPa (4.0 psia) or greater, that is used as a fuel for internal combustion engines.

Impurity means HAP substances that are present in a commodity or that are produced in a process coincidentally with the primary product or commodity and that are 0.5 percent total HAP by weight or less. An impurity does not serve a useful purpose in the production

or use of the primary product or commodity and is not isolated.

Leak means a reading of 10,000 parts per million volume (ppmv) or greater as methane that is determined using the test methods in Method 21, appendix A of part 60 of this chapter.

Lightering or *Lightering operation* means the offshore transfer of a bulk liquid cargo from one marine tank vessel to another vessel.

Loading berth means the loading arms, pumps, meters, shutoff valves, relief valves, and other piping and valves necessary to fill marine tank vessels. The loading berth includes those items necessary for an offshore loading terminal.

Loading cycle means the time period from the beginning of filling a single marine tank vessel until commodity flow to the marine tank vessel ceases.

Maintenance allowance means a period of time that an affected source is allowed to perform maintenance on the loading berth without controlling emissions from marine tank vessel loading operations.

Marine tank vessel loading operation means any operation under which a commodity is bulk loaded onto a marine tank vessel from a terminal, which may include the loading of multiple marine tank vessels during one loading operation. Marine tank vessel loading operations do not include refueling of marine tank vessels.

Marine vessel or *Marine tank vessel* means any tank ship or tank barge that transports liquid product such as gasoline or crude oil in bulk.

Nonvapor-tight means any marine tank vessel that does not pass the required vapor-tightness test.

Offshore loading terminal means a location that has at least one loading berth that is 0.81 km (0.5 miles) or more from the shore that is used for mooring a marine tank vessel and loading liquids from shore.

Primary fuel means the fuel that provides the principal heat input to the device. To be considered primary, the fuel must be able to sustain operation of the device without the addition of other fuels.

Process heater means a device that transfers heat liberated by burning fuel to fluids contained in tubes, including all fluids except water that are heated to produce steam.

Recovery device means an individual unit of equipment, including, but not limited to, a carbon adsorber, condenser/refrigeration unit, or absorber that is capable of and used for the purpose of removing vapors and recovering liquids or chemicals.

Routine loading means, with respect to the VMT source, marine tank vessel loading operations that occur as part of normal facility operation over a loading berth when no loading berths are inoperable due to maintenance.

Secondary fuel means any fuel other than the primary fuel. The secondary fuel provides supplementary heat in addition to the heat provided by the primary fuel and is generally fired through a burner other than the primary burner.

Source(s) means any location where at least one dock or loading berth is bulk loading onto marine tank vessels, except offshore drilling platforms and lightering operations.

Source(s) with emissions less than 10 and 25 tons means major source(s) having aggregate actual HAP emissions from marine tank vessel loading operations at all loading berths as follows:

(1) Prior to the compliance date, of less than 9.1 Mg (10 tons) of each individual HAP calculated on a 24-month annual average basis after September 19, 1997 and less than 22.7 Mg (25 tons) of all HAP combined calculated on a 24-month annual average basis after September 19, 1997, as determined by emission estimation in § 63.565(l) of this subpart; and

(2) After the compliance date, of less than 9.1 Mg (10 tons) of each individual HAP calculated annually after September 20, 1999 and less than 22.7 Mg (25 tons) of all HAP combined calculated annually after September 20, 1999, as determined by emission estimation in § 63.565(l) of this subpart.

Source(s) with emissions of 10 or 25 tons means major source(s) having aggregate actual HAP emissions from marine tank vessels loading operations at all loading berths as follows:

(1) Prior to the compliance date, emissions of 9.1 Mg (10 tons) or more of each individual HAP calculated on a 24-month annual average basis after September 19, 1997 or of 22.7 Mg (25 tons) or more of all HAP combined calculated on a 24-month annual average basis after September 19, 1997, as determined by emission estimation in § 63.565(l); or

(2) After the compliance date, emissions of 9.1 Mg (10 tons) or more of each individual HAP calculated annually after September 20, 1999 or of 22.7 Mg (25 tons) or more of all HAP combined calculated annually after September 20, 1999, as determined by emission estimation in § 63.565(l).

Source(s) with throughput less than 10 M barrels and 200 M barrels means source(s) having aggregate loading from marine tank vessel loading operations at all loading berths as follows:

(1) Prior to the compliance date, of less than 1.6 billion liters (10 million (M) barrels) of gasoline on a 24-month annual average basis and of less than 32 billion liters (200 M barrels) of crude oil on a 24-month annual average basis after September 19, 1996; and

(2) After the compliance date, of less than 1.6 billion liters (10 M barrels) of gasoline annually and of less than 32 billion liters (200 M barrels) of crude oil annually after September 21, 1998.

Source(s) with throughput of 10 M barrels or 200 M barrels means source(s) having aggregate loading from marine tank vessel loading operations at all loading berths as follows:

(1) Prior to the compliance date, of 1.6 billion liters (10 M barrels) or more of gasoline on a 24-month annual average basis or of 32 billion liters (200 M barrels) or more of crude oil on a 24-month annual average basis after September 19, 1996; or

(2) After the compliance date, of 1.6 billion liters (10 M barrels) or more of gasoline annually or of 32 billion liters (200 M barrels) or more of crude oil annually after September 21, 1998.

Terminal means all loading berths at any land or sea based structure(s) that loads liquids in bulk onto marine tank vessels.

Twenty-four-month (24-month) annual average basis means annual HAP emissions, with respect to MACT standards, or annual loading throughput, with respect to RACT standards, from marine tank vessel loading operations averaged over a 24-month period.

Valdez Marine Terminal (VMT) source means the major source that is permitted under the Trans-Alaska Pipeline Authorization Act (TAPAA) (43 U.S.C. § 1651 *et seq.*). The source is located in Valdez, Alaska in Prince William Sound.

Vapor balancing system means a vapor collection system or piping system that is designed to collect organic HAP vapors displaced from marine tank vessels during marine tank vessel loading operations and that is designed to route the collected organic HAP vapors to the storage vessel from which the liquid being loaded originated or to compress collected organic HAP vapors and commingle with the raw feed of a process unit.

Vapor collection system means any equipment located at the source, i.e., at the terminal, that is not open to the atmosphere, that is composed of piping, connections, and flow inducing devices, and that is used for containing and transporting vapors displaced during

the loading of marine tank vessels to a control device or for vapor balancing. This does not include the vapor collection system that is part of any marine vessel vapor collection manifold system.

Vapor-tight marine vessel means a marine tank vessel that has demonstrated within the preceding 12 months to have no leaks. A marine tank vessel loaded at less than atmospheric pressure is assumed to be vapor tight for the purpose of this standard.

Volatile organic compounds or *VOC* is as defined in 40 CFR 51.100(s) of this chapter.

§ 63.562 Standards.

(a) The emissions limitations in paragraphs (b), (c), and (d) of this section apply during marine tank vessel loading operations.

(b) *MACT standards, except for the VMT source.*

(1)(i) *Vapor collection system of the terminal.* The owner or operator of a new source with emissions less than 10 and 25 tons and an existing or new source with emissions of 10 or 25 tons shall equip each terminal with a vapor collection system that is designed to collect HAP vapors displaced from marine tank vessels during marine tank vessel loading operations and to prevent HAP vapors collected at one loading berth from passing through another loading berth to the atmosphere, except for those commodities exempted under § 63.560(d).

(ii) *Ship-to-shore compatibility.* The owner or operator of a new source with emissions less than 10 and 25 tons and an existing or new source with emissions of 10 or 25 tons shall limit marine tank vessel loading operations to those vessels that are equipped with vapor collection equipment that is compatible with the terminal's vapor collection system, except for those commodities exempted under § 63.560(d).

(iii) *Vapor tightness of marine vessels.* The owner or operator of a new source with emissions less than 10 and 25 tons and an existing or new source with emissions of 10 or 25 tons shall limit marine tank vessel loading operations to those vessels that are vapor tight and to those vessels that are connected to the vapor collection system, except for those commodities exempted under § 63.560(d).

(2) *MACT standards for existing sources with emissions of 10 or 25 tons.* The owner or operator of an existing source with emissions of 10 or 25 tons, except offshore loading terminals and the VMT source, shall reduce captured HAP emissions from marine tank vessel loading operations by 97 weight-percent, as determined using methods in § 63.565 (d) and (l).

(3) *MACT standards for new sources.* The owner or operator of a new source with emissions less than 10 and 25 tons or a new source with emissions of 10 or 25 tons, except offshore loading terminals and the VMT source, shall reduce HAP emissions from marine tank vessel loading operations by 98 weight-percent, as determined using methods in § 63.565 (d) and (l).

(4) *MACT standards for new major source offshore loading terminals.* The owner or operator of a new major source offshore loading terminal shall reduce HAP emissions from marine tank vessel loading operations by 95 weight-percent, as determined using methods in § 63.565 (d) and (l).

(5) *Prevention of carbon adsorber emissions during regeneration.* The owner or operator of a source subject to paragraph (b)(2), (3), or (4) shall prevent HAP emissions from escaping to the atmosphere from the regeneration of the carbon bed when using a carbon adsorber to control HAP emissions from marine tank vessel loading operations.

(6) *Maintenance allowance for loading berths.* The owner or operator of a source subject to paragraph (b)(2), (3) or (4), may apply for approval to the Administrator for a maintenance allowance for loading berths based on a percent of annual throughput or annual marine tank vessel loading operation time for commodities not exempted in § 63.560(d). The owner or operator shall maintain records for all maintenance performed on the air pollution control equipment. The Administrator will consider the following in approving the maintenance allowance:

(i) The owner or operator expects to be in violation of the emissions standards due to maintenance;

(ii) Due to conditions beyond the reasonable control of the owner or operator, compliance with the emissions standards during maintenance would result in unreasonable economic hardship;

(iii) The economic hardship cannot be justified by the resulting air quality benefit;

(iv) The owner or operator has given due consideration to curtailing marine vessel loading operations during maintenance;

(v) During the maintenance allowance, the owner or operator will endeavor to reduce emissions from other loading berths that are controlled as well as from the loading berth the owner or operator is seeking the maintenance allowance; and

(vi) During the maintenance allowance, the owner or operator will monitor and report emissions from the loading berth to which the maintenance allowance applies.

(c) *RACT standards, except the VMT source.*

(1) *Commencement of construction.* The owner or operator of a source with throughput of 10 M barrels or 200 M barrels, except the VMT source, with an initial startup date on or before September 21, 1998 shall provide the Agency no later than 2 years after the effective date with proof that it has commenced construction of its vapor collection system and air pollution control device.

(2) (i) *Vapor collection system of the terminal.* The owner or operator of a source with throughput of 10 M barrels or 200 M barrels shall equip each terminal with a vapor collection system that is designed to collect VOC vapors displaced from marine tank vessels during loading and to prevent VOC vapors collected at one loading berth from passing through another loading berth to the atmosphere, except for those commodities exempted under § 63.560(d).

(ii) *Ship-to-shore compatibility.* The owner or operator of a source with throughput of 10 M barrels or 200 M barrels shall limit marine tank vessel loading operations to those vessels that are equipped with vapor collection equipment that is compatible with the terminal's vapor collection system, except for those commodities exempted under § 63.560(d).

(iii) *Vapor tightness of marine vessels.* The owner or operator of a source with throughput of 10 M barrels or 200 M barrels shall limit marine tank vessel loading operations to those vessels that are vapor-tight and to those vessels that are connected to the vapor collection system, except for those commodities exempted under § 63.560(d).

(3) *RACT standard for sources with throughput of 10 M or 200 M barrels, except the VMT source.* The owner or operator of a source with throughput of 10 M barrels or 200 M barrels, except the VMT source, shall reduce captured VOC emissions from marine tank vessel loading operations by 98 weight-percent when using a combustion device or reduce captured VOC emissions by 95 weight-percent when using a recovery device, as determined using methods in § 63.565(d) and (l).

(4) The owner or operator of a source with throughput of 10 M barrels or 200 M barrels, except the VMT source, may meet the requirements of paragraph (c)(3) by reducing gasoline loading

emissions to, at most, 1,000 ppmv outlet VOC concentration.

(5) *Prevention of carbon adsorber emissions during regeneration.* The owner or operator of a source with throughput of 10 M barrels or 200 M barrels shall prevent HAP emissions from escaping to the atmosphere from the regeneration of the carbon bed when using a carbon adsorber to control HAP emissions from marine tank vessel loading operations.

(6) *Maintenance allowance for loading berths.* The owner or operator of a source with throughput of 10 M barrels or 200 M barrels may apply for approval to the Administrator for a maintenance allowance for loading berths based on a percent of annual throughput or annual marine tank vessel loading operation time for commodities not exempted in § 63.560(d). The owner or operator shall maintain records for all maintenance performed on the air pollution control equipment. The Administrator will consider the following in approving the maintenance allowance:

(i) The owner or operator expects to be in violation of the emissions standards due to maintenance;

(ii) Due to conditions beyond the reasonable control of the owner or operator, compliance with the emissions standards during maintenance would result in unreasonable economic hardship;

(iii) The economic hardship cannot be justified by the resulting air quality benefit;

(iv) The owner or operator has given due consideration to curtailing marine vessel loading operations during maintenance;

(v) During the maintenance allowance, the owner or operator will endeavor to reduce emissions from other loading berths that are controlled as well as from the loading berth the owner or operator is seeking the maintenance allowance; and

(vi) During the maintenance allowance, the owner or operator will monitor and report emissions from the loading berth to which the maintenance allowance applies.

(d) *MACT and RACT standards for the VMT source.*

(1) (i) *Vapor collection system of the terminal.* The owner or operator of the VMT source shall equip each terminal subject under paragraph (d)(2) with a vapor collection system that is designed to collect HAP vapors displaced from marine tank vessels during marine tank vessel loading operations and to prevent HAP vapors collected at one loading berth from passing through another loading berth to the atmosphere, except for those commodities exempted under § 63.560(d).

(ii) *Ship-to-shore compatibility.* The owner or operator of the VMT source shall limit marine tank vessel loading operations at berths subject under paragraph (d)(2) of this section to those vessels that are equipped with vapor collection equipment that is compatible with the terminal's vapor collection system, except for those commodities exempted under § 63.560(d).

(iii) *Vapor tightness of marine vessels.* The owner or operator of the VMT source shall limit marine tank vessel loading operations at berths subject under paragraph (d)(2) of this section to those vessels that are vapor-tight and to those vessels that are connected to the vapor collection system, except for those commodities exempted under § 63.560(d).

(2) The owner or operator of the VMT source shall reduce captured HAP and VOC emissions by 98 weight-percent, as determined using methods in § 63.565(d) and (l) for loading berths subject under this paragraph according to paragraphs (d)(2)(i), (ii), (iii), and (iv):

(i) The owner or operator of the VMT source shall equip at least two loading berths and any additional berths indicated pursuant to paragraph (d)(2)(iii) with a vapor collection system and air pollution control device and shall load marine tank vessels over loading berths equipped with a vapor collection system and control device to the maximum extent practicable. The owner or operator shall equip all loading berths that will be used for routine loading after March 19, 1998 with a vapor collection system and control device if the annual average daily loading rate for all loading berths exceeds the limits in paragraphs (d)(2)(i)(A), (B), and (C) of this section.

(A) For 1995, 1,630,000 barrels per day; and

(B) For 1996, 1,546,000 barrels per day; and

(C) For 1997, 1,445,000 barrels per day.

(ii) Maximum extent practicable means that the total annual average daily loading over all loading berths not equipped with a vapor collection system and control device shall not exceed the totals in paragraphs (d)(2)(ii)(A) and (B):

(A) *Loading allowances for marine tank vessel loading operations at loading berths not equipped with control devices.* The following maximum annual average daily loading rate for routine loading at loading berths not equipped with control devices in any of the following years shall not exceed:

(*a*) For 1998, 275,000 barrels per day;

(*b*) For 1999, 205,000 barrels per day;

(*c*) For 2000, 118,000 barrels per day;

(*d*) For 2001, 39,000 barrels per day; and

(*e*) For 2002 and subsequent years, no marine tank vessel loading operations shall be performed at berths not equipped with a vapor collection system and control device, except as allowed for maintenance under paragraph (B).

(B) *Maintenance allowances for loading berths subject under paragraph (d)(2)(i).* Beginning in the year 2000, the owner or operator of the VMT source may have a maximum of 40 calendar days per calendar year use of loading berths not equipped with a vapor collection system and control device, in accordance with the limits in paragraph (d)(2)(ii)(B)(*a*), (*b*), or (*c*), to allow for maintenance of loading berths subject to paragraph (d)(2)(i). Beginning in the year 2002, the total annual average daily loading of crude oil over all loading berths not equipped with a vapor collection system and control device shall not exceed the amount stated in paragraph (d)(2)(ii)(B)(*b*). The 40 days allowed for maintenance shall be converted into a compliance measure of annual average daily loading over the loading berths not equipped with a vapor collection system and control device as follows:

(*a*) If the total annual average daily volume of crude oil loaded at the facility was greater than or equal to 1,100,000 barrels per day in the prior calendar year, the maintenance allowance shall not exceed an annual average daily loading of 60,000 barrels per day.

(*b*) If the total annual average daily volume of crude oil loaded at the facility was less than 1,100,000 barrels per day and greater than or equal to 550,000 barrels per day in the prior calendar year, the maintenance allowance for the calendar year shall not exceed Q_m:

$$Q_m = \frac{(P - 550{,}000) \times 40}{365}$$

Where:

Q_m = maintenance allowance, barrels per day

P = prior calendar year's average daily volume of crude oil loaded at the facility, barrels per day.

(*c*) If the total annual average daily volume of crude oil loaded at the facility was less than 550,000 barrels per day in the prior calendar year, there shall be no maintenance allowance.

(iii) If the average daily loading rate for the loading berths not equipped with a vapor collection system and control device is greater than the combined

amounts in any year listed in paragraphs (d)(2)(i)(A), (B), and (C) and (d)(2)(ii)(A) and (B), then the owner or operator of the VMT source shall equip all loading berths used for routine loading with a vapor collection system and control device within 2 years of the exceedance except that in an emergency situation the Administrator may, instead of requiring controls, approve an alternative plan to reduce loading over the unequipped berth(s) to a level which will ensure compliance with the applicable limit. Beginning in the year 2002, the owner or operator of the VMT source shall equip all uncontrolled loading berths used for marine tank vessel loading operations beyond the maintenance allowance in paragraph (d)(2)(ii)(B) with a vapor collection system and control device.

(iv) The owner or operator of the VMT source shall develop a program to communicate to relevant facility operations and marine transportation personnel and engage their active and consistent participation in honoring the intent and goal of minimizing loaded volumes over the unequipped berths and maximizing the loaded volumes at the berths equipped with a vapor collection system and control device to prevent exceedance of the load volume limits in paragraphs (d)(2)(ii)(A) and (B). This program is to be presented semi-annually during the first year of compliance and annually thereafter until the use of unequipped berths for routine loading is no longer required.

(3) The owner or operator of the VMT source shall submit annual reports on or before January 31 of each year to the Administrator certifying the annual average daily loading rate for the previous calendar year. Beginning on January 31, 1996, for the reported year 1995, the annual report shall specify the annual average daily loading rate over all loading berths. Beginning on January 31, 1999, for the reported year 1998, the annual report shall specify the annual average daily loading rate over all loading berths, over each loading berth equipped with a vapor collection system and control device, and over each loading berth not equipped with a vapor collection system and control device. The annual average daily loading rate under this section is calculated as the total amount of crude oil loaded during the calendar year divided by 365 days or 366 days, as appropriate.

(e) *Operation and maintenance requirements for air pollution control equipment and monitoring equipment for affected sources.* At all times, including periods of startup, shutdown, and malfunction, owners or operators of affected sources shall operate and maintain a source, including associated air pollution control equipment, in a manner consistent with safety and good air pollution control practices for minimizing emissions. Determination of whether acceptable operation and maintenance procedures are being used will be based on information available to the Administrator which may include, but is not limited to, monitoring results, review of operation and maintenance procedures, review of operation and maintenance records, and inspection of the source.

(1) The Administrator will determine compliance with design, equipment, work practice, or operational emission standards by evaluating an owner or operator's conformance with operation and maintenance requirements.

(2) The owner or operator of an affected source shall develop and implement a written operation and maintenance plan that describes in detail a program of corrective action for varying (i.e., exceeding baseline parameters) air pollution control equipment and monitoring equipment, based on monitoring requirements in § 63.564, used to comply with these emissions standards. The plan shall also identify all routine or otherwise predictable continuous monitoring system (thermocouples, pressure transducers, continuous emissions monitors (CEMS), etc.) variances.

(i) The plan shall specify procedures (preventive maintenance) to be followed to ensure that pollution control equipment and monitoring equipment functions properly and variances of the control equipment and monitoring equipment are minimal.

(ii) The plan shall identify all operating parameters to be monitored and recorded for the air pollution control device as indicators of proper operation and shall establish the frequency at which the parameters will be monitored (see § 63.564).

(iii) Owners or operators of affected sources shall incorporate a standardized inspection schedule for each component of the control device used to comply with the emissions standards in § 63.562(b), (c), and (d). To satisfy the requirements of this paragraph, the owner or operator may use the inspection schedule recommended by the vendor of the control system or any other technical publication regarding the operation of the control system.

(iv) Owners or operators shall develop and implement a continuous monitoring system (CMS) quality control program. The owner or operator shall develop and submit to the Administrator for approval upon request a site-specific performance evaluation test plan for the CMS performance evaluation required in § 63.8(e) of subpart A of this part. Each quality control program shall include, at a minimum, a written protocol that describes procedures for initial and any subsequent calibration of the CMS; determination and adjustment of the calibration drift of the CMS; preventive maintenance of the CMS, including spare parts inventory; data recording, calculations, and reporting; and accuracy audit procedures, including sampling and analysis methods. The owner or operation shall maintain records of the procedures that are part of the quality control program developed and implemented for CMS.

(3) Based on the results of the determination made under paragraph (e)(2), the Administrator may require that an owner or operator of an affected source make changes to the operation and maintenance plan for that source. Revisions may be required if the plan:

(i) Does not address a variance of the air pollution control equipment or monitoring equipment that has occurred that increases emissions;

(ii) Fails to provide for operation during a variance of the air pollution control equipment or the monitoring equipment in a manner consistent with safety and good air pollution control practices; or

(iii) Does not provide adequate procedures for correcting a variance of the air pollution control equipment or monitoring equipment as soon as reasonable.

(4) If the operation and maintenance plan fails to address or inadequately addresses a variance event at the time the plan was initially developed, the owner or operator shall revise the operation and maintenance plan within 45 working days after such an event occurs. The revised plan shall include procedures for operating and maintaining the air pollution control equipment or monitoring equipment during similar variance events and a program for corrective action for such events.

(5) The operation and maintenance plan shall be developed by the source's compliance date. The owner or operator shall keep the written operation and maintenance plan on record to be made available for inspection, upon request, by the Administrator for the life of the source. In addition, if the operation and maintenance plan is revised, the owner or operator shall keep previous (i.e., superseded) versions of the plan on record to be made available for inspection upon request by the Administrator for a period of 5 years after each revision to the plan.

(6) To satisfy the requirements of the operation and maintenance plan, the owner or operator may use the source's standard operating procedures (SOP) manual, an Occupational Safety and Health Administration (OSHA) plan, or other existing plans provided the alternative plans meet the requirements of this section and are made available for inspection when requested by the Administrator.

§ 63.563 Compliance and performance testing.

(a) The following procedures shall be used to determine compliance with the emissions limits under § 63.562(b)(1), (c)(2), and (d)(1):

(1) *Vent stream by-pass requirements for the terminal's vapor collection system.*

(i) In accordance with § 63.562(b)(1)(i), (c)(2)(i), and (d)(1)(i), each valve in the terminal's vapor collection system that would route displaced vapors to the atmosphere, either directly or indirectly, shall be secured closed during marine tank vessel loading operations either by using a car-seal or a lock-and-key type configuration, or the by-pass line from the valve shall be equipped with a flow indicator, except for those valves used for pressure/vacuum relief, analyzers, instrumentation devices, sampling, and venting for maintenance. Marine tank vessel loading operations shall not be performed with open by-pass lines.

(ii) Repairs shall be made to valves, car-seals, or closure mechanisms no later than 15 days after a change in the position of the valve or a break in the car-seal or closure mechanism is detected or no later than prior to the next marine tank vessel loading operation, whichever is later.

(2) *Ship-to-shore compatibility of vapor collection systems.* Following the date on which the initial performance test is completed, marine tank vessel loading operations must be performed only if the marine tank vessel's vapor collection equipment is compatible to the terminal's vapor collection system; marine tank vessel loading operations must be performed only when the marine tank vessel's vapor collection equipment is connected to the terminal's vapor collection system, as required in § 63.562(b)(1)(ii), (c)(2)(ii), and (d)(1)(ii).

(3) *Pressure/vacuum settings for the marine tank vessel's vapor collection equipment.* During the initial performance test required in paragraph (b)(1) of this section, the owner or operator of an affected source shall demonstrate compliance with operating pressure requirements of 33 CFR 154.814 using the procedures in § 63.565(b).

(4) *Vapor-tightness requirements of the marine vessel.* The owner or operator of an affected source shall use the procedures in paragraph (a)(4)(i), (ii), (iii), or (iv) of this section to ensure that marine tank vessels are vapor tight, as required in § 63.562(b)(1)(iii), (c)(2)(iii), and (d)(1)(iii).

(i) *Pressure test documentation for determining vapor tightness of the marine vessel.* The owner or operator of a marine tank vessel, who loads commodities containing HAP not determined to be exempt under § 63.560(d) at an affected source, shall provide a copy of the vapor-tightness pressure test documentation described in § 63.567(i) for each marine tank vessel prior to loading. The date of the test listed in the documentation must be within the preceding 12 months, and the test must be conducted in accordance with the procedures in § 63.565(c)(1). Following the date on which the initial performance test is completed, the affected source must check vapor-tightness pressure test documentation for marine tank vessels loaded at positive pressure.

(ii) *Leak test documentation for determining vapor tightness of the marine vessel.* If no documentation of the vapor tightness pressure test as described in paragraph (a)(4)(i) of this section is available, the owner or operator of a marine tank vessel, who loads commodities containing HAP not determined to be exempt under § 63.560(d) at an affected source, shall provide the leak test documentation described in § 63.567(i) for each marine tank vessel prior to loading. The date of the test listed in the documentation must be within the preceding 12 months, and the test must be conducted in accordance with the procedures in § 63.565(c)(2). If the marine tank vessel has failed its most recent vapor-tightness leak test at that terminal, the owner or operator of the non-vapor-tight marine tank vessel shall provide documentation that the leaks detected during the previous vapor-tightness test have been repaired and documented with a successful vapor-tightness leak test described in § 63.565(c)(2) conducted during loading. If the owner or operator of the marine tank vessel can document that repair is technically infeasible without cleaning and gas freeing or dry-docking the vessel, the owner or operator of the affected source may load the marine tank vessel. Following the date on which the initial performance test is completed, an affected source must check the vapor-tightness leak test documentation for marine tank vessels loaded at positive pressure.

(iii) *Leak test performed during loading using Method 21 for determining vapor tightness of the marine vessel.* If no documentation of vapor tightness as described in paragraphs (a)(4)(i) or (ii) of this section is available, the owner or operator of a marine tank vessel, who loads commodities containing HAP not determined to be exempt under § 63.560(d) at an affected source, shall perform a leak test of the marine tank vessel during marine tank vessel loading operation using the procedures described in § 63.565(c)(2).

(A) If no leak is detected, the owner or operator of a marine tank vessel shall complete the documentation described in § 63.567(i) prior to departure of the vessel.

(B) If a leak is detected, the owner or operator of the marine tank vessel shall document the vapor-tightness failure for the marine tank vessel prior to departure of the vessel. The leaking component shall be repaired prior to the next marine tank vessel loading operation at a controlled terminal unless the repair is technically infeasible without cleaning and gas freeing or dry-docking the vessel. If the owner or operator of the vessel provides documentation that repair of such equipment is technically infeasible without cleaning and gas freeing or dry-docking the vessel, the equipment responsible for the leak will be excluded from future Method 21 tests until repairs are effected. A copy of this documentation shall be maintained by the owner or operator of the affected source. Repair of the equipment responsible for the leak shall occur the next time the vessel is cleaned and gas freed or dry-docked. For repairs that are technically feasible without dry-docking the vessel, the owner or operator of the affected source shall not load the vessel again unless the marine tank vessel owner or operator can document that the equipment responsible for the leak has been repaired.

(iv) *Negative pressure loading.* The owner or operator of an affected source shall ensure that a marine tank vessel is loaded with the product tank below atmospheric pressure (i.e., at negative gauge pressure). The pressure shall be measured between the facility's vapor connection and its manual isolation valve, and the measured pressure must be below atmospheric pressure. Following the date on which the initial performance test is completed, marine tank vessel loading operations for nonvapor-tight vessels must be performed below atmospheric pressure

(i.e., at negative gauge pressure) in the product tank.

(b) *Compliance determination for affected sources.* The following procedures shall be used to determine compliance with the emissions limits under § 63.562(b), (c), and (d).

(1) *Initial performance test.* An initial performance test shall be conducted using the procedures listed in § 63.7 of subpart A of this part according to the applicability in Table 1 of § 63.560, the procedures listed in this section, and the test methods listed in § 63.565. The initial performance test shall be conducted within 180 days after the compliance date for the specific affected source. During this performance test, sources subject to MACT standards under § 63.562(b)(2), (3), (4), and (5) and (d)(2) shall determine the reduction of HAP emissions, as VOC, for all combustion or recovery devices other than flares. Sources subject to RACT standards under § 63.562(c)(3), (4), and (5) and (d)(2) shall determine the reduction of VOC emissions for all combustion or recovery devices other than flares.

(2) *Performance test exemptions.* An initial performance test required in this section and in § 63.565(d) and the continuous monitoring in § 63.564(e) is not required in the following cases:

(i) When a boiler or process heater with a design heat input capacity of 44 Megawatts or less is used to comply with § 63.562(b)(2), (3), or (4), (c)(3) or (4), or (d)(2) and the vent stream is used as the primary fuel or with the primary fuel;

(ii) When a boiler or process heater with a design heat input capacity of 44 Megawatts or greater is used to comply with § 63.562(b)(2), (3) or (4), (c)(3) or (4), or (d)(2); or

(iii) When a boiler subject to 40 CFR part 266, subpart H, ''Hazardous Waste Burned in Industrial Furnaces,'' that has demonstrated 99.99 percent destruction or recovery efficiency is used to comply with § 63.562(b)(2), (3), or (4), (c)(3) or (4), or (d)(2).

(3) *Operation and maintenance inspections.* If the 3-hour or 3-cycle block average operating parameters in paragraphs (b)(4) through (9) of this section, outside the acceptable operating ranges, are measured and recorded, i.e., variances of the pollution control device or monitoring equipment, the owner or operator of the affected source shall perform an unscheduled inspection of the control device and monitoring equipment and review of the parameter monitoring data. The owner or operator of the affected source shall perform an inspection and review when total parameter variance time for the control device is greater than 10 percent of the operating time for marine tank vessel loading operations on a 30-day, rolling-average basis. The inspection and review shall be conducted within 24 hours after passing the allowable variance time of 10 percent. The inspection checklist from the requirements of § 63.562(e)(2)(iii) and the monitoring data from requirements in §§ 63.562(e)(2)(ii) and 63.564 should be used to identify any maintenance problems that may be associated with the variance. The unscheduled inspection should encompass all components of the control device and monitoring equipment that can be inspected while in operation. If any maintenance problem is identified during the inspection, the owner or operator of the affected source must take corrective action (e.g., adjustments to operating controls, etc.) as soon as practicable. If no immediate maintenance problems are identified from the inspection performed while the equipment is operating, a complete inspection in accordance with § 63.562(e)(2) must be conducted prior to the next marine tank vessel loading operation and corrective action (e.g., replacement of defective parts) must be taken as soon as practicable for any maintenance problem identified during the complete inspection.

(4) *Combustion device, except flare.* During the initial performance test required in paragraph (b)(1) of this section, the owner or operator shall determine the efficiency of and/or the outlet VOC concentration from the combustion device used to comply with § 63.562(b)(2), (3), and (4), (c)(3) and (4), and (d)(2) using the test methods in § 63.565(d). The owner or operator shall comply with paragraph (b)(4)(i) or (ii) of this section.

(i) *Outlet VOC concentration limit for required percent combustion efficiency.* The owner or operator shall establish as an operating parameter the baseline VOC concentration using the procedures described in § 63.565(g). Following the date on which the initial performance test is completed, the facility shall be operated with a block average outlet VOC concentration as determined in § 63.564(e)(1) no more than 20 percent above the baseline VOC concentration.

(ii) *Baseline temperature for required percent combustion efficiency.* The owner or operator shall establish as an operating parameter the baseline temperature using the procedures described in § 63.565(f). Following the date on which the initial performance test is completed, the facility shall be operated with the block average temperature as determined in § 63.564(e)(2) or (3) no more than 28°C (50°F) below the baseline temperature.

(5) *Flare.* During the initial performance test required in paragraph (b)(1) of this section, the owner or operator shall establish that the flare used to comply with the emissions standards in § 63.562(b)(2), (3), and (4), (c)(3) and (4), and (d)(2) is in compliance with the design requirements for flares cited in § 63.565(e). Following the date on which the initial determination of compliance is established, the facility shall operate with the presence of a pilot flame in the flare, as determined in § 63.564(f).

(6) *Carbon adsorber.* During the initial performance test required in paragraph (b)(1) of this section, the owner or operator shall determine the efficiency of and/or the outlet VOC concentration from the recovery device used to comply with § 63.562(b)(2), (3), (4), and (5), (c)(3), (4), and (5), and (d)(2) using the test methods in § 63.565(d). The owner or operator shall comply with paragraph (b)(6)(i) as well as either paragraph (b)(6)(ii) or (iii) of this section. The owner or operator of affected sources complying with paragraph (b)(6)(ii)(B) or (C) of this section shall conduct a performance test once each year.

(i) *Compliance determination for carbon bed regeneration.* Desorbed hydrocarbons from regeneration of the off-line carbon bed shall be vented to the on-line carbon bed.

(ii) *Baseline parameters for required percent recovery efficiency.* The owner or operator shall comply with paragraph (b)(6)(ii)(A), (B), or (C) of this section.

(A) *Outlet VOC concentration limit for required percent recovery efficiency.* The owner or operator shall establish as an operating parameter the baseline VOC concentration using the procedures described in § 63.565(g). Following the date on which the initial performance test is completed, the facility shall be operated with a block average outlet VOC concentration as determined in § 63.564(g)(1) no more than 20 percent above the baseline VOC concentration.

(B) *Carbon adsorbers with vacuum regeneration.* The owner or operator shall establish as operating parameters the baseline regeneration time for the vacuum stage of carbon bed regeneration using the procedures described in § 63.565(h) and shall establish the baseline vacuum pressure (negative gauge pressure) using the procedures described in § 63.565(i). Following the date on which the initial performance test is completed, the facility shall be operated with block average regeneration time of the vacuum

stage of carbon bed regeneration as determined in § 63.564(g)(2) no more than 20 percent below the baseline regeneration time, and the facility shall be operated with the block average vacuum pressure (negative gauge pressure) as determined in § 63.564(g)(2) no more than 20 percent above the baseline vacuum pressure.

(C) *Carbon adsorbers with steam regeneration.* The owner or operator shall establish as operating parameters the baseline total stream flow using the procedures described in § 63.565(j) and a baseline carbon bed temperature after cooling of the bed using the procedures in § 63.565(f)(2). Following the date on which the initial performance test is completed, the facility shall be operated with the total stream flow, as determined in § 63.564(g)(3), no more than 20 percent below the baseline stream flow and with the carbon bed temperature (measured within 15 minutes after completion of the cooling cycle), as determined in § 63.564(g)(3), no more than 10 percent or 5.6°C (10°F) above the baseline carbon bed temperature, whichever is less stringent.

(iii) *Outlet VOC concentration of 1,000 ppmv for gasoline loading.* Following the date on which the initial performance test is completed, the facility shall operate with a block average outlet VOC concentration as determined in § 63.564(g)(1) of no more than 1,200 ppmv VOC.

(7) *Condenser/refrigeration unit.* During the initial performance test required in paragraph (b)(1) of this section, the owner or operator shall determine the efficiency of and/or the outlet VOC concentration from the recovery device used to comply with § 63.562(b)(2), (3), and (4), (c)(3) and (4), and (d)(2) using the test methods in § 63.565(d). The owner or operator shall comply with either paragraph (b)(7)(i), (ii), or (iii) of this section.

(i) *VOC outlet concentration limit for required percent recovery efficiency.* The owner or operator shall establish as an operating parameter the baseline VOC concentration using the procedures described in § 63.565(g). Following the date on which the initial performance test is completed, the facility shall be operated with a block average outlet VOC concentration as determined in § 63.564(h)(2) no more than 20 percent above the baseline VOC concentration.

(ii) *Baseline temperature for required percent recovery efficiency.* The owner or operator shall establish as an operating parameter the baseline temperature using the procedures described in § 63.565(f). Following the date on which the initial performance test is completed, the facility shall operate with a block average temperature, as determined in § 63.564(h)(1), no more than 28°C (50°F) above the baseline temperature.

(iii) *Baseline parameters for 1,000 ppmv VOC concentration limit for gasoline loading.* The owner or operator shall monitor either the outlet VOC concentration or the outlet temperature of the unit. For sources monitoring temperature, the owner or operator shall establish as an operating parameter the baseline temperature using the procedures described in § 63.565(f). Following the date on which the initial performance test is completed, the facility shall operate with a block average outlet VOC concentration, as determined in § 63.564(h)(2), of no more than 1,200 ppmv VOC or with a block average temperature, as determined in § 63.564(h)(1), no more than 28°C (50°F) above the baseline temperature.

(8) *Absorber.* During the initial performance test required in paragraph (b)(1) of this section, the owner or operator shall determine the efficiency of the absorber and/or the outlet VOC concentration from the recovery device used to comply with § 63.562(b)(2), (3), and (4), (c)(3) and (4), and (d)(2) using the test methods in § 63.565(d). The owner or operator shall comply with either paragraph (b)(8)(i) or (ii) of this section.

(i) *VOC outlet concentration limit for required percent recovery efficiency.* The owner or operator shall establish as an operating parameter the baseline VOC concentration using the procedures described in § 63.565(g). Following the date on which the initial performance test is completed, the facility shall be operated with a block average outlet VOC concentration as determined in § 63.564(i)(1) no more than 20 percent above the baseline VOC concentration.

(ii) *Baseline liquid-to-vapor ratio for required percent recovery efficiency.* The owner or operator shall establish as an operating parameter the baseline liquid flow to vapor flow (L/V) ratio using the procedures described in § 63.565(k). Following the date on which the initial performance test is completed, the facility shall operate with a block average L/V ratio, as determined in § 63.564(i)(2), no more than 20 percent below the baseline L/V ratio.

(9) *Alternative control devices.* For sources complying with § 63.562(b)(2), (3), and (4), (c)(3) and (4), and (d)(2) with the use of a control technology other than the devices discussed in paragraphs (b)(4) through (8) of this section, the owner or operator of an affected source shall provide to the Administrator information describing the design and operation of the air pollution control system, including recommendations for the operating parameter(s) to be monitored to indicate proper operation and maintenance of the air pollution control system. Based on this information, the Administrator shall determine the operating parameter(s) to be established during the performance test. During the initial performance test required in paragraph (b)(1) of this section, the owner or operator shall determine the efficiency of the air pollution control system using the test methods in § 63.565(d). The device shall achieve at least the percent destruction efficiency or recovery efficiency required under § 63.562(b)(2), (3), and (4), (c)(3) and (4), and (d)(2). The owner or operator shall establish the operating parameter(s) approved by the Administrator. Following the date on which the initial performance test is complete, the facility shall operate either above or below a maximum or minimum operating parameter, as appropriate.

(10) *Emission estimation.* The owner or operator of a source subject to § 63.562(b)(2), (3), and (4) shall use the emission estimation procedures in § 63.565(l) to calculate HAP emissions.

(c) *Leak detection and repair for vapor collection systems and control devices.* The following procedures are required for all sources subject to § 63.562(b), (c), or (d).

(1) *Annual leak detection and repair for vapor collection systems and control devices.* The owner or operator of an affected source shall inspect and monitor all ductwork and piping and connections to vapor collection systems and control devices once each calendar year using Method 21.

(2) *Ongoing leak detection and repair for vapor collection systems and control devices.* If evidence of a potential leak is found by visual, audible, olfactory, or any other detection method, all ductwork and piping and connections to vapor collection systems and control devices shall be inspected to the extent necessary to positively identify the potential leak and any potential leaks shall be monitored within 5 days by Method 21. Each detection of a leak shall be recorded, and the leak shall be tagged until repaired.

(3) When a leak is detected, a first effort to repair the vapor collection system and control device shall be made within 15 days or prior to the next marine tank vessel loading operation, whichever is later.

§ 63.564 Monitoring requirements.

(a) (1) The owner or operator of an affected source shall comply with the

monitoring requirements in § 63.8 of subpart A of this part in accordance with the provisions for applicability of subpart A to this subpart in Table 1 of § 63.560 and the monitoring requirements in this section.

(2) Each owner or operator of an affected source shall monitor the parameters specified in this section. All monitoring equipment shall be installed such that representative measurements of emissions or process parameters from the source are obtained. For monitoring equipment purchased from a vendor, verification of the operational status of the monitoring equipment shall include completion of the manufacturer's written specifications or recommendations for installation, operation, and calibration of the system.

(3) Except for system breakdowns, out-of-control periods, repairs, maintenance periods, calibration checks, and zero (low-level) and high-level calibration drift adjustments, all continuous parametric monitoring systems (CPMS) and CEMS shall be in continuous operation while marine tank vessel loading operations are occuring and shall meet minimum frequency of operation requirements. Sources monitoring by use of CEMS and CPMS shall complete a minimum of one cycle of operation (sampling, analyzing, and/or data recording) for each successive 15-minute period.

(4) The owner or operator of a CMS installed in accordance with these emissions standards shall comply with the performance specifications either in performance specification (PS) 8 in 40 CFR part 60, appendix B for CEMS or in § 63.7(c)(6) of subpart A of this part for CPMS.

(5) A CEMS is out of control when the measured values (i.e., daily calibrations, multipoint calibrations, and performance audits) exceed the limits specified in either PS 8 or in § 63.8(c)(7) of subpart A of this part. The owner or operator of a CEMS that is out of control shall submit all information concerning out of control periods, including start and end dates and hours and descriptions of corrective actions taken, in the excess emissions and continuous monitoring system performance report required in § 63.567(e).

(b) *Vapor collection system of terminal.* Owners or operators of a source complying with § 63.563(a)(1) that uses a vapor collection system that contains valves that could divert a vent stream from a control device used to comply with the provisions of this subpart shall comply with paragraph (b)(1), (2), or (3) of this section.

(1) Measure and record the vent stream flowrate of each by-pass line once every 15 minutes. The owner or operator shall install, calibrate, maintain, and operate a flow indicator and data recorder. The flow indicator shall be installed immediately downstream of any valve (i.e., entrance to by-pass line) that could divert the vent stream from the control device to the atmosphere.

(2) Measure the vent stream flowrate of each by-pass line once every 15 minutes. The owner or operator shall install, calibrate, maintain, and operate a flow indicator with either an audio or visual alarm. The flow indicator and alarm shall be installed immediately downstream of any valve (i.e., entrance to by-pass line) that could divert the vent stream from the control device to the atmosphere. The alarm shall be checked every 6 months to demonstrate that it is functioning properly.

(3) Visually inspect the seal or closure mechanism once during each marine tank vessel loading operation and at least once every month to ensure that the valve is maintained in the closed position and that the vent stream is not diverted through the by-pass line; record all times when the car seals have been broken and the valve position has been changed. Each by-pass line valve shall be secured in the closed position with a car-seal or a lock-and-key type configuration.

(c) *Pressure/vacuum settings for the marine tank vessel's vapor collection equipment.* Owners or operators of a source complying with § 63.563(a)(3) shall measure continuously the operating pressure of the marine tank vessel during loading.

(d) *Loading at negative pressure.* Owners or operators of a source complying with § 63.563(a)(4)(iv) that load vessels at less than atmospheric pressure (i.e., negative gauge pressure) shall measure and record the loading pressure. The owner or operator shall install, calibrate, maintain, and operate a recording pressure measurement device (magnehelic gauge or equivalent device) and an audible and visible alarm system that is activated when the pressure vacuum specified in § 63.563(a)(4)(iv) is not attained. The owner or operator shall place the alarm system so that it can be seen and heard where cargo transfer is controlled. The owner or operator shall verify the accuracy of the pressure device once each calendar year with a reference pressure monitor (traceable to National Institute of Standards and Technology (NIST) standards or an independent pressure measurement device dedicated for this purpose).

(e) *Combustion device, except flare.* For sources complying with § 63.563(b)(4), use of a combustion device except a flare, the owner or operator shall comply with paragraph (e)(1), (2), or (3) of this section. Owners or operators complying with paragraphs (e)(2) or (3) shall also comply with paragraph (e)(4) of this section.

(1) *Outlet VOC concentration.* Monitor the VOC concentrations at the exhaust point of the combustion device and record the output from the system. For sources monitoring the outlet VOC concentration established during the performance test, a data acquisition system shall record a concentration every 15 minutes and shall compute and record an average concentration each cycle (same time period or cycle as the performance test) and a 3-cycle block average concentration every third cycle. For sources monitoring the 1,000 ppmv VOC concentration for gasoline loading, a data acquisition system shall record a concentration every 15 minutes and shall compute and record an average concentration each hour and a 3-hour block average concentration every third hour. The owner or operator will install, calibrate, operate, and maintain a CEMS consistent with the requirements of PS 8 to measure the VOC concentration. The daily calibration requirements are required only on days when marine tank vessel loading operations occur.

(2) *Operating temperature determined during performance testing.* If the baseline temperature was established during the performance test, the data acquisition system shall record the temperature every 15 minutes and shall compute and record an average temperature each cycle (same time period or cycle of the performance test) and a 3-cycle block average every third cycle.

(3) *Manufacturer's recommended operating temperature.* If the baseline temperature is based on the manufacturer recommended operating temperature, the data acquisition system shall record the temperature every 15 minutes and shall compute and record an average temperature each hour and a 3-hour block average every third hour.

(4) *Temperature monitor.* The owner or operator shall install, calibrate, operate, and maintain a temperature monitor accurate to within ±5.6°C (±10°F) or within 1 percent of the baseline temperature, whichever is less stringent, to measure the temperature. The monitor shall be installed at the exhaust point of the combustion device but not within the combustion zone. The owner or operator shall verify the accuracy of the temperature monitor once each calendar year with a reference temperature monitor (traceable to National Institute of Standards and

Technology (NIST) standards or an independent temperature measurement device dedicated for this purpose). During accuracy checking, the probe of the reference device shall be at the same location as that of the temperature monitor being tested.

(f) *Flare.* For sources complying with § 63.563(b)(5), use of a flare, the owner or operator shall monitor and record continuously the presence of the flare pilot flame. The owner or operator shall install, calibrate, maintain, and operate a heat sensing device (an ultraviolet beam sensor or thermocouple) at the pilot light to indicate the presence of a flame during the entire loading cycle.

(g) *Carbon adsorber.* For sources complying with § 63.563(b)(6), use of a carbon adsorber, the owner or operator shall comply with paragraph (g)(1), (2), or (3) of this section.

(1) *Outlet VOC concentration.* Monitor the VOC concentrations at the exhaust point of each carbon adsorber unit and record the output from the system. For sources monitoring the outlet VOC concentration established during the performance test, a data acquisition system shall record a concentration every 15 minutes and shall compute and record an average concentration each cycle (same time period or cycle as the performance test) and a 3-cycle block average concentration every third cycle. For sources monitoring the 1,000 ppmv VOC concentration for gasoline loading, a data acquisition system shall record a concentration every 15 minutes and shall compute and record an average concentration each hour and a 3-hour block average concentration every third hour. The owner or operator will install, calibrate, operate, and maintain a CEMS consistent with the requirements of PS 8 to measure the VOC concentration. The daily calibration requirements are required only on days when marine tank vessel loading operations occur.

(2) *Carbon adsorbers with vacuum regeneration.* Monitor and record the regeneration time for carbon bed regeneration and monitor and record continuously the vacuum pressure of the carbon bed regeneration cycle. The owner or operator will record the time when the carbon bed regeneration cycle begins and when the cycle ends for a single carbon bed and will calculate a 3-cycle block average every third cycle. The owner or operator shall install, calibrate, maintain, and operate a recording pressure measurement device (magnehelic gauge or equivalent device). A data acquisition system shall record and compute a 3-cycle (carbon bed regeneration cycle) block average vacuum pressure every third cycle. The owner or operator shall verify the accuracy of the pressure device once each calendar year with a reference pressure monitor (traceable to National Institute of Standards and Technology (NIST) standards or an independent pressure measurement device dedicated for this purpose). During accuracy checking, the probe of the reference device shall be at the same location as that of the pressure monitor being tested.

(3) *Carbon adsorbers with steam regeneration.* Monitor and record the total stream mass flow and monitor and record the carbon bed temperature after regeneration (but within 15 minutes of completion of the cooling cycle). The owner or operator will install, calibrate, maintain, and operate an integrating stream flow monitoring device that is accurate within ±10 percent and that is capable of recording the total stream mass flow for each regeneration cycle. The owner or operator will install, calibrate, maintain, and operate a temperature monitor accurate to within ±5.6°C (10°F) or within 1 percent of the baseline carbon bed temperature, whichever is less stringent, to measure the carbon bed temperature. The monitor shall be installed at the exhaust point of the carbon bed. The data acquisition system shall record the carbon bed temperature after each cooling cycle (measured within 15 minutes of completion of the cooling cycle). The owner or operator shall verify the accuracy of the temperature monitor once each calendar year with a reference temperature monitor (traceable to National Institute of Standards and Technology (NIST) standards or an independent temperature measurement device dedicated for this purpose). During accuracy checking, the probe of the reference device shall be at the same location as that of the temperature monitor being tested.

(h) *Condenser/refrigeration unit.* For sources complying with § 63.563(b)(7), use of a condenser/refrigeration unit, the owner or operator shall comply with either paragraph (h)(1) or (2) of this section.

(1) *Baseline temperature.* Monitor and record the temperature at the outlet of the unit. The owner or operator shall install, calibrate, operate, and maintain a temperature monitor accurate to within ±5.6°C (±10°F) or within 1 percent of the baseline temperature, whichever is less stringent, to measure the temperature. The monitor shall be installed at the exhaust point of the condenser/refrigeration unit. For sources monitoring the temperature established during the performance test, the data acquisition system shall record the temperature every 15 minutes and shall compute and record an average temperature each cycle (same time period or cycle of the performance test) and a 3-hour block average every third cycle. For sources monitoring the manufacturer recommended temperature, the data acquisition system shall record the temperature every 15 minutes and shall compute and record an average temperature each hour and a 3-hour block average every third hour. The owner or operator shall verify the accuracy of the temperature monitor once each calendar year with a reference temperature monitor (traceable to National Institute of Standards and Technology (NIST) standards or an independent temperature measurement device dedicated for this purpose). During accuracy checking, the probe of the reference device shall be at the same location as that of the temperature monitor being tested.

(2) *Outlet VOC concentration.* Monitor the VOC concentrations at the outlet of the unit and record the output from the system. For sources monitoring the outlet VOC concentration established during the performance test, a data acquisition system shall record a concentration every 15 minutes and shall compute and record an average concentration each cycle (same time period or cycle as the performance test) and a 3-cycle block average concentration every third cycle. For sources monitoring the 1,000 ppmv VOC concentration for gasoline loading, a data acquisition system shall record a concentration every 15 minutes and shall compute and record an average concentration each hour and a 3-hour block average concentration every third hour. The owner or operator will install, calibrate, operate, and maintain a VOC CEMS consistent with the requirements of PS 8 to measure the VOC concentration. The daily calibration requirements are required only on days when marine tank vessel loading operations occur.

(i) *Absorber.* For sources complying with § 63.563(b)(8), use of an absorber, the owner or operator shall comply with either paragraph (i)(1) or (2) of this section.

(1) *Outlet VOC concentration.* Monitor the VOC concentrations at the outlet of the absorber and record the output from the system. For sources monitoring the outlet VOC concentration established during the performance test, a data acquisition system shall record a concentration every 15 minutes and shall compute and record an average concentration each cycle (same time period or cycle as the

performance test) and a 3-cycle block average concentration every third cycle. For sources monitoring the 1,000 ppmv VOC concentration for gasoline loading, a data acquisition system shall record a concentration every 15 minutes and shall compute and record an average concentration each hour and a 3-hour block average concentration every third hour. The owner or operator will install, calibrate, operate, and maintain a VOC CEMS consistent with the requirements of PS 8. The daily calibration requirements are required only on days when marine tank vessel loading operations occur.

(2) *L/V ratio.* Monitor and record the inlet liquid flowrate and the inlet gas flowrate to the absorber and record the calculated L/V ratio. The owner or operator shall install, calibrate, maintain, and operate liquid and gas flow indicators. For sources monitoring the L/V ratio established during the performance test, a data acquisition system shall record the flowrates and calculated ratio every 15 minutes and shall compute and record an average ratio each cycle (same time period or cycle as the performance test) and a 3-cycle block average ratio every third cycle. For sources monitoring the manufacturer recommended L/V ratio, a data acquisition system shall record the flowrates and calculated ratio every 15 minutes and shall compute and record an average ratio each hour and a 3-hour average ratio every third hour. The liquid and gas flow indicators shall be installed immediately upstream of the respective inlet lines to the absorber.

(j) *Alternate monitoring procedures.* Alternate procedures to those described in this section may be used upon application to, and approval by, the Administrator. The owner or operator shall comply with the procedures for use of an alternative monitoring method in § 63.8(f).

§ 63.565 Test methods and procedures.

(a) *Performance testing.* The owner or operator of an affected source in § 63.562 shall comply with the performance testing requirements in § 63.7 of subpart A of this part in accordance with the provisions for applicability of subpart A to this subpart in Table 1 of § 63.560 and the performance testing requirements in this section.

(b) *Pressure/vacuum settings of marine tank vessel's vapor collection equipment.* For the purpose of determining compliance with § 63.563(a)(3), the following procedures shall be used:

(1) Calibrate and install a pressure measurement device (liquid manometer, magnehelic gauge, or equivalent instrument) capable of measuring up to the maximum relief set pressure of the pressure-vacuum vents;

(2) Connect the pressure measurement device to a pressure tap in the terminal's vapor collection system, located as close as possible to the connection with the marine tank vessel; and

(3) During the performance test required in § 63.563(b)(1), record the pressure every 5 minutes while a marine tank vessel is being loaded and record the highest instantaneous pressure and vacuum that occurs during each loading cycle.

(c) *Vapor-tightness test procedures for the marine tank vessel.* When testing a vessel for vapor tightness to comply with the marine vessel vapor-tightness requirements of § 63.563(a)(4)(i), the owner or operator of a source shall use the methods in either paragraph (c)(1) or (2) in this section.

(1) *Pressure test for the marine tank vessel.*

(i) Each product tank shall be pressurized with dry air or inert gas to no more than the pressure of the lowest pressure relief valve setting.

(ii) Once the pressure is obtained, the dry air or inert gas source shall be shut off.

(iii) At the end of one-half hour, the pressure in the product tank and piping shall be measured. The change in pressure shall be calculated using the following formula:

$$P=P_i-P_f$$

Where:

P=change in pressure, inches of water.

P_i=pressure in tank when air/gas source is shut off, inches of water.

P_f=pressure in tank at the end of one-half hour after air/gas source is shut off, inches of water.

(iv) The change in pressure, P, shall be compared to the pressure drop calculated using the following formula:

$$PM=0.861\ P_{ia}\ L/V$$

Where:

PM=maximum allowable pressure change, inches of water.

P_{ia}=pressure in tank when air/gas source is shut off, psia.

L=maximum permitted loading rate of vessel, barrels per hour.

V=total volume of product tank, barrels.

(v) If P≤PM, the vessel is vapor tight.

(vi) If P>PM, the vessel is not vapor tight and the source of the leak must be identified and repaired prior to retesting.

(2) *Leak test for the marine tank vessel.* Each owner or operator of a source complying with §§ 63.563(a)(4)(ii) or (iii) shall use Method 21 as the vapor-tightness leak test for marine tank vessels. The test shall be conducted during the final 20 percent of loading of each product tank of the marine vessel, and it shall be applied to any potential sources of vapor leaks on the vessel.

(d) *Combustion (except flare) and recovery control device performance test procedures.*

(1) All testing equipment shall be prepared and installed as specified in the appropriate test methods.

(2) All testing shall be performed during the last 20 percent of loading of a tank or compartment.

(3) All emission testing intervals shall consist of each 5 minute period during the performance test. For each interval, the following shall be performed:

(i) *Readings.* The reading from each measurement instrument shall be recorded.

(ii) *Sampling Sites.* Method 1 or 1A of appendix A of part 60 of this chapter, as appropriate, shall be used for selection of sampling sites. Sampling sites shall be located at the inlet and outlet of the combustion device or recovery device except for owners or operators complying with the 1,000 ppmv VOC emissions limit for gasoline vapors under § 63.563(b)(6) or (7), where the sampling site shall be located at the outlet of the recovery device.

(iii) *Volume exhausted.* The volume exhausted shall be determined using Method 2, 2A, 2C, or 2D of appendix A of part 60 of this chapter, as appropriate.

(4) *Combustion devices, except flares.* The average VOC concentration in the vent upstream and downstream of the control device shall be determined using Method 25 of appendix A of part 60 of this chapter for combustion devices, except flares. The average VOC concentration shall correspond to the volume measurement by taking into account the sampling system response time.

(5) *Recovery devices.* The average VOC concentration in the vent upstream and downstream of the control device shall be determined using Method 25A of appendix A of part 60 of this chapter for recovery devices. The average VOC concentration shall correspond to the volume measurement by taking into account the sampling system response time.

(6) The VOC mass at the inlet and outlet of the combustion or recovery device during each testing interval shall be calculated as follows:

$$M_j=FKV_sC_{VOC}$$

Where:

M_j=mass of VOC at the inlet and outlet of the combustion or recovery

device during testing interval j, kilograms (kg).

$F=10^{-6}$=conversion factor, (cubic meters VOC/cubic meters air)(1/ppmv) (m^3 VOC/m^3 air)(1/ppmv).

K=density, kilograms per cubic meter (kg/m^3 VOC), standard conditions, 20 °C and 760 mm Hg.

V_s=volume of air-vapor mixture at the inlet and outlet of the combustion or recovery device, cubic meters (m^3) at standard conditions, 20 °C and 760 mm Hg.

C_{VOC}=VOC concentration (as measured) at the inlet and outlet of the combustion or recovery device, ppmv, dry basis.

s=standard conditions, 20 °C and 760 mm Hg.

(7) The VOC mass emission rates at the inlet and outlet of the recovery or combustion device shall be calculated as follows:

$$E_i = \frac{\sum_{j=1}^{n} M_{ij}}{T}$$

$$E_o = \frac{\sum_{j=1}^{n} M_{oj}}{T}$$

Where:

E_i, E_o=mass flow rate of VOC at the inlet (i) and outlet (o) of the recovery or combustion device, kilogram per hour (kg/hr).

M_{ij}, M_{oj}=mass of VOC at the inlet (i) or outlet (o) during testing interval j, kg.

T=Total time of all testing intervals, hour.

n=number of testing intervals.

(8) Where Method 25 or 25A is used to measure the percent reduction in VOC, the percent reduction across the combustion or recovery device shall be calculated as follows:

$$R = \frac{E_i - E_o}{E_i}(100\%)$$

Where:

R=control efficiency of control device, percent.

E_i=mass flow rate of VOC at the inlet to the combustion or recovery device as calculated under paragraph (c)(7) of this section, kg/hr.

E_o=mass flow rate of VOC at the outlet of the combustion or recovery device, as calculated under paragraph (c)(7) of this section, kg/hr.

(9) Repeat the procedures in paragraph (d)(1) through (d)(8) of this section 3 times. The arithmetic average percent efficiency of the three runs shall determine the overall efficiency of the control device.

(10) Use of methods other than Method 25 or Method 25A shall be validated pursuant to Method 301 of appendix A of part 63 of this chapter.

(e) *Performance test for flares.* When a flare is used to comply with § 63.562(b)(2), (3), and (4), (c)(3) and (4), and (d)(2), the source must demonstrate that the flare meets the requirements of § 63.11 of subpart A of this part. In addition, a performance test according to Method 22 of appendix A of part 63 shall be performed to determine visible emissions. The observation period shall be at least 2 hours and shall be conducted according to Method 22. Performance testing shall be conducted during three complete loading cycles with a separate test run for each loading cycle. The observation period for detecting visible emissions shall encompass each loading cycle. Integrated sampling to measure process vent stream flow rate shall be performed continuously during each loading cycle. The owner or operator shall record all visible emission readings, heat content determinations, flow rate measurements, maximum permitted velocity calculations, and exit velocity determinations made during the performance test.

(f) *Baseline temperature.* The procedures in this paragraph shall be used to determine the baseline temperature required in § 63.563(b)(4), (6), and (7) for combustion devices, carbon adsorber beds, and condenser/refrigeration units, respectively, and to monitor the temperature as required in § 63.564(e), (g), and (h). The owner or operator shall comply with either paragraph (f)(1) or (2) of this section.

(1) *Baseline temperature from performance testing.* The owner or operator shall establish the baseline temperature as the temperature at the outlet point of the unit averaged over three test runs from paragraph (d) of this section. Temperature shall be measured every 15 minutes.

(2) *Baseline temperature from manufacturer.* The owner or operator shall establish the baseline temperature as the manufacturer recommended minimum operating temperature for combustion devices, maximum operating temperature for condenser units, and maximum operating temperature for carbon beds of carbon adsorbers.

(g) *Baseline outlet VOC concentration.* The procedures in this paragraph shall be used to determine the outlet VOC concentration required in § 63.563(b)(4), (6), (7), and (8) for combustion devices except flare, carbon adsorbers, condenser/refrigeration units, and absorbers, respectively, and to monitor the VOC concentration as required in § 63.564(e), (g), (h), and (i). The owner or operator shall use the procedures outlined in Method 25A. For the baseline VOC concentration, the arithmetic average of the outlet VOC concentration from three test runs from paragraph (d) of this section shall be calculated for the control device. The VOC concentration shall be measured at least every 15 minutes. Compliance testing of VOC CEMS shall be performed using PS 8.

(h) *Baseline regeneration time for carbon bed regeneration.* The procedures in this paragraph shall be used to demonstrate the baseline regeneration time for the vacuum stage of carbon bed regeneration required in § 63.563(b)(6) for a carbon adsorber and to monitor the regeneration time for the vacuum regeneration as required in § 63.564(g). The owner or operator shall comply with paragraph (h)(1) or (2).

(1) *Baseline regeneration time from performance testing.* The owner or operator shall establish the baseline regeneration time as the length of time for the vacuum stage of carbon bed regeneration averaged over three test runs from paragraph (d) of this section.

(2) *Baseline regeneration time from manufacturer recommendation.* The owner or operator shall establish the baseline regeneration time as the manufacturer recommended minimum regeneration time for the vacuum stage of carbon bed regeneration.

(i) *Baseline vacuum pressure for carbon bed regeneration.* The procedures in this paragraph shall be used to demonstrate the baseline vacuum pressure for the vacuum stage of carbon bed regeneration required in § 63.563(b)(6) for a carbon adsorber and to monitor the vacuum pressure as required in § 63.564(g). The owner or operator shall establish the baseline vacuum pressure as the manufacturer recommended minimum vacuum for carbon bed regeneration.

(j) *Baseline total stream flow.* The procedures in this paragraph shall be used to demonstrate the baseline total stream flow for steam regeneration required in § 63.563(b)(6) for a carbon adsorber and to monitor the total stream flow as required in § 63.564(g). The owner or operator shall establish the baseline stream flow as the manufacturer recommended minimum total stream flow for carbon bed regeneration.

(k) *Baseline L/V ratio.* The procedures in this paragraph shall be used to

determine the baseline L/V ratio required in § 63.563(b)(8) for an absorber and to monitor the L/V ratio as required in § 63.564(i). The owner or operator shall comply with either paragraph (k)(1) or (2) of this section.

(1) *Baseline L/V ratio from performance test.* The owner or operator shall establish the baseline L/V ratio as the calculated value of the inlet liquid flow divided by the inlet gas flow to the absorber averaged over three test runs using the procedures in paragraph (d) of this section.

(2) *Baseline L/V ratio from manufacturer.* The owner or operator shall establish the baseline L/V ratio as the manufacturer recommended minimum L/V ratio for absorber operation.

(l) *Emission estimation procedures.* For sources with emissions less than 10 or 25 tons and sources with emissions of 10 or 25 tons, the owner or operator shall calculate an annual estimate of HAP emissions, excluding commodities exempted by § 63.560(d), from marine tank vessel loading operations. Emission estimates and emission factors shall be based on test data, or if test data is not available, shall be based on measurement or estimating techniques generally accepted in industry practice for operating conditions at the source.

(m) *Alternate test procedures.*

(1) Alternate test procedures to those described in this section may be used upon application to, and approval by, the Administrator.

(2) If the owner or operator intends to demonstrate compliance by using an alternative to any test method specified, the owner or operator shall refrain from conducting the performance test until the Administrator approves the use of the alternative method when the Administrator approves the site-specific test plan (if review of the site-specific test plan is requested) or until after the alternative method is approved (see § 63.7(f) of subpart A of this part). If the Administrator does not approve the site-specific test plan (if review is requested) or the use of the alternative method within 30 days before the test is scheduled to begin, the performance test dates specified in § 63.563(b)(1) shall be extended such that the owner or operator shall conduct the performance test within 60 calendar days after the Administrator approves the site-specific test plan or after use of the alternative method is approved. Notwithstanding the requirements in the preceding two sentences, the owner or operator may proceed to conduct the performance test as required in this section (without the Administrator's prior approval of the site-specific test plan) if he/she subsequently chooses to use the specified testing and monitoring methods instead of an alternative.

§ 63.566 Construction and reconstruction.

(a) The owner or operator of an affected source shall fulfill all requirements for construction or reconstruction of a source in § 63.5 of subpart A of this part in accordance with the provisions for applicability of subpart A to this subpart in Table 1 of § 63.560 and construction or reconstruction requirements in this section.

(b) (1) *Application for approval of construction or reconstruction.* The provisions of this paragraph and § 63.5(d)(1)(ii) and (iii), (2), (3), and (4) of subpart A implement section 112(i)(1) of the Act.

(2) *General application requirements.* An owner or operator who is subject to the requirements of § 63.5(b)(3) of subpart A shall submit to the Administrator an application for approval of the construction of a new source, the reconstruction of a source, or the reconstruction of a source not subject to the emissions standards in § 63.562 such that the source becomes an affected source. The application shall be submitted as soon as practicable before the construction or reconstruction is planned to commence. The application for approval of construction or reconstruction may be used to fulfill the initial notification requirements of § 63.567(b)(3). The owner or operator may submit the application for approval well in advance of the date construction or reconstruction is planned to commence in order to ensure a timely review by the Administrator and that the planned commencement date will not be delayed.

(c) *Approval of construction or reconstruction based on prior State preconstruction review.* The owner or operator shall submit to the Administrator the request for approval of construction or reconstruction under this paragraph and § 63.5(f)(1) of subpart A of this part no later than the application deadline specified in paragraph (b)(2) of this section. The owner or operator shall include in the request information sufficient for the Administrator's determination. The Administrator will evaluate the owner or operator's request in accordance with the procedures specified in § 63.5(e) of subpart A of this part. The Administrator may request additional relevant information after the submittal of a request for approval of construction or reconstruction.

§ 63.567 Recordkeeping and reporting requirements.

(a) The owner or operator of an affected source shall fulfill all reporting and recordkeeping requirements in §§ 63.9 and 63.10 of subpart A of this part in accordance with the provisions for applicability of subpart A to this subpart in Table 1 of § 63.560 and fulfill all reporting and recordkeeping requirements in this section. These reports will be made to the Administrator at the appropriate address identified in § 63.13 of subpart A of this part.

(1) Reports required by subpart A and this section may be sent by U.S. mail, facsimile (fax), or by another courier.

(i) Submittals sent by U.S. mail shall be postmarked on or before the specified date.

(ii) Submittals sent by other methods shall be received by the Administrator on or before the specified date.

(2) If acceptable to both the Administrator and the owner or operator of a source, reports may be submitted on electronic media.

(b) *Notification requirements.* The owner or operator of an affected source shall fulfill all notification requirements in § 63.9 of subpart A of this part in accordance with the provisions for applicability of that section to this subpart in Table 1 of § 63.560 and the notification requirements in this paragraph.

(1) *Applicability.* If a source that otherwise would not be subject to the emissions standards subsequently increases its HAP emissions calculated on a 24-month annual average basis after September 19, 1997 or increases its annual HAP emissions after September 20, 1999 or subsequently increases its gasoline or crude loading throughput calculated on a 24-month annual average basis after September 19, 1996 or increases its gasoline or crude loading annual throughput after September 21, 1998 such that the source becomes subject to the emissions standards, such source shall be subject to the notification requirements of § 63.9 of subpart A of this part and the notification requirements of this paragraph.

(2) *Initial notification for sources with startup before the effective date.* The owner or operator of a source with initial startup before the effective date shall notify the Administrator in writing that the source is subject to the relevant standard. The notification shall be submitted not later than 365 days after the effective date of the emissions standards and shall provide the following information:

(i) The name and address of the owner or operator;

(ii) The address (i.e., physical location) of the source;

(iii) An identification of this emissions standard that is the basis of the notification and the source's compliance date;

(iv) A brief description of the nature, size, design, and method of operation of the source;

(v) A statement that the source is a major source.

(3) *Initial notification for sources with startup after the effective date.* The owner or operator of a new or reconstructed source or a source that has been reconstructed such that it is subject to the emissions standards that has an initial startup after the effective date but before the compliance date, and for which an application for approval of construction or reconstruction is not required under § 63.5(d) of subpart A of this part and § 63.566 of this subpart, shall notify the Administrator in writing that the source is subject to the standard no later than 365 days or 120 days after initial startup, whichever occurs before notification of the initial performance test in § 63.9(e) of subpart A of this part. The notification shall provide all the information required in paragraph (b)(2) of this section, delivered or postmarked with the notification required in paragraph (b)(4) of this section.

(4) *Initial notification requirements for constructed/reconstructed sources.* After the effective date of these standards, whether or not an approved permit program is effective in the State in which a source subject to these standards is (or would be) located, an owner or operator subject to the notification requirements of § 63.5 of subpart A of this part and § 63.566 of this subpart who intends to construct a new source subject to these standards, reconstruct a source subject to these standards, or reconstruct a source such that it becomes subject to these standards, shall comply with paragraphs (b)(4)(i), (ii), (iii), and (iv) of this section.

(i) *Notify the Administrator in writing of the intended construction or reconstruction.* The notification shall be submitted as soon as practicable before the construction or reconstruction is planned to commence. The notification shall include all the information required for an application for approval of construction or reconstruction as specified in § 63.5 of subpart A of this part. The application for approval of construction or reconstruction may be used to fulfill the requirements of this paragraph.

(ii) Submit a notification of the date when construction or reconstruction was commenced, delivered or postmarked not later than 30 days after such date, if construction was commenced after the effective date.

(iii) Submit a notification of the anticipated date of startup of the source, delivered or postmarked not more than 60 days nor less than 30 days before such date;

(iv) Submit a notification of the actual date of startup of the source, delivered or postmarked within 15 calendar days after that date.

(5) *Additional initial notification requirements.* The owner or operator of sources subject to § 63.562(b)(2), (3), and (4), MACT standards, shall also include in the initial notification report required by paragraph (b)(2) and (3) the 24-month annual average or the annual actual HAP emissions from marine tank vessel loading operations, as appropriate, at all loading berths, as calculated according to the procedures in § 63.565(l). Emissions will be reported by commodity and type of marine tank vessel (barge or tanker) loaded.

(ii) As an alternative to reporting the information in paragraph (b)(5)(i) of this section, the source may submit documentation showing that all HAP-containing marine tank vessel loading operations, not exempt by § 63.560(d), occurred using vapor tight vessels that comply with the procedures of § 63.563(a) and that the emissions were routed to control devices meeting the requirements specified in § 63.563(b).

(c) *Request for extension of compliance.* If the owner or operator has installed BACT or technology to meet LAER consistent with § 63.6(i)(5) of subpart A of this part, he/she may submit to the Administrator (or State with an approved permit program) a request for an extension of compliance as specified in § 63.6(i)(4)(i)(B), (i)(5), and (i)(6) of subpart A of this part.

(d) *Reporting for performance testing of flares.* The owner or operator of a source required to conduct an opacity performance test shall report the opacity results and other information required by § 63.565(e) and § 63.11 of subpart A of this part with the notification of compliance status.

(e) *Summary reports and excess emissions and monitoring system performance reports.*

(1) *Schedule for summary report and excess emissions and monitoring system performance reports.* Excess emissions and parameter monitoring exceedances are defined in § 63.563(b). The owner or operator of a source subject to these emissions standards that is required to install a CMS shall submit an excess emissions and continuous monitoring system performance report and/or a summary report to the Administrator once each year, except, when the source experiences excess emissions, the source shall comply with a semi-annual reporting format until a request to reduce reporting frequency under paragraph (e)(2) of this section is approved.

(2) *Request to reduce frequency of excess emissions and continuous monitoring system performance reports.* An owner or operator who is required to submit excess emissions and continuous monitoring system performance and summary reports on a semi-annual basis may reduce the frequency of reporting to annual if the following conditions are met:

(i) For 1 full year the sources's excess emissions and continuous monitoring system performance reports continually demonstrate that the source is in compliance; and

(ii) The owner or operator continues to comply with all recordkeeping and monitoring requirements specified in this subpart and subpart A of this part.

(3) The frequency of reporting of excess emissions and continuous monitoring system performance and summary reports required may be reduced only after the owner or operator notifies the Administrator in writing of his or her intention to make such a change and the Administrator does not object to the intended change. In deciding whether to approve a reduced frequency of reporting, the Administrator may review information concerning the source's entire previous performance history during the 5-year recordkeeping prior to the intended change, including performance test results, monitoring data, and evaluations of an owner or operator's conformance with operation maintenance requirements. Such information may be used by the Administrator to make a judgement about the source's potential for noncompliance in the future. If the Administrator will notify the owner or operator in writing within 45 days after receiving notice of the owner or operator's intention. The notification from the Administrator to the owner or operator will specify the grounds on which the disapproval is based. In the absence of a notice of disapproval within 45 days, approval is automatically granted.

(4) *Content and submittal dates for excess emissions and monitoring system performance reports.* All excess emissions and monitoring system performance reports and all summary reports, if required per paragraph (e)(5) and (6) of this section, shall be delivered or postmarked within 30 days following

the end of each calendar year, or within 30 days following the end of each six month period, if appropriate. Written reports of excess emissions or exceedances of process or control system parameters shall include all information required in § 63.10(c)(5) through (13) of subpart A of this part as applicable in Table 1 of § 63.560 and information from any calibration tests in which the monitoring equipment is not in compliance with PS 8 or other methods used for accuracy testing of temperature, pressure, or flow monitoring devices. The written report shall also include the name, title, and signature of the responsible official who is certifying the accuracy of the report. When no excess emissions or exceedances have occurred or monitoring equipment has not been inoperative, repaired, or adjusted, such information shall be stated in the report. This information will be kept for a minimum of 5 years and made readily available to the Administrator or delegated State authority upon request.

(5) If the total duration of excess emissions or control system parameter exceedances for the reporting period is less than 5 percent of the total operating time for the reporting period, and CMS downtime for the reporting period is less than 10 percent of the total operating time for the reporting period, only the summary report of § 63.10(e)(3)(vi) of subpart A of this part shall be submitted, and the full excess emissions and continuous monitoring system performance report of paragraph (e)(4) of this section need not be submitted unless required by the Administrator.

(6) If the total duration of excess emissions or process or control system parameter exceedances for the reporting period is 5 percent or greater of the total operating time for the reporting period, or the total CMS downtime for the reporting period is 10 percent or greater of the total operating time for the reporting period, both the summary report of § 63.10(e)(3)(vi) of subpart A of this part and the excess emissions and continuous monitoring system performance report of paragraph (e)(4) of this section shall be submitted.

(f) *Vapor collection system of the terminal.* Each owner or operator of an affected source shall submit with the initial performance test and maintain in an accessible location on site an engineering report describing in detail the vent system, or vapor collection system, used to vent each vent stream to a control device. This report shall include all valves and vent pipes that could vent the stream to the atmosphere, thereby bypassing the control device, and identify which valves are car-sealed opened and which valves are car-sealed closed.

(g) If a vent system, or vapor collection system, containing valves that could divert the emission stream away from the control device is used, each owner or operator of an affected source shall keep for at least 5 years up-to-date, readily accessible continuous records of:

(1) All periods when flow bypassing the control device is indicated if flow indicators are installed under § 63.563(a)(1) and § 63.564(b), and

(2) All times when maintenance is performed on car-sealed valves, when the car-seal is broken, and when the valve position is changed (i.e., from open to closed for valves in the vent piping to the control device and from closed to open for valves that vent the stream directly or indirectly to the atmosphere bypassing the control device) if valves are monitored under § 63.564(b).

(h) The owner or operator of an affected source shall keep the vapor-tightness documentation required under § 63.563(a)(4) on file at the source in a permanent form available for inspection.

(i) *Vapor tightness test documentation for marine tank vessels.* The owner or operator of an affected source shall maintain a documentation file for each marine tank vessel loaded at that source to reflect current test results as determined by the appropriate method in § 63.565(c)(1) and (2). Updates to this documentation file shall be made at least once per year. The owner or operator shall include, as a minimum, the following information in this documentation:

(1) Test title;

(2) Marine vessel owner and address;

(3) Marine vessel identification number;

(4) Loading time, according to § 63.563(a)(4)(ii) or (iii), if appropriate;

(5) Testing location;

(6) Date of test;

(7) Tester name and signature;

(8) Test results from § 63.565(c)(1) or (2), as appropriate;

(9) Documentation provided under § 63.563(a)(4)(ii) and (iii)(B) showing that the repair of leaking components attributed to a failure of a vapor-tightness test is technically infeasible without dry-docking the vessel; and

(10) Documentation that a marine tank vessel failing a pressure test or leak test has been repaired.

(j) *Emission estimation reporting and recordkeeping procedures.* The owner or operator of each source complying with the emission limits specified in § 63.562(b)(2), (3), and (4) shall comply with the following provisions:

(1) Maintain records of all measurements, calculations, and other documentation used to identify commodities exempted under § 63.560(d);

(2) Keep readily accessible records of the emission estimation calculations performed in § 63.565(l) for 5 years; and

(3) Submit an annual report of the source's HAP control efficiency calculated using the procedures specified in § 63.565(l), based on the source's actual throughput.

(4) Owners or operators of marine tank vessel loading operations specified in § 63.560(a)(3) shall retain records of the emissions estimates determined in § 65.565(l) and records of their actual throughputs by commodity, for 5 years.

(k) *Leak detection and repair of vapor collection systems and control devices.* When each leak of the vapor collection system, or vapor collection system, and control device is detected and repaired as specified in § 63.563(c) the following information required shall be maintained for 5 years:

(1) Date of inspection;

(2) Findings (location, nature, and severity of each leak);

(3) Leak determination method;

(4) Corrective action (date each leak repaired, reasons for repair interval); and

(5) Inspector name and signature.

[FR Doc. 95–22725 Filed 9–18–95; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

42 CFR Parts 405 and 411

[BPD–841–FC]

RIN 0938–AH21

Medicare Program; Criteria and Procedures for Extending Coverage to Certain Devices and Related Services

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

ACTION: Final rule with comment period.

SUMMARY: This final rule establishes in regulations that certain devices with an investigational device exemption (IDE) approved by the Food and Drug Administration (FDA) and certain services related to those devices may be covered under Medicare. Specifically, it sets forth the process by which the FDA will assist HCFA in identifying non-experimental investigational devices that are potentially covered under Medicare.

This rule responds to the mandate that Federal agencies streamline their regulatory processes to make them less burdensome and more customer-focused. It is intended to provide Medicare beneficiaries with greater access to advances in medical technology and encourage clinical researchers to conduct high quality studies of newer technologies.

DATES: *Effective Date:* This rule is effective November 1, 1995.

Comment Date: Comments will be considered if we receive them at the appropriate address, as provided below, no later than 5 p.m. on November 20, 1995.

ADDRESSES: Mail written comments (1 original and 3 copies) to the following address:

Health Care Financing Administration, Department of Health and Human Services, Attention: BPD–841–FC, P.O. Box 26688, Baltimore, MD 21207–0519.

If you prefer, you may deliver your written comments (1 original and 3 copies) to one of the following addresses:

Room 309–G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201, or

Room C5–09–26, 7500 Security Boulevard, Baltimore, MD 21244–1850.

Because of staffing and resource limitations, we cannot accept comments by facsimile (FAX) transmission. In commenting, please refer to file code BPD–841–FC. Comments received timely will be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, in Room 309–G of the Department's offices at 200 Independence Avenue, SW., Washington, DC, on Monday through Friday of each week from 8:30 a.m. to 5 p.m. (phone: (202) 690–7890).

Copies: To order copies of the Federal Register containing this document, send your request to: New Orders, Superintendent of Documents, P.O. Box 371954, Pittsburgh, PA 15250–7954. Specify the date of the issue requested and enclose a check or money order payable to the Superintendent of Documents, or enclose your Visa or Master Card number and expiration date. Credit card orders can also be placed by calling the order desk at (202) 512–1800 or by faxing to (202) 512–2250. The cost for each copy is $8. As an alternative, you can view and photocopy the Federal Register document at most libraries designated as Federal Depository Libraries and at many other public and academic libraries throughout the country that receive the Federal Register.

FOR FURTHER INFORMATION CONTACT: Sharon Hippler, (410) 786–4633.

SUPPLEMENTARY INFORMATION:

I. Background

A. Statutory Basis

The Social Security Act (the Act) provides Medicare coverage for broad categories of benefits through the hospital insurance program, known as Part A, and the supplementary medical insurance program, known as Part B.

The Act does not, however, provide an all-inclusive list of covered items, services, treatments, procedures, or technologies. Except for certain items of durable medical equipment identified in section 1861(n) of the Act, some of the medical and other health services listed in section 1861(s) of the Act, and exclusions from coverage listed in section 1862 of the Act, the statute does not specify devices that are covered or excluded from coverage.

The Congress understood that questions about the coverage of specific services would invariably arise and would require a specific decision of coverage by the Secretary. Thus, it vested in the Secretary the authority to make those decisions. Among the provisions relevant to the determination of coverage is section 1862(a)(1)(A) of the Act, which states ''Notwithstanding any other provision of this title, no payment may be made under Part A or Part B for any expenses incurred for items or services which * * * are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member.'' This is a key provision since the words ''notwithstanding any other provision of this title * * *'' make this an overriding exclusion that may be applicable in a given situation despite the existence of provisions that would otherwise permit coverage. Thus, while the Congress provided for the coverage of certain services, with limited exceptions specified by HCFA, coverage for those services is prohibited unless they are ''reasonable'' and ''necessary.''

B. Implementation of the Law

Historically, HCFA has interpreted the statutory terms ''reasonable'' and ''necessary'' to mean that a device must be safe and effective, medically necessary, and not experimental. For most Medicare coverage purposes, the term experimental has been used synonymously with the term investigational. Therefore, a device categorized by the FDA as being investigational served as an indication that it was not ''reasonable'' and ''necessary'' within the meaning of the Medicare program. As a general rule, these devices currently are not covered.

There is increasing recognition, however, that there are devices that are refinements of existing technologies or replications of existing technologies by other manufacturers. The FDA places many of these devices within the investigational device exemption (IDE) category as a means of gathering the scientific information necessary to establish the safety and effectiveness of the particular device, even though there is scientific evidence that similar devices can be safe and effective. Arguably, these devices could be viewed as ''reasonable'' and ''necessary'' under Medicare and recognized for payment if it were possible to identify them in the FDA's process.

C. January 1989 Proposed Rule on Coverage Decision Process

On January 30, 1989, we published a proposed rule (54 FR 4302) that proposed to establish in regulations generally applicable criteria for determining whether a service is ''reasonable'' and ''necessary'' under the Medicare program, and the coverage decisionmaking process. In response to that rule, we received comments pertaining to the coverage of experimental procedures and services related to those procedures. In this rule, we are choosing to respond to comments on investigational devices and services related to those devices and to announce our final policy. We have not completed our deliberations on the other issues addressed in the January 1989 proposed rule. This rule does not respond to comments other than those pertaining to devices.

Comment: Twenty-two commenters suggested that we revise our proposed policy so that we do not automatically exclude from Medicare coverage all devices that the FDA considers investigational. Several of these commenters recommended that we allow coverage of investigational devices when they are used in FDA-approved clinical trials.

Response: We agree that there are some investigational devices that should be considered for coverage if they are used in accordance with an FDA-approved protocol. The devices that will be considered for possible coverage are those investigational devices for which the FDA has determined that the device type can be safe and effective. For example, we will consider for possible coverage those investigational devices

that are of the same type as a device for which a manufacturer has received FDA clearance or approval for marketing. We have entered into an interagency agreement with the FDA to identify those investigational devices that are of a device type for which the underlying questions of safety and effectiveness have been resolved. These devices may be covered if all other applicable Medicare coverage requirements are met.

Comment: One commenter recommended that we not change our previous policy that excluded coverage of investigational devices.

Response: We do not agree. We believe that there are certain investigational devices that should be covered if all other applicable coverage requirements are met. However, the investigational devices that we will consider for coverage will not include any device for which the FDA is unsure whether the device type in general can be safe and effective.

Comment: A number of commenters requested that we clarify the coverage rules concerning the furnishing of services related to experimental procedures (for example, a hospital stay).

Response: As stated earlier, we are limiting the focus of this rule to Medicare coverage of certain investigational devices and services related to those devices. Also, in the preamble to this rule and in new § 405.207, we explain our coverage policy concerning services related to a noncovered device.

II. Provisions of This Final Rule

While the policies contained in this final rule will be effective November 1, 1995, we are providing a 60-day comment period for the receipt of public comments. We believe it is appropriate to provide an opportunity for comment on these policies because we are broadening the proposals concerning certain devices contained in the January 1989 proposed rule. Consequently, beneficiaries, providers, and suppliers that may have chosen not to comment because they may have believed they were not affected by the 1989 proposals may wish to comment on these broadened final policies. If our consideration of the comments we receive leads us to a change in these policies, we will publish another document.

A. HCFA Coverage Decision Process

The Administration has set forth a mandate that all Federal agencies must streamline their regulatory processes to make them less burdensome and more customer-focused. Agencies have been directed to review their policies and processes to determine which requirements can be reduced or eliminated without lowering health and safety standards. In accordance with this directive, the FDA reviewed its regulatory processes for devices and HCFA reviewed its Medicare coverage policies. This rule results in an improved process for covering certain investigational devices that is expected to benefit Medicare beneficiaries.

This new policy will lead to broader coverage of certain investigational devices and certain services related to those devices. A long-term benefit is to facilitate the collection of information about these devices through approved clinical trials, which will enable the marketing of these devices. Medicare beneficiaries will have earlier access to the latest advances in medical technology.

To assist HCFA in its coverage decision process, the FDA will follow a categorization process that differentiates between the clinical assessment of novel, first-of-a-kind devices and newer generations of legally marketed devices. The policy changes in this rule reflect the categorization of investigational devices that are the subject of FDA-approved IDEs.

The FDA uses the definition of a device that appears in 21 U.S.C. 321(h). A device, for purposes of the FDA process, refers to an instrument, apparatus, implement, machine, contrivance, implant, *in vitro* reagent, or other similar or related article, including any component, part, or accessory, which is—

- Recognized in the official National Formulary, or the U.S. Pharmacopeia, or any supplement to them,
- Intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals,
- Intended for use in the diagnosis of conditions other than diseases such as pregnancy,
- Intended to affect the structure or any function of the body of man or other animals, or
- Considered an *in vitro* diagnostic product, including those previously regulated as drugs, and which does not achieve any of its principal intended purposes through chemical action within or on the body of man or other animals

and which is not dependent upon being metabolized for the achievement of any of its principal intended purposes.

When a sponsor (usually a manufacturer) submits a marketing application for clearance or approval of a device to the FDA, the FDA evaluates the safety and effectiveness of the device. If sufficient information exists to determine its safety and effectiveness, the FDA may clear the device for marketing. In some instances, for certain devices, the FDA may require that clinical trials be conducted to obtain clinical information to determine the device's safety and effectiveness. Generally, in order for these devices to be shipped lawfully for purposes of conducting the clinical trial, the sponsor must obtain an approved investigational device exemption (IDE).

Under the Food, Drug, and Cosmetic Act (21 U.S.C. 360c), devices fall into one of three classes:

Class I—Devices for which the general controls of the Food, Drug, and Cosmetic Act, such as adherence to good manufacturing practice regulations, are sufficient to provide a reasonable assurance of safety and effectiveness.

Class II—Devices that, in addition to general controls, require special controls, such as performance standards or postmarket surveillance, to provide a reasonable assurance of safety and effectiveness.

Class III—Devices that cannot be classified into Class I or Class II because insufficient information exists to determine that either special or general controls would provide reasonable assurance of safety and effectiveness. Class III devices require premarket approval.

Under the new categorization process to assist HCFA, the FDA assigns each device with an FDA-approved IDE to one of two categories: Experimental/Investigational (Category A) Devices, or Non-Experimental/Investigational (Category B) Devices. Under this categorization process, an experimental/investigational device (Category A) is an innovative device in Class III for which ''absolute risk'' of the device type has not been established (that is, initial questions of safety and effectiveness have not been resolved and the FDA is unsure whether the device type can be safe and effective). A non-experimental/investigational (Category B) device is a device believed to be in Class I or Class II, or a device believed to be in Class III for which the incremental risk is the primary risk in question (that is, underlying questions of safety and effectiveness of that device type have been resolved), or it is known that the device type can be safe and effective because, for example, other manufacturers have obtained FDA approval for that device type. The criteria the FDA will use to categorize

an investigational device is described in the addendum to this rule.

Currently there are about 1,200 FDA-approved clinical trials of devices. The FDA is categorizing those devices as ''experimental/investigational (Category A)'' or ''non-experimental/investigational (Category B),'' a process that is expected to be completed by November 1, 1995. The great majority of these devices in clinical trials are likely to be categorized as ''non-experimental/investigational (Category B)''.

The FDA will notify HCFA, when it notifies the sponsor, either by electronic means or written communication, of its categorization decisions. Through these categorization decisions, the FDA will be advising HCFA as to the similarity of a device that has been approved for use in an FDA-approved clinical trial to a device that has been approved or cleared by the FDA for marketing.

HCFA excludes from Medicare coverage a device with an IDE that is categorized by the FDA as experimental/investigational (Category A). HCFA will continue to view these experimental/investigational (Category A) devices as not satisfying the statutory requirement that Medicare pay for only devices determined to be reasonable and necessary. HCFA is not changing its policy on this issue because essential considerations of health and safety are involved.

This rule does not affect HCFA's policy on services related to a noncovered device. That is, services related to the use of a noncovered device are not covered under Medicare. We are codifying in the regulations a provision explaining that services related to a noncovered device are not covered under Medicare. These services include all services furnished in preparation for the use of a noncovered device, services furnished contemporaneously with and necessary to the use of a noncovered device, and services furnished as necessary after-care that are incident to recovery from the use of the device or from receiving related noncovered services.

Services furnished to address medical complications arising from the use of the device (and that are not incident to normal recovery) may be covered. Services not related to the use of a noncovered device, which meet all other coverage requirements, can be covered under Medicare.

The following are some examples of services ''related to'' and ''not related to'' noncovered devices furnished while the beneficiary is an inpatient:

- A beneficiary is hospitalized to receive a noncovered device and breaks a leg while in the hospital. Services related to care of the broken leg during this stay are ''not related to'' services and are covered under Medicare.
- A beneficiary is admitted to the hospital for a covered service and during the hospital stay received a noncovered investigational device. The services related to the admitting condition are covered because the reason for the admission was to receive covered services and not related to the diagnoses that led to the need for the noncovered device.
- A beneficiary is admitted to the hospital for covered services related to a condition that led to receiving a noncovered device during the same hospital stay. We would review all of the services and make a comparison of the date they are received to the date the beneficiary is identified as needing the noncovered device. If our review reveals that services were required because of receiving the noncovered device, the services ''related to'' the noncovered device will not be covered.
- After a beneficiary is discharged from a hospital stay during which he or she receives a noncovered investigational device, medical and hospital services to treat a condition or complication that arises as a result of the noncovered device or related noncovered services may be covered when they are reasonable and necessary in all other respects. Thus, coverage could be provided for subsequent inpatient hospital stays or outpatient treatment ordinarily covered by Medicare, even if the need for treatment arose because of a previous noncovered device or related noncovered services. Any subsequent services that could be expected to have been incorporated into a global fee, however, will not be covered.

The related services policy will also apply to experimental/investigational (Category A) and non-experimental/investigational (Category B) devices that are excluded from Medicare coverage. Therefore, Medicare policy will continue to preclude coverage of certain devices and services related to the use of those devices when they are furnished as part of a hospital stay.

It is our intention that a beneficiary not pay for a noncovered device or services related to a noncovered device when a beneficiary did not know that the device or related services are not covered. Existing regulations concerning limitations on liability in §§ 411.400 through 411.406 will apply to this broader coverage of certain investigational devices and services related to those devices. Medicare payment may be made for certain assigned claims for a service related to a noncovered device if the service was excluded from coverage in accordance with § 411.15(k) as not medically necessary under section 1862(a)(1)(A) of the Act. A beneficiary who did not know and could not reasonably have been expected to know that payment would be denied under section 1862(a)(1)(A) of the Act receives protection from financial liability in accordance with §§ 411.400 through 411.406 under the limitation on liability provision of section 1879 of the Act. Similarly, when the beneficiary is protected and the provider or supplier also did not know and could not reasonably have been expected to know that payment would be denied, the provider or supplier also receives protection from financial liability in accordance with the limitation on liability provision. Consequently, Medicare payment may be made to the provider or supplier.

For unassigned claims for related physician services excluded from coverage as not medically necessary under section 1862(a)(1)(A) of the Act, a beneficiary who did not know and could not reasonably have been expected to know that payment would be denied as not medically necessary may receive protection from financial liability in accordance with existing § 411.408 under the refund requirement provision of section 1842(l) of the Act. If the beneficiary is found not to have known, and the provider or supplier also did not know and could not reasonably have been expected to know that payment would be denied, the provider or supplier will receive protection from financial liability under the refund requirement provision.

Under changes made by this final rule, HCFA will consider coverage of a device with an FDA-approved IDE, categorized by the FDA as non-experimental/investigational (Category B) for Medicare beneficiaries participating in FDA-approved clinical trials. As a general rule for all medical care, HCFA has authority to conduct a separate assessment of an item—s or service's appropriateness for Medicare coverage, including whether it is reasonable and necessary specifically for its intended use for Medicare beneficiaries. Medicare coverage of a non-experimental/investigational (Category B) device will be subject to the same process and criteria used by Medicare contractors when making coverage decisions for legally marketed devices. Coverage of the device is dependent on it meeting all other Medicare coverage requirements contained in the statute, regulations, and instructions issued by HCFA.

The FDA-approved IDE study protocols restrict investigational device shipment to a limited number of investigational sites for testing on a specific number of patients. To the extent Medicare covers a non-experimental/investigational (Category B) device, coverage is limited to beneficiaries meeting the protocol requirements. For example, coverage of an investigational device may be limited to Medicare beneficiaries participating in trials conducted by certain health care practitioners in an approved clinical trial.

Medicare coverage of a non-experimental/investigational (Category B) device is predicated, in part, upon the device continuing to meet criteria that led to this designation by the FDA. In the event a device fails to meet the criteria for Category B designation or its use violates relevant IDE requirements necessitating the withdrawal of the IDE approval, the FDA will immediately notify the sponsor and HCFA. HCFA will re-evaluate the device's continued eligibility for Medicare payment.

Payment under Medicare for a non-experimental/investigational (Category B) device will be based on, and may not exceed, the amount that would have been paid for a currently used device serving the same medical purpose that has been approved or cleared for marketing by the FDA. In cases involving a hospital stay, the diagnosis related group (DRG) payment under the prospective payment system ordinarily will not be affected.

B. Re-evaluation of Categorization Decision

We anticipate that instances will arise under which a device sponsor believes that a device, categorized by the FDA as experimental/investigational (Category A), should be categorized as non-experimental/investigational (Category B). In these instances, the sponsor may request that the FDA re-evaluate its categorization decision. Only after the FDA has completed its re-evaluation, and concluded that the device still is an experimental/investigational (Category A) device, may a sponsor request review by HCFA. A sponsor may request review by HCFA even if no Medicare claims are involved.

1. FDA Action

Under this process, the sponsor may submit a written request for re-evaluation to the FDA (at the same address it submitted its original application), together with information and rationale that it believes support recategorization. Only the sponsor of a device may seek a re-evaluation of the FDA IDE categorization decision.

Time limits on seeking a re-evaluation will not be imposed. The FDA will review the request and inform the sponsor, and HCFA, of its decision. If the FDA does not agree to recategorize the device, the sponsor may seek further review by HCFA.

2. HCFA Action

Upon written request to the HCFA Administrator from the sponsor of a device with an FDA-approved IDE, HCFA will review the categorization of the device. As part of this process, HCFA will review all information submitted by the sponsor and the FDA's recommendation. HCFA will review only information in the FDA record to determine whether to change the categorization. HCFA will not accept or review any information from the sponsor that was not previously reviewed by the FDA. While HCFA, during the re-evaluation process, will be the final decisionmaker concerning categorization of a device for Medicare coverage purposes, HCFA relies heavily on the FDA review of the scientific information related to the device and consequently the FDA recommendation. HCFA will issue a written decision and notify the sponsor and the FDA. No further reviews will be available to the sponsor.

3. Update of Categorization Decision

If the circumstances that led to the initial categorization decision change (for example, a premarket approval application is approved for a device similar to one under investigation), the FDA will re-evaluate the categorization designation and notify the sponsor and HCFA of any change. Neither the FDA categorization and re-evaluation nor HCFA's review constitute an initial determination for purposes of the Medicare appeals processes under 42 CFR part 405, subparts G or H, or parts 417, 473, or 498.

C. Quarterly Announcement of Categorization Decisions

HCFA publishes quarterly in the Federal Register a notice that lists HCFA manual instructions, substantive and interpretive regulations and other Federal Register notices, and statements of policy that relate to the Medicare and Medicaid programs. HCFA will announce in the quarterly notice all IDE categorizations, using IDE numbers the FDA assigns. The initial notice will include all FDA-approved IDE numbers organized by the categories to which the device numbers are assigned (that is, Category A or Category B, and identified by the IDE number). Subsequent notices will include the additions and deletions to the initial list of all devices with an FDA-approved IDE.

D. Confidentiality of Investigational Device Exemption Information

Data and information otherwise exempt from public disclosure may be revealed in judicial proceedings if the data or information are relevant. HCFA will take appropriate measures, or request that appropriate measures be taken, to reduce disclosure to the minimum necessary under the circumstances. Because HCFA relies on information submitted to the FDA under 21 U.S.C. 360j(g), HCFA will consult with the FDA to ensure that the confidentiality of the information is protected to the extent possible.

E. Contractor Coverage Decisions of Devices With an FDA-approved IDE

1. Current Contractor Functions

Sections 1816 and 1842 of the Act provide for most claims processing and administrative functions for Medicare to be handled by public or private insurance organizations (commercial insurers or Blue Cross/Blue Shield Associations) acting as fiscal agents or contractors for the Medicare program.

The contractors responsible for the administration of Part A benefits are called fiscal intermediaries. The major role of the intermediaries is to review and pay claims submitted by providers (such as hospitals, skilled nursing facilities, and home health agencies) for covered services furnished to Medicare beneficiaries. The intermediary makes payments for hospital inpatient services generally under the prospective payment system. It makes payments for hospital and other provider outpatient services by reviewing submitted cost reports and making reasonable cost determinations or payment determinations under a fee schedule following policies set by HCFA.

Under Part B, the contractors are called carriers. Part B services are paid on a fee schedule, reasonable charge, or reasonable cost basis. One of the major functions of the carriers is to determine the appropriate amount of payment for each medical care service paid for under the program. Carriers also are responsible for reviewing and paying claims to or on behalf of beneficiaries for the services furnished.

The functions performed by Medicare contractors include utilization review, beneficiary hearings and appeals, professional relations, and statistical activities, in addition to claims review and processing. Currently, there are 29

carriers, 46 intermediaries, and some other entities under contract with HCFA that perform reviews and process claims for Medicare beneficiaries.

2. Current Criteria and Procedures for Contractor Coverage Decisions

Contractors make Medicare coverage decisions within the parameters set by statutory authority and regulations and program instructions issued by HCFA. If HCFA has issued a national coverage decision, contractors are bound by that decision. If no national coverage decision has been issued, a contractor must decide whether the service in question is reasonable and necessary and therefore covered by Medicare.

Medicare contractors may specifically consider, among other factors, whether the service is—

- Medically necessary in the particular case and whether the amount, duration, and frequency of use or application of the service are medically appropriate;
- Furnished in accordance with accepted standards of medical practice; and
- Furnished in a setting appropriate to the patient's medical needs and condition (such as inpatient care at a hospital or skilled nursing facility, outpatient care at a hospital or physician's office, or home care).

3. Changes to Contractor Process

Under this rule, contractors will review the instructions HCFA issues to determine if a non-experimental/investigational (Category B) device is potentially covered under Medicare. After determining that a device is potentially covered, the contractor will apply HCFA's long-standing criteria and procedures for making coverage decisions. When considering whether a non-experimental/investigational (Category B) device is furnished in accordance with accepted standards of medical practice, it will consider those standards that relate to an FDA-approved clinical trial.

In accordance with HCFA coverage policy, Medicare contractors are precluded from covering any device that is an experimental/investigational (Category A) device.

F. Appeals Under Part A and Part B

While the categorization decision is not itself an initial determination, if HCFA denies a Medicare claim on the basis that the device is an experimental/investigational (Category A) device, the initial determination denying the claim encompasses the categorization decision. A proper party to the denied Medicare claim has a right to appeal the experimental/investigational (Category A) categorization as an initial determination under 42 CFR part 405, subparts G or H.

A decision that a device is experimental/investigational (Category A) means that the device is experimental and, therefore, excluded from coverage as not reasonable and necessary under section 1862(a)(1)(A) of the Act. HCFA's acceptance of the FDA categorization of an experimental/investigational (Category A) device constitutes a national coverage decision and is binding on HCFA's contractors. In accordance with section 1869(b)(3)(A) of the Act, national coverage decisions made by HCFA under section 1862(a)(1) of the Act may not be reviewed by administrative law judges.

III. Regulatory Impact Statement

Consistent with the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 through 612), we prepare a regulatory flexibility analysis unless we certify that a rule will not have a significant economic impact on a substantial number of small entities. For purposes of the RFA, all device manufacturers and providers are considered to be small entities. Individuals and States are not included in the definition of a small entity.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area and has fewer than 50 beds.

This regulation removes certain investigational devices from being presumed excluded by Medicare and places them in a category under which they may be covered. On a claim-by-claim basis, Medicare contractors verify or determine that devices are covered under the circumstances presented by the claim or bill. This regulation does not change that process, except the contractors must ascertain whether these devices were furnished to beneficiaries participating in, and in accordance with the requirements of, approved clinical trials. Once coverage is verified, payment is made at the level established for a similar device that has been approved as covered by Medicare.

We anticipate that this regulation will lead to a beneficial but not a major expansion of coverage of devices. Each year the FDA receives approximately 200 IDE applications for review. The majority of these IDEs are approved for study. At the present time, there are approximately 1,200 clinical trials underway involving devices, which are being conducted under FDA-approved IDEs.

We expect that this regulation will have a number of beneficial effects. It will provide Medicare beneficiaries with greater access to advances in medical technology. It will allow Medicare beneficiaries faced with a decision of choosing between a fully covered device and one undergoing clinical trials to choose the investigational device without losing Medicare coverage. Because Medicare payment is based on the payment for a fully covered device, that choice would not result in increased costs to Medicare for those devices.

At the present time, device manufacturers and the providers that furnish services involving non-experimental/investigational devices (Category B) are not eligible for Medicare payments. We estimate that this regulation will result in negligible costs to the Medicare program. We expect affected entities would receive less than $10 million per year over the next 5 years.

Virtually all of these devices replace devices for which Medicare coverage is currently available and which would have been furnished to beneficiaries if we had not changed the policy. The services are primarily furnished on an inpatient basis in hospitals. Hospitals are paid on a prospective basis so that prices are not adjusted based on changes in the price-components (that is, device costs) of individual DRGs. Instead, the payment base under the prospective payment system is annually updated based on a host of considerations, including the increased cost of inputs. As a result, this change in coverage will not significantly affect Medicare's current payments and will only affect its future payments in concert with the other factors affecting the DRG update decisions.

For these reasons, we are not preparing analyses for either the RFA or section 1102(b) of the Act because we have determined, and we certify, that this rule will not have a significant economic impact on a substantial number of small entities or a significant impact on the operations of a substantial number of small rural hospitals.

In accordance with the provisions of Executive Order 12866, this regulation was reviewed by the Office of Management and Budget.

IV. Collection of Information Requirements

This document does not impose information collection and recordkeeping requirements. Consequently, it need not be reviewed by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 et seq.).

V. Response to Comments

Because of the large number of items of correspondence we normally receive on Federal Register documents published for comment, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the ''DATES'' section of this preamble, and, if we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

List of Subjects

42 CFR Part 405

Administrative practice and procedure, Health facilities, Health professions, Kidney diseases, Medicare, Reporting and recordkeeping requirements, Rural areas, X-rays.

42 CFR Part 411

Kidney diseases, Medicare, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, 42 CFR Chapter IV is amended as follows:

A. 42 CFR part 405 is amended to read as follows:

PART 405—FEDERAL HEALTH INSURANCE FOR THE AGED AND DISABLED

1. A new subpart B, consisting of §§ 405.201–405.215, is added to read as follows:

Subpart B—Medical Services Coverage Decisions That Relate to Health Care Technology

Sec.

405.201 Scope of subpart and definitions.
405.203 FDA categorization of investigational devices.
405.205 Coverage of a non-experimental/investigational (Category B) device.
405.207 Services related to a noncovered device.
405.209 Payment for a non-experimental/investigational (Category B) device.
405.211 Procedures for Medicare contractors in making coverage decisions for a non-experimental/investigational (Category B) device.
405.213 Re-evaluation of a device categorization.
405.215 Confidential commercial and trade secret information.

Subpart B—Medical Services Coverage Decisions That Relate to Health Care Technology

Authority: Secs. 1102, 1862, and 1871 of the Social Security Act as amended (42 U.S.C. 1302, 1395y, and 1395hh).

§ 405.201 Scope of subpart and definitions.

(a) *Scope.* This subpart establishes that—

(1) HCFA uses the FDA categorization of a device as a factor in making Medicare coverage decisions; and

(2) HCFA may consider for Medicare coverage certain devices with an FDA-approved investigational device exemption (IDE) that have been categorized as non-experimental/investigational (Category B).

(b) *Definitions.* As used in this subpart—

Class I refers to devices for which the general controls of the Food, Drug, and Cosmetic Act, such as adherence to good manufacturing practice regulations, are sufficient to provide a reasonable assurance of safety and effectiveness.

Class II refers to devices that, in addition to general controls, require special controls, such as performance standards or postmarket surveillance, to provide a reasonable assurance of safety and effectiveness.

Class III refers to devices that cannot be classified into Class I or Class II because insufficient information exists to determine that either special or general controls would provide reasonable assurance of safety and effectiveness. Class III devices require premarket approval.

Contractors refers to carriers, fiscal intermediaries, and other entities that contract with HCFA to review and adjudicate claims for Medicare services.

Experimental/investigational (Category A) device refers to an innovative device believed to be in Class III for which ''absolute risk'' of the device type has not been established (that is, initial questions of safety and effectiveness have not been resolved and the FDA is unsure whether the device type can be safe and effective).

IDE stands for investigational device exemption. An FDA-approved IDE application permits a device, which would otherwise be subject to marketing clearance, to be shipped lawfully for the purpose of conducting a clinical trial in accordance with 21 U.S.C. 360j(g) and 21 CFR parts 812 and 813.

Non-experimental/investigational (Category B) device refers to a device believed to be in Class I or Class II, or a device believed to be in Class III for which the incremental risk is the primary risk in question (that is, underlying questions of safety and effectiveness of that device type have been resolved), or it is known that the device type can be safe and effective because, for example, other manufacturers have obtained FDA approval for that device type.

PMA stands for ''premarket approval'' and refers to a marketing application for a Class III device, which includes all information submitted with or incorporated by reference in the application in accordance with 21 U.S.C. 360e and 360j and 21 CFR 814.3(e).

Sponsor refers to a person or entity that initiates, but does not conduct, an investigation under an IDE.

§ 405.203 FDA categorization of investigational devices.

(a) The FDA assigns a device with an FDA-approved IDE to one of two categories:

(1) Experimental/Investigational (Category A) Devices.

(2) Non-Experimental/Investigational (Category B) Devices.

(b) The FDA notifies HCFA, when it notifies the sponsor, that the device is categorized by FDA as experimental/investigational (Category A) or non-experimental/investigational (Category B).

(c) HCFA uses the categorization of the device as a factor in making Medicare coverage decisions.

§ 405.205 Coverage of a non-experimental/investigational (Category B) device.

(a) For any device that meets the requirements of the exception at § 411.15(o) of this chapter, the following procedures apply:

(1) The FDA notifies HCFA, when it notifies the sponsor, that the device is categorized by FDA as non-experimental/investigational (Category B).

(2) HCFA uses the categorization of the device as a factor in making Medicare coverage decisions.

(b) If the FDA becomes aware that a categorized device no longer meets the requirements of the exception at § 411.15(o) of this chapter, the FDA notifies the sponsor and HCFA and the procedures described in paragraph (a)(2) of this section apply.

§ 405.207 Services related to a noncovered device.

(a) *When payment is not made.* Medicare payment is not made for medical and hospital services that are related to the use of a device that is not covered because HCFA determines the device is not ''reasonable'' and

''necessary'' under section 1862(a)(1)(A) of the Act or because it is excluded from coverage for other reasons. These services include all services furnished in preparation for the use of a noncovered device, services furnished contemporaneously with and necessary to the use of a noncovered device, and services furnished as necessary after-care that are incident to recovery from the use of the device or from receiving related noncovered services.

(b) *When payment is made.* Medicare payment may be made for services, ordinarily covered by Medicare, to treat a condition or complication that arises because of the use of a noncovered device or from the furnishing of related noncovered services.

§ 405.209 Payment for a non-experimental/investigational (Category B) device.

Payment under Medicare for a non-experimental/investigational (Category B) device is based on, and may not exceed, the amount that would have been paid for a currently used device serving the same medical purpose that has been approved or cleared for marketing by the FDA.

§ 405.211 Procedures for Medicare contractors in making coverage decisions for a non-experimental/investigational (Category B) device.

(a) *General rule.* In their review of claims for payment, Medicare contractors are bound by the statute, regulations, and all HCFA administrative issuances, including all national coverage decisions.

(b) *Potentially covered non-experimental/investigational (Category B) devices.* Medicare contractors may approve coverage for any device with an FDA-approved IDE categorized as a non-experimental/investigational (Category B) device if all other coverage requirements are met.

(c) *Other considerations.* Medicare contractors must consider whether any restrictions concerning site of service, indications for use, or any other list of conditions for coverage have been placed on the device's use.

§ 405.213 Re-evaluation of a device categorization.

(a) *General rules.* (1) Any sponsor that does not agree with an FDA decision that categorizes its device as experimental/investigational (Category A) may request re-evaluation of the categorization decision.

(2) A sponsor may request review by HCFA only after the requirements of paragraph (b) of this section are met.

(3) No reviews other than those described in paragraphs (b) and (c) of this section are available to the sponsor.

(4) Neither the FDA original categorization or re-evaluation (described in paragraph (b) of this section) nor HCFA's review (described in paragraph (c) of this section) constitute an initial determination for purposes of the Medicare appeals processes under part 405, subpart G or subpart H, or parts 417, 473, or 498 of this chapter.

(b) *Request to FDA.* A sponsor that does not agree with the FDA's categorization of its device may submit a written request to the FDA at any time requesting re-evaluation of its original categorization decision, together with any information and rationale that it believes support recategorization. The FDA notifies both HCFA and the sponsor of its decision.

(c) *Request to HCFA.* If the FDA does not agree to recategorize the device, the sponsor may seek review from HCFA. A device sponsor must submit its request in writing to HCFA. HCFA obtains copies of relevant portions of the application, the original categorization decision, and supplementary materials. HCFA reviews all material submitted by the sponsor and the FDA's recommendation. HCFA reviews only information in the FDA record to determine whether to change the categorization of the device. HCFA issues a written decision and notifies the sponsor of the IDE and the FDA.

§ 405.215 Confidential commercial and trade secret information.

To the extent that HCFA relies on confidential commercial or trade secret information in any judicial proceeding, HCFA will maintain confidentiality of the information in accordance with Federal law.

Subpart G—[Amended]

2. The authority citation for subpart G continues to read as follows:

Authority: Secs. 1102, 1151, 1154, 1155, 1869(b), 1871, 1872, and 1879 of the Social Security Act (42 U.S.C. 1302, 1320c, 1320c–3, 1320c–4, 1395ff(b), 1395hh, 1395ii and 1395pp).

3. In subpart G, a new § 405.753 is added to read as follows:

§ 405.753 Appeal of a categorization of a device.

(a) HCFA's acceptance of the FDA categorization of a device as an experimental/investigational (Category A) device under § 405.203 is a national coverage decision under section 1862(a)(1) of the Act.

(b) HCFA's acceptance of the FDA categorization of a device as an experimental/investigational (Category A) device under § 405.203 is an aspect of an initial determination that, under section 1862 of the Act, payment may not be made.

(c) In accordance with section 1869(b)(3)(A) of the Act, HCFA's acceptance of the FDA categorization of a device as an experimental/investigational (Category A) device under § 405.203 may not be reviewed by an administrative law judge.

Subpart H—[Amended]

4. The authority citation for subpart H continues to read as follows:

Authority: Secs. 1102, 1842(b)(3)(C), and 1869(b) of the Social Security Act (42 U.S.C. 1302, 1395u(b)(3)(C), 1395ff(b)).

5. In subpart H, a new § 405.877 is added to read as follows:

§ 405.877 Appeal of a categorization of a device.

(a) HCFA's acceptance of the FDA categorization of a device as an experimental/investigational (Category A) device under § 405.203 is a national coverage decision under section 1862(a)(1) of the Act.

(b) HCFA's acceptance of the FDA categorization of a device as an experimental/investigational (Category A) device under § 405.203 is an aspect of an initial determination that, under section 1862 of the Act, payment may not be made.

(c) In accordance with section 1869(b)(3)(A) of the Act, HCFA's acceptance of the FDA categorization of a device as an experimental/investigational (Category A) device under § 405.203 may not be reviewed by an administrative law judge.

B. 42 CFR part 411 is amended as set forth below:

PART 411—EXCLUSIONS FROM MEDICARE AND LIMITATIONS ON MEDICARE PAYMENT

1. The authority citation for part 411 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

2. In § 411.15, the introductory text is republished and new paragraph (o) is added to read as follows:

§ 411.15 Particular services excluded from coverage.

The following services are excluded from coverage.

* * * * *

(o) *Experimental or investigational devices, except for certain devices—*

(1) Categorized by the FDA as a non-experimental/investigational (Category B) device defined in § 405.201(b) of this chapter; and

(2) Furnished in accordance with the FDA-approved protocols governing clinical trials.

3. In § 411.406, paragraph (e) is revised to read as follows:

§ 411.406 Criteria for determining that a provider, practitioner, or supplier knew that services were excluded from coverage as custodial care or as not reasonable and necessary.

* * * * *

(e) *Knowledge based on experience, actual notice, or constructive notice.* It is clear that the provider, practitioner, or supplier could have been expected to have known that the services were excluded from coverage on the basis of the following:

(1) Its receipt of HCFA notices, including manual issuances, bulletins, or other written guides or directives from intermediaries, carriers, or PROs, including notification of PRO screening criteria specific to the condition of the beneficiary for whom the furnished services are at issue and of medical procedures subject to preadmission review by a PRO.

(2) Federal Register publications containing notice of national coverage decisions or of other specifications regarding noncoverage of an item or service.

(3) Its knowledge of what are considered acceptable standards of practice by the local medical community.

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; and Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: September 11, 1995.

Bruce C. Vladeck,

Administrator, Health Care Financing Administration.

Dated: September 12, 1995.

Donna E. Shalala,

Secretary.

Note: This addendum will not appear in the Code of Federal Regulations.

Addendum—Criteria for Categorization of Investigational Devices

Category A: Experimental/ Investigational

Category A devices include the following:

(1) Class III devices of a type for which no marketing application has been approved through the premarket approval (PMA) process for any indication for use. (For pre-amendments [1] Class III devices, refer to the criteria under Category B).

(2) Class III devices that would otherwise be in Category B but have undergone significant modification for a new indication for use.

Category B: Non-experimental/ Investigational

Category B devices include the following:

(1) Devices, regardless of the classification, under investigation to establish substantial equivalence to a predicate device, that is, to establish substantial equivalence to a previously/ currently legally marketed device.

(2) Class III devices whose technological characteristics and indications for use are comparable to a PMA-approved device.

(3) Class III devices with technological advances compared to a PMA-approved device, that is, a device with technological changes that represent advances to a device that has already received PMA-approval (generational changes).

(4) Class III devices that are comparable to a PMA-approved device but are under investigation for a new indication for use. For purposes of studying the new indication, no significant modifications to the device were required.

(5) Pre-amendments Class III devices that become the subject of an IDE after the FDA requires premarket approval, that is, no PMA application was submitted or the PMA application was denied.

(6) Nonsignificant risk device investigations for which the FDA required the submission of an IDE.

Note: Some investigational devices may exhibit unique characteristics or raise safety concerns that make additional consideration necessary. For these devices, HCFA and the FDA will agree on the additional criteria to be used. The FDA will use these criteria to assign the device(s) to a category. As experience is gained in the categorization process, this addendum may be modified.

[FR Doc. 95–23132 Filed 9–13–95; 4:00 pm]

BILLING CODE 4120–01–P

[1] Pre-amendments devices are devices that were marketed before the enactment of the 1976 Medical Device Amendments to the Food, Drug, and Cosmetic Act; that is, in commercial distribution before May 28, 1976.

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Pat 73

[MM Docket No. 90–189; RM–6904, RM–7114, RM–7186, 7415, RM–7298]

Radio Broadcasting Services; Farmington, Grass Valley, Jackson, CA

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: This document allots Channel 232A to Farmington, California, and substitutes Channel 232B1 for Channel 232A at Grass Valley, California, and modifies the license of Station KNCO, Grass Valley to specify operation on Channel 232B1. to accommodate these actions, this document substitutes Channel 259A for Channel 232A at Jackson, California, and modifies the license of Station KNGT, Jackson, California, to specify operation on Channel 259A. The reference coordinates for the Channel 232A allotment at Farmington, California, are 37–57–00 and 121–00–00. The reference coordinates for Channel 232B1 at Grass Valley, California, are 39–14–44 and 120–57–52. The reference coordinates for Channel 259A at Jackson, California, are 38–20–24 and 120–43–13. *See* 55 FR 13810 (April 12, 1990).

EFFECTIVE DATE: October 27, 1995.

FOR FURTHER INFORMATION CONTACT: Robert Hayne, Mass Media Bureau, (202) 776–1654.

SUPPLEMENTARY INFORMATION: This is a synopsis of the *First Report and Order* in MM Docket No. 90–189, adopted September 1, 1995, and released September 12, 1995. The full text of this decision is available for inspection and copying during normal business hours in the FCC Dockets Branch (Room 230), 1919 M Street, NW., Washington, DC. The complete text of this decision may also be purchased from the Commission's copy contractor, International Transcription Service, (202) 857–3800, 2100 M Street, NW., Washington, DC 20037.

List of Subjects in 47 CFR Part 73

Radio broadcasting.

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

PART 73—[AMENDED]

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

Authority: Secs.303, 48 Stat., as amended, 1082; 47 U.S.C. 154, as amended.

§ 73.202 [Amended]

2. Section 73.202(b), the Table of FM Allotments under California, is amended by adding Channel 232A at Farmington.

3. Section 73.202(b), the Table of FM Allotments under California, is amended by removing Channel 232A and adding Channel 232B1 at Grass Valley.

4. Section 73.202(b), the Table of FM Allotments under California, is amended by removing Channel 232A and adding Channel 259A at Jackson.

Federal Communications Commission.

John A.Karousos,

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

[FR Doc. 95–22943 Filed 9–18–95; 8:45 am]

BILLING CODE 6712–01–F

---

47 CFR Part 73

[FCC 95–385]

Mass Media: AM Expanded Band Allotment Plan

AGENCY: Federal Communications Commission.

ACTION: Final rule; Interpretation.

SUMMARY: On September 1, 1995, in response to requests for reconsideration, the FCC adopted a Memorandum Opinion and Order which rescinded its original AM Expanded Band Allotment Plan, released October 14, 1994, and provides a thirty-day period for comments to correct the AM database and a thirty-day period for comments on the procedures which will be used to generate a new plan based on recalculated ranking factors. A fifteen-day reply period is also provided. This will enable an accurate AM expanded Band Allotment Plan to be issued by the FCC.

DATES: Comments to correct the AM database must be filed on or before October 19, 1995. Comments regarding the procedures which will be used to generate a new Allotment Plan must be submitted on or before October 19, 1995. Reply comments are due on or before November 3, 1995.

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

FOR FURTHER INFORMATION CONTACT: Jim Burtle, Audio Services Division, Mass Media Bureau, (202) 418–2670.

SUPPLEMENTARY INFORMATION: This is a summary of the Commission's Memorandum Opinion and Order adopted September 1, 1995, and released September 6, 1995. The full text of this Commission decision is available for inspection and copying during normal business hours in the FCC Dockets Branch (Room 230), 1919 M St., NW, Washington, DC (See MM Docket 87–267). The complete text of this decision may also be purchased from the Commission's copy contractor, Downtown Copy Center, 1990 M St., NW, Suite 640, Washington, DC 30036.

The FCC rescinded the AM Expanded Band Allotment Plan Adopted October 14, 1994 (DA 94–1154). The Allotment Plan identified stations that were eligible to apply for authorization for specific expanded band (1605 kHz–1705 kHz) frequency allotments. The Commission also verified that certain errors existed in the AM database used to generate the improvement factor rankings on which the Allotment Plan was based (June 30, 1993–A database) and rescinded the improvement factor ranking list. The Commission called for changes to the June 30, 1993–A AM database to be filed within thirty days of the publication of this Memorandum Opinion and Order in the Federal Register.

The FCC further identified and clarified the standards used to implement a new Allotment Plan and gave interested parties a period of thirty days from the publication of the Memorandum Opinion and Order in the Federal Register to comment thereon. Reply comments may be filed within fifteen days of the comment date.

Final Regulatory Flexibility Analysis

The FCC granted in part requests for reconsideration and review of the AM Expanded Band Allotment Plan adopted October 14, 1994 (DA 94–1154) and rescinded the Allotment Plan and improvement factor ranking list. The Commission will receive requests to change the June 30, 1993–A database during a thirty-day comment period. The FCC also sets forth the procedures to implement the Allotment Plan and provides for a thirty-day comment period and fifteen-day reply period, thereon.

This action is authorized under Sections 4(i) and 303(r) of the Communications Act of 1934, as amended, and 303(r), and Section 553(b)(3)(A) of the Administrative Procedures Act.

Ordering Clause

Accordingly, it is ordered that the public is afforded thirty days from September 19, 1995 to change the June 30, 1993–A database, thirty days from September 19, 1995 to comment on the allotment plan procedures; and fifteen days from the comment date to file replies to the comments.

List of Subjects in 47 CFR Part 73

Radio.

Federal Communications Commission.

William F. Caton,

Acting Secretary.

[FR Doc. 95–23171 Filed 9–18–95; 8:45 am]

BILLING CODE 6712–01–M

Proposed Rules

Federal Register
Vol. 60, No. 181
Tuesday, September 19, 1995

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.

NUCLEAR REGULATORY COMMISSION

10 CFR Part 50

RIN 3150–AD10

Acceptance of Products Purchased for Use in Nuclear Power Plant Structures, Systems, and Components; Withdrawal

AGENCY: Nuclear Regulatory Commission.

ACTION: Advance notice of proposed rulemaking: Withdrawal.

SUMMARY: The Nuclear Regulatory Commission is withdrawing an advance notice of proposed rulemaking (ANPR) concerning the procurement and dedication of commercial grade items. The ANPR sought comment on the need for additional regulatory requirements and for obtaining an improved understanding of alternatives to regulatory requirements. On the basis of its findings, the NRC staff recommended to the Commission that this ANPR be withdrawn. The Commission has approved the withdrawal of this rulemaking.

FOR FURTHER INFORMATION CONTACT: Gregory Cwalina, Office of Nuclear Reactor Regulation, Division of Technical Support, Special Inspection Branch, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, telephone (301) 415–2983.

SUPPLEMENTARY INFORMATION: On March 6, 1989 (54 FR 9229), the NRC staff published in the Federal Register an ANPR, on the need for regulatory actions to effect improvements for procurement, receipt inspection and testing, and dedication programs, in response to the findings of 13 inspections performed on licensees from 1986 through 1989. In the ANPR, the NRC staff explained that the NRC was considering the need for additional regulatory requirements and needed to obtain an improved understanding of alternatives to regulatory requirements.

The inspections on commercial grade dedication programs identified major programmatic deficiencies. On February 21, 1990, the NRC staff submitted to the Commission SECY–90–057, ''Acceptance of Products Purchased for Use in Nuclear Power Plant Structures, Systems, and Components,'' to summarize the NRC's analysis of the public comments on the ANPR and its actions regarding the proposed rulemaking. The NRC staff concluded that (1) More regulatory guidance and direction may be necessary to ensure that the basic requirements for procurement and dedication are clearly stated and understood, (2) the NRC may not need to perform the rulemaking if the industry properly implemented the initiatives it had begun, and (3) the NRC staff would monitor the industry's efforts to determine if the progress made warranted deferring the rulemaking.

On March 7, 1990, the NRC staff forwarded to the Commission SECY–90–076, ''Inspection and Enforcement Initiatives for Commercial-Grade Procurement and Dedication Programs,'' in which the NRC staff described its actions to defer programmatic inspections of licensees' procurement and dedication programs for about 1 year while monitoring the industry's developments, improvements, and initiatives in this area.

On August 24, 1990, the NRC staff forwarded to the Commission SECY–90–304, ''Nuclear Management and Resources Council (NUMARC) Initiatives on Procurement,'' in which the NRC staff reported the status of NUMARC's initiatives on general procurement practices. The NRC staff stated it would conduct assessments at selected sites to review the licensees' implementation of improved procurement and commercial grade dedication programs and to assess improvements made in the areas covered by the NUMARC initiatives. The NRC staff began the first of eight planned assessments on February 4, 1991.

On April 9, 1991, the NRC staff issued Generic Letter 91–05, ''Licensee Commercial-Grade Procurement and Dedication Programs,'' in which the NRC staff expressed NRC positions regarding certain aspects of licensee procurement and dedication programs and discussed a number of deficiencies in licensees' commercial grade dedication programs noted during previous team inspections.

On September 16, 1991, the NRC staff forwarded to the Commission SECY–91–291, ''Status of NRC's Procurement Assessments and Resumption of Programmatic Inspection Activity,'' in which the NRC staff reported on the findings of its assessments from February 1991 through July 1991. The NRC staff concluded that although improvements had been made in licensees' procurement and dedication programs, weaknesses in implementation still existed. The NRC staff began developing an inspection procedure (IP) and conducted five pilot inspections between December 1991 and June 1992. The NRC staff continued to identify weaknesses in the implementation of licensees' dedication programs. Because of the findings of these inspections, the NRC staff held numerous meetings with NUMARC, industry, and licensees from November 1992 to March 1993. After the pilot inspections were completed, the IP was revised and in March 1993, the NRC staff submitted the draft IP for public comment.

Weaknesses identified during the procurement assessments and pilot inspections were related to implementation of the programs (i.e., dedication of specific items), and not to the programs themselves. Adoption of the industry guidance has, for the most part, resulted in licensees having acceptable programs for the dedication of commercial grade items. These programs also adequately assure that counterfeit, substandard or fraudulently marketed materials will not be accepted for use. The NRC staff's assessment and inspection activities did not identify any instances of counterfeit or fraudulent material being accepted for use by any of the plants examined.

In April 1993, the NRC staff held a public workshop, at which the draft IP and various dedication issues were discussed. The public comment period closed in May 1993. The comment analysis and the revisions to the IP and dedication guidance were finished in June 1993. On November 8, 1993, the NRC staff issued the IP. Recent experience with the new IP demonstrated that the current inspection approach provides an effective means for assuring that licensee procurement and dedication

activities will prevent the acceptance of counterfeit and fraudulent materials.

Based on the findings of the original inspections, assessments, and pilot inspections, the NRC staff believes that problems identified with respect to the quality of items dedicated for use in safety-related applications are adequately addressed by the requirements of Appendix B of Part 50 and are problems of compliance, rather than of inadequate rules. The NRC staff and industry worked closely together to improve industry efforts in procurement and commercial grade dedication. Therefore, there appears to be no need for new regulations addressed to the quality of items dedicated for use in safety-related applications.

Part of the NRC staff's reason for originally proposing rulemaking was to reduce the likelihood of counterfeit or fraudulently marketed products from being accepted for use. The NRC staff has issued numerous information notices regarding specific cases of fraudulent parts being found in nuclear facilities and guidance on how to detect them. The NRC staff has also issued two generic letters presenting information regarding procurement program improvements to help prevent the acceptance and use of counterfeit or fraudulently marketed products. This issue is also addressed as part of the NUMARC Comprehensive Procurement Initiative.

Finally, the Commission issued a rule change to 10 CFR Part 50 (§ 50.5, Deliberate misconduct) that gives the NRC staff an additional regulatory tool to pursue cases in which a licensee contractor or subcontractor has deliberately provided material, goods, or services that causes or may cause the licensee to be in violation of a rule. A supplier providing counterfeit and/or substandard materials to be used in safety-related applications is subject to that rule. Therefore, additional rulemaking to specifically address fraudulent parts appears unnecessary.

For these reasons, the Commission has concluded that the nuclear industry has made significant progress toward improving its procurement and commercial grade dedication programs and believes that problems identified with respect to the quality of items dedicated for use in safety-related applications are adequately addressed by the requirements of 10 CFR Part 50, Appendix B. Therefore, there appears to be no need for new regulations addressed to the quality of items dedicated for use in safety-related applications. Accordingly, the Commission is withdrawing the ANPR.

Dated at Rockville, Maryland, this 8th day of September, 1995.

For the Nuclear Regulatory Commission.

James M. Taylor,

Executive Director for Operations.

[FR Doc. 95–23178 Filed 9–18–95; 8:45 am]

BILLING CODE 7590–01–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 95–SW–19–AD]

Airworthiness Directives; Flight Trails Helicopters, Inc., Hardpoint Assemblies Installed on McDonnell Douglas Helicopter Systems Model 369D, 369E, 369F, 369FF, and 500N Helicopters

AGENCY: Federal Aviation Administration, DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This document proposes the adoption of a new airworthiness directive (AD) that is applicable to Flight Trails Helicopters, Inc. hardpoint assemblies, installed in accordance with Supplemental Type Certificate (STC) No. SH6080NM, or in accordance with Federal Aviation Administration (FAA) Form 337, ''Major Repair and Alteration,'' approved on McDonnell Douglas Helicopter Systems (MDHS) Model 369D, 369E, 369F, 369FF, and 500N helicopters. This proposal would require removing any Flight Trails Helicopters, Inc. hardpoint assembly not identified by part number (P/N) and serial number (S/N). This proposal is prompted by two incidents in which the hardpoint assembly used to support a search light or night vision system reportedly failed. The actions specified by the proposed AD are intended to prevent failure of the hardpoint assembly, separation of the hardpoint assembly from the helicopter, and subsequent contact between the hardpoint assembly and the fuselage or rotor system of the helicopter.

DATES: Comments must be received by November 20, 1995.

ADDRESSES: Submit comments in triplicate to the FAA, Office of the Assistant Chief Counsel, Attention: Rules Docket No. 95–SW–19–AD, 2601 Meacham Blvd., Room 663, Fort Worth, Texas 76137. Comments may be inspected at this location between 9:00 a.m. and 3:00 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Mr. James Wang, Aerospace Engineer, FAA, Los Angeles Aircraft Certification Office, 3960 Paramount Blvd., Lakewood, California 90712, telephone (310) 627–5232, fax (310) 627–5210.

SUPPLEMENTARY INFORMATION:

Comments Invited

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

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

Commenters wishing the FAA to acknowledge receipt of their comments submitted in response to this notice must submit a self-addressed, stamped postcard on which the following statement is made: ''Comments to Docket No. 95–SW–19–AD.'' The postcard will be date stamped and returned to the commenter.

Availability of NPRMs

Any person may obtain a copy of this NPRM by submitting a request to the FAA, Office of the Assistant Chief Counsel, Attention: Rules Docket No. 95–SW–19–AD, 2601 Meacham Blvd., Room 663, Fort Worth, Texas 76137.

Discussion

This document proposes the adoption of a new AD that is applicable to Flight Trails Helicopters, Inc. hardpoint assemblies installed in accordance with STC No. SH6080NM, or in accordance with FAA Form 337, ''Major Repair and Alteration,'' approved on MDHS Model 369D, 369E, 369F, 369FF, and 500N helicopters. Two incidents have occurred in which the hardpoint assembly reportedly failed at its installation weld. The hardpoint assembly is used to attach equipment such as a search light or night vision

system to the helicopter's fuselage. In the first incident, a failure occurred in the hardpoint installation weld area due to a fatigue crack. The discovery of a crack in the hardpoint assembly installation weld on a second helicopter occurred during a visual ground check. This condition, if not corrected, could result in failure of the hardpoint assembly, separation of the hardpoint assembly from the helicopter, and subsequent contact between the hardpoint assembly and the fuselage or rotor system of the helicopter.

Since an unsafe condition has been identified that is likely to exist or develop on other Flight Trails Helicopters, Inc. hardpoint assemblies installed on MDHS Model 369D, 369E, 369F, 369FF, and 500N helicopters of the same type design, the proposed AD would require, before further flight, removing the hardpoint assembly that secures a searchlight or night vision system to the helicopter.

The FAA estimates that 59 helicopters of U.S. registry would be affected by this proposed AD, that it would take approximately 1 work hour per helicopter to accomplish the proposed actions, and that the average labor rate is $60 per work hour. Based on these figures, the total cost impact of the proposed AD on U.S. operators is estimated to be $3,540.

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

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

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Safety.

The Proposed Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

Authority: 49 U.S.C. 106(g), 40101, 40113, 44701.

§ 39.13 [Amended]

2. Section 39.13 is amended by adding a new airworthiness directive to read as follows:

Flight Trails Helicopters, Inc.: Docket No. 95–SW–19–AD.

Applicability: McDonnell Douglas Helicopters Systems (MDHS) Model 369D, 369E, 369F, 369FF, and 500N helicopters, that have been modified in accordance with Supplemental Type Certificate (STC) No. SH6080NM, or in accordance with a Federal Aviation Administration (FAA) Form 337, ''Major Repair and Alteration,'' using Flight Trails Helicopters, Inc. hardpoint assemblies, certificated in any category.

Note 1: This AD applies to each helicopter identified in the preceding applicability provision, regardless of whether it has been modified, altered, or repaired in the area subject to the requirements of this AD. For helicopters that have been modified, altered, or repaired so that the performance of the requirements of this AD is affected, the owner/operator must use the authority provided in paragraph (b) to request approval from the FAA. This approval may address either no action, if the current configuration eliminates the unsafe condition, or different actions necessary to address the unsafe condition described in this AD. Such a request should include an assessment of the effect of the changed configuration on the unsafe condition addressed by this AD. In no case does the presence of any modification, alteration, or repair remove any helicopter from the applicability of this AD.

Note 2: Information concerning the hardpoint assemblies may be obtained from Flight Trails Helicopters, Inc., ATTN: Mr. Larry Anderson, 4805 Falcon Drive, Mesa, Arizona, 85205, telephone (602) 396–8242.

Compliance: Required as indicated, unless accomplished previously. To prevent failure of the hardpoint assembly, separation of the hardpoint assembly from the helicopter, and subsequent contact between the hardpoint assembly and the fuselage or rotor system of the helicopter, accomplish the following:

(a) Before further flight, remove from the helicopter any Flight Trails Helicopters, Inc. hardpoint assembly not marked with a part number (P/N) and serial number (S/N) by removing the NAS 1351–3 cap screw that secures the hardpoint assembly to the jacking fitting, P/N 369H2521, and slipping the hardpoint assembly out of the step mount.

The only Flight Trails Helicopters, Inc. hardpoint assemblies that are considered airworthy and eligible for installation are those hardpoint assemblies marked with a serial number and either P/N FTH 105 LH Mod 1, for a hardpoint assembly mounted on the left side of the helicopter, or P/N FTH 105 RH Mod 1, for a hardpoint assembly mounted on the right side.

(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, Los Angeles Aircraft Certification Office, FAA. Operators shall submit their requests through an FAA Principal Maintenance Inspector, who may concur or comment and then send it to the Manager, Los Angeles Aircraft Certification Office.

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

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

Issued in Fort Worth, Texas, on September 11, 1995.

Eric Bries,

Acting Manager, Rotorcraft Directorate, Aircraft Certification Service.

[FR Doc. 95–23123 Filed 9–18–95; 8:45 am]

BILLING CODE 4910–13–P

---

14 CFR Part 39

[Docket No. 95–CE–44–AD]

Airworthiness Directives; Jetstream Aircraft Limited HP137 Mk1, Jetstream Series 200, and Jetstream Models 3101 and 3201 Airplanes

AGENCY: Federal Aviation Administration, DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This document proposes to adopt a new airworthiness directive (AD) that would apply to Jetstream Aircraft Limited (JAL) HP137 Mk1, Jetstream series 200, and Jetstream Models 3101 and 3201 airplanes. The proposed AD would require repetitively inspecting the main landing gear (MLG) pintle to cylinder interface for cracks, and replacing any cylinder that has a crack exceeding certain limits. Reports of MLG cracks in the area of the pintle to cylinder interface on three of the affected airplanes prompted the proposed action. The actions specified by the proposed AD are intended to prevent failure of the MLG caused by cracks in the pintle to cylinder interface area, which, if not detected and

corrected, could result in loss of control of the airplane during landing operations.

DATES: Comments must be received on or before November 17, 1995.

ADDRESSES: Submit comments in triplicate to the Federal Aviation Administration (FAA), Central Region, Office of the Assistant Chief Counsel, Attention: Rules Docket No. 95–CE–44–AD, Room 1558, 601 E. 12th Street, Kansas City, Missouri 64106. Comments may be inspected at this location between 8 a.m. and 4 p.m., Monday through Friday, holidays excepted.

Service information that applies to the proposed AD may be obtained from Jetstream Aircraft Limited, Prestwick International Airport, Ayrshire, KA9 2RW, Scotland, telephone (44–292) 79888; facsimile (44–292) 79703; or Jetstream Aircraft Inc., Librarian, P.O. Box 16029, Dulles International Airport, Washington, DC 20041–6029; telephone (703) 406–1161; facsimile (703) 406–1469. This information also may be examined at the Rules Docket at the address above.

FOR FURTHER INFORMATION CONTACT: Mr. Raymond A. Stoer, Program Officer, Brussels Aircraft Certification Office, FAA, Europe, Africa, and Middle East Office, c/o American Embassy, B–1000 Brussels, Belgium; telephone (322) 513.3830; facsimile (322) 230.6899; or Mr. Sam Lovell, Project Officer, Small Airplane Directorate, Airplane Certification Service, FAA, 1201 Walnut, suite 900, Kansas City, Missouri 64105; telephone (816) 426–6932; facsimile (816) 426–2169.

SUPPLEMENTARY INFORMATION:

Comments Invited

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

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

Commenters wishing the FAA to acknowledge receipt of their comments submitted in response to this notice must submit a self-addressed, stamped postcard on which the following statement is made: ''Comments to Docket No. 95–CE–44–AD.'' The postcard will be date stamped and returned to the commenter.

Availability of NPRMs

Any person may obtain a copy of this NPRM by submitting a request to the FAA, Central Region, Office of the Assistant Chief Counsel, Attention: Rules Docket No. 95–CE–44–AD, Room 1558, 601 E. 12th Street, Kansas City, Missouri 64106.

Discussion

The Civil Aviation Authority (CAA), which is the airworthiness authority for the United Kingdom, recently notified the FAA that an unsafe condition may exist on JAL HP137 Mk1, Jetstream series 200, and Jetstream Models 3101 and 3201 airplanes. The CAA reports that the main landing gear (MLG) has cracked in the area of the pintle to cylinder interface on three of the affected airplanes. This condition, if not detected and corrected, could result in failure of the MLG and possible loss of control of the airplane.

Jetstream has issued Alert Service Bulletin (ASB) 32–A–JA 941245, Revision 2, dated March 28, 1995, which specifies procedures for preparing the affected airplanes for a non-destructive testing (NDT) eddy current inspection of the MLG pintle to cylinder interface. The procedures for the NDT eddy current inspection are included in AP Precision Hydraulics Ltd. Service Bulletin (SB) 32–56, Revision 3, dated February 1995.

The CAA classified these service bulletins as mandatory in order to assure the continued airworthiness of these airplanes in the United Kingdom. The CAA classifying a service bulletin as mandatory is considered equivalent in the United Kingdom to the FAA issuing an AD in the United States.

The airplane models are manufactured in the United Kingdom and are type certificated for operation in the United States under the provisions of section 21.29 of the Federal Aviation Regulations (14 CFR 21.29) and the applicable bilateral airworthiness agreement. Pursuant to this bilateral airworthiness agreement, the CAA has kept the FAA informed of the situation described above. The FAA has examined the findings of the CAA, reviewed all available information including the above-referenced service information, and determined that AD action is necessary for products of this type design that are certificated for operation in the United States.

Since an unsafe condition has been identified that is likely to exist or develop in other JAL HP137 Mk1, Jetstream series 200, and Jetstream Models 3101 and 3201 airplanes of the same type design, the proposed AD would require repetitively inspecting (using NDT eddy current methods) the MLG pintle to cylinder interface for cracks, and replacing any cylinder that has a crack exceeding certain limits. Accomplishment of the proposed inspections would be in accordance with Jetstream ASB 32–A–JA 941245, Revision 2, dated March 28, 1995, and AP Precision Hydraulics Ltd. SB 32–56, Revision 3, dated February 1995.

The FAA estimates that 250 airplanes in the U.S. registry would be affected by the proposed AD, that it would take approximately 6 workhours per airplane to accomplish the proposed action, and that the average labor rate is approximately $60 an hour. Based on these figures, the total cost impact of the proposed inspection on U.S. operators is estimated to be $90,000. This figure does not take into account the cost of repetitive inspections or the cost of replacement cylinders if cracks are found that exceed certain limits. The FAA has no way of determining the number of repetitive inspections each operator would incur or the number of cylinders that may be found cracked during the inspections proposed by this action.

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

For the reasons discussed above, I certify that this action (1) is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and (3) if promulgated, will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act. A copy of the draft regulatory evaluation prepared for this action has been placed in the Rules

Docket. A copy of it may be obtained by contacting the Rules Docket at the location provided under the caption **ADDRESSES.**

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Safety.

The Proposed Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

Authority: 49 USC 106(g), 40101, 40113, 44701.

§ 39.13 [Amended]

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

Jetstream Aircraft Limited: Docket No. 95–CE–44–AD.

Applicability: HP 137 Mk1, Jetstream Series 200, and Jetstream Models 3101 and 3201 airplanes (all serial numbers), certificated in any category, that are equipped with one of the following main landing gear (MLG) part numbers:

1863, 1863/4A, 1863/4B, 1863/4C, 1864, 1864/4A, 1864/4B, 1864/4C, BOOA702850A, BOOA702851A, BOOA702925A, BO1A702925A, BOOA703065A, BO1A703065A, BOOA703030A, BOOA702926A, BO1A702926A, BOOA703066A, BO1A703066A, BOOA703031A,

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

Compliance: Required initially upon the accumulation of 8,500 landings on an affected MLG or within the next 100 landings after the effective date of this AD, whichever occurs later, unless already accomplished, and thereafter as indicated.

Note 2: If the number of MLG landings is unknown, hours time-in-service (TIS) may be used by multiplying the number of hours TIS times 0.75. If hours TIS are utilized to come up with the number of landings, this would make the AD effective ''initially upon the accumulation of 11,333 hours TIS or within the next 133 hours TIS after the effective date of this AD, whichever occurs later.''

To prevent failure of the MLG caused by cracks in the pintle to cylinder interface area, which, if not detected and corrected, could result in loss of control of the airplane during landing operations, accomplish the following:

(a) Using non-destructive testing (NDT) eddy current methods, inspect the MLG pintle to cylinder interface for cracks in accordance with the following:

(1) Jetstream Alert Service Bulletin 32–A–JA 941245, Revision 2, dated March 28, 1995; and

(2) AP Precision Hydraulics Ltd. Service Bulletin 32–56, Revision 3, dated February 1995.

(b) Based on the inspection results, accomplish the following, as applicable:

(1) If any crack is found that is .05 inch or more in length, prior to further flight, replace the cylinder with a new part, and reinspect at intervals not to exceed 4,000 landings provided the MLG pintle to cylinder interface is crack-free.

(2) If any crack is found that is less than .05 inch, reinspect at intervals not to exceed 40 landings provided the crack remains less than .05 inch or replace the cylinder with a new part and reinspect at intervals not to exceed 4,000 landings provided the MLG pintle to cylinder interface is crack-free.

(3) If no cracks are found, reinspect at intervals not to exceed 4,000 landings provided the MLG pintle to cylinder interface is crack-free.

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

(d) An alternative method of compliance or adjustment of the initial and repetitive compliance times that provides an equivalent level of safety may be approved by the Manager, Brussels Aircraft Certification Office (ACO), Europe, Africa, Middle East office, FAA, c/o American Embassy, B–1000 Brussels, Belgium. The request should be forwarded through an appropriate FAA Maintenance Inspector, who may add comments and then send it to the Manager, Brussels ACO.

Note 3: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the Brussels ACO.

(e) All persons affected by this directive may obtain copies of the documents referred to herein upon request to Jetstream Aircraft Limited, Manager Product Support, Prestwick Airport, Ayrshire, KA9 2RW Scotland; or Jetstream Aircraft Inc., Librarian, P.O. Box 16029, Dulles International Airport, Washington, DC, 20041–6029; or may examine these documents at the FAA, Central Region, Office of the Assistant Chief Counsel, Room 1558, 601 E. 12th Street, Kansas City, Missouri 64106.

Issued in Kansas City, Missouri, on September 13, 1995.

Gerald W. Pierce,

Acting Manager, Small Airplane Directorate, Aircraft Certification Service.

[FR Doc. 95–23218 Filed 9–18–95; 8:45 am]

BILLING CODE 4910–13–U

---

14 CFR Part 39

[Docket No. 95–CE–40–AD]

Airworthiness Directives; Fairchild Aircraft SA226 and SA227 Series Airplanes

AGENCY: Federal Aviation Administration, DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This document proposes to adopt a new airworthiness directive (AD) that would apply to certain Fairchild Aircraft SA226 and SA227 series airplanes. The proposed action would require drilling inspection access holes in the elevator torque tube arm, inspecting the elevator torque tube for corrosion, replacing any corroded elevator torque tube, and applying a corrosion preventive compound. Several reports of corrosion found in the elevator torque tube area on the affected airplanes prompted the proposed action. The actions specified by the proposed AD are intended to prevent failure of the flight control system caused by a corroded elevator torque tube, which, if not detected and corrected, could result in loss of control of the airplane.

DATES: Comments must be received on or before November 17, 1995.

ADDRESSES: Submit comments in triplicate to the Federal Aviation Administration (FAA), Central Region, Office of the Assistant Chief Counsel, Attention: Rules Docket No. 95–CE–40–AD, Room 1558, 601 E. 12th Street, Kansas City, Missouri 64106. Comments may be inspected at this location between 8 a.m. and 4 p.m., Monday through Friday, holidays excepted.

Service information that applies to the proposed AD may be obtained from Fairchild Aircraft, P.O. Box 790490, San Antonio, Texas 78279–0490; telephone (210) 824–9421. This information also may be examined at the Rules Docket at the address above.

FOR FURTHER INFORMATION CONTACT: Mr. Hung Viet Nguygen, Aerospace Engineer, FAA, Airplane Certification Office, 2601 Meacham Boulevard, Fort Worth, Texas 76193–0150; telephone (817) 222–5155; facsimile (817) 222–5960.

SUPPLEMENTARY INFORMATION:

Comments Invited

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

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

Commenters wishing the FAA to acknowledge receipt of their comments submitted in response to this notice must submit a self-addressed, stamped postcard on which the following statement is made: ''Comments to Docket No. 95–CE–40–AD.'' The postcard will be date stamped and returned to the commenter.

Availability of NPRMs

Any person may obtain a copy of this NPRM by submitting a request to the FAA, Central Region, Office of the Assistant Chief Counsel, Attention: Rules Docket No. 95–CE–40–AD, Room 1558, 601 E. 12th Street, Kansas City, Missouri 64106.

Discussion

The FAA has received reports of internal corrosion found in the elevator torque tube on over 20 Fairchild Aircraft SA226 and SA227 series airplanes. This condition, if not detected and corrected, could result in failure of the airplane flight control system and subsequent loss of control of the airplane.

Fairchild Aircraft Service Bulletin (SB) 226–27–050 and SB 227–27–028, both issued: January 22, 1990, specify procedures for the following:

- Drilling inspection access holes in the elevator torque tube arm;
- Inspecting the elevator torque tube for corrosion; and
- Applying a corrosion preventive compound.

After examining the circumstances and reviewing all available information related to the incidents described above including the referenced service information, the FAA has determined that AD action should be taken to prevent failure of the flight control system caused by a corroded elevator torque tube, which, if not detected and corrected, could result in loss of control of the airplane.

Since an unsafe condition has been identified that is likely to exist or develop in other Fairchild Aircraft SA226 and SA227 series airplanes of the same type design, the proposed AD would require drilling inspection access holes in the elevator torque tube arm, inspecting the elevator torque tube for corrosion, replacing any corroded elevator torque tube, and applying a corrosion preventive compound. Accomplishment of the proposed inspection access hole drilling, the inspection, and the corrosion preventive compound application would be in accordance with either Fairchild SB 226–27–050 or SB 227–27–028, both issued: January 22, 1990.

The compliance time for the proposed AD is presented in calendar time instead of hours time-in-service (TIS). The FAA has determined that a calendar time for compliance would be the most desirable method because the unsafe condition described by the proposed AD is caused by corrosion. Corrosion can occur on airplanes regardless of whether the airplane is in service or on the ground.

The FAA estimates that 390 airplanes in the U.S. registry would be affected by the proposed AD, that it would take approximately 10 workhours to accomplish the proposed actions, and that the average labor rate is approximately $60 an hour. Based on these figures, the total cost impact of the proposed AD on U.S. operators is estimated to be $234,000. This figure is based on the assumption that no owner/operator of the affected airplanes has accomplished the proposed inspection access hole drilling, inspection, or corrosion preventive compound application. It also is based on the assumption that no elevator torque tube would be found corroded and need replaced. The FAA has no way of determining how many owners/operators of the affected airplanes may have already complied with the proposed AD.

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

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

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Safety.

The Proposed Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

Authority: 49 USC 106(g), 40101, 40113, 44701.

§ 39.13 [Amended]

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

Fairchild Aircraft: Docket No. 95–CE–40–AD.

Applicability: The following airplane models and serial numbers, certificated in any category:

Model	Serial Nos.
SA226–T	T201 through T275 and T277 through T291.
SA226–T(B)	T(B)276 and T(B)292 through T(B)417.
SA226–AT	AT001 through AT074.
SA226–TC	TC201 through TC419.
SA227–TT	TT421 through TT541.
SA227–AT	AT423 through AT695.
SA227–AC	AC406, AC415, AC416, and AC420 through AC772.

Note 1: This AD applies to each airplane identified in the preceding applicability

revision, regardless of whether it has been modified, altered, or repaired in the area subject to the requirements of this AD. For airplanes that have been modified, altered, or repaired so that the performance of the requirements of this AD is affected, the owner/operator must request approval for an alternative method of compliance in accordance with paragraph (e) of this AD. The request should include an assessment of the effect of the modification, alteration, or repair on the unsafe condition addressed by this AD; and, if the unsafe condition has not been eliminated, the request should include specific proposed actions to address it. Compliance: Required within the next 6 calendar months after the effective date of this AD, unless already accomplished.

To prevent failure of the flight control system caused by a corroded elevator torque tube, which, if not detected and corrected, could result in loss of control of the airplane, accomplish the following:

(a) Drill two .5 inch diameter holes in the inboard side of the elevator torque tube arm in accordance with the ACCOMPLISHMENT INSTRUCTIONS section of and as specified in Figure 1 of Fairchild Aircraft Service Bulletin (SB) 226–27–050 or SB 227–27–028, both Issued: January 22, 1990, as applicable.

(b) Inspect the elevator torque tube in accordance with the ACCOMPLISHMENT INSTRUCTIONS section of Fairchild Aircraft SB 226–27–050 or SB 227–27–028, both Issued: January 22, 1990, as applicable. Prior to prior further flight, replace any corroded elevator torque tube with a new part of like design in accordance with the applicable maintenance manual.

(c) Apply a corrosion preventive compound in accordance with the ACCOMPLISHMENT INSTRUCTIONS section of Fairchild Aircraft SB 226–27–050 or SB 227–27–028, both Issued: January 22, 1990, as applicable.

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

(e) An alternative method of compliance or adjustment of the compliance time that provides an equivalent level of safety may be approved by the Manager, Airplane Certification Office (ACO), FAA, 2601 Meacham Boulevard, Fort Worth, Texas 76193–0150. The request shall be forwarded through an appropriate FAA Maintenance Inspector, who may add comments and then send it to the Manager, Fort Worth ACO.

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

(f) All persons affected by this directive may obtain copies of the service bulletins referred to herein upon request to Fairchild Aircraft, P.O. Box 790490, San Antonio, Texas 78279–0490; or may examine these service bulletins at the FAA, Central Region, Office of the Assistant Chief Counsel, Room 1558, 601 E. 12th Street, Kansas City, Missouri 64106.

Issued in Kansas City, Missouri, on September 13, 1995.

Gerald W. Pierce,

Acting Manager, Small Airplane Directorate, Aircraft Certification Service.

[FR Doc. 95–23216 Filed 9–18–95; 8:45 am]

BILLING CODE 4910–13–U

---

14 CFR Part 39

[Docket No. 95–CE–35–AD]

Airworthiness Directives; The New Piper Aircraft, Inc. (Formerly Piper Aircraft Corporation) Models PA23, PA23–150, PA23–160, PA23–235, and PA23–250 Airplanes

AGENCY: Federal Aviation Administration, DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This document proposes to supersede Airworthiness Directive (AD) 92–13–04, which currently requires preflight draining procedures on The New Piper Aircraft, Inc. (Piper) Models PA23–150 and PA23–160 airplanes. This proposed action would require installing external fuel ramp assemblies on Piper Models PA23, PA23–150, PA23–160, PA23–235, and PA23–250 airplanes, and incorporating pilots' operating handbook (POH) revisions for Piper Models PA23, PA23–150, and PA23–160 airplanes. Reports of water-in-the-fuel on the affected airplanes, regardless of whether the airplane owners/operators have accomplished preflight draining procedures, prompted the proposed action. The actions specified by the proposed AD are intended to prevent rough engine operation or complete loss of engine power caused by water-in-the-fuel.

DATES: Comments must be received on or before December 26, 1995.

ADDRESSES: Submit comments in triplicate to the Federal Aviation Administration (FAA), Central Region, Office of the Assistant Chief Counsel, Attention: Rules Docket No. 95–CE–35–AD, Room 1558, 601 E. 12th Street, Kansas City, Missouri 64106. Comments may be inspected at this location between 8 a.m. and 4 p.m., Monday through Friday, holidays excepted.

FFC Engineering Specification 2810–002, Revision A, dated March 21, 1995, may be obtained from Floats & Fuel Cells, 4010 Pilot Drive, suite 3, Memphis, Tennessee 38118. Piper Service Bulletin (SB) No. 827A, dated November 4, 1988, may be obtained from The New Piper Aircraft, Inc., Customer Services, 2926 Piper Drive, Vero Beach, Florida 32960. This information also may be examined at the Rules Docket at the address above.

FOR FURTHER INFORMATION CONTACT: Ms. Juanita Craft-Lloyd, Aerospace Engineer, FAA, Atlanta Aircraft Certification Office, Campus Building, 1701 Columbia Avenue, suite 2–160, College Park, Georgia 30337–2748; telephone (404) 305–7373; facsimile (404) 305–7348.

SUPPLEMENTARY INFORMATION:

Comments Invited

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

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

Commenters wishing the FAA to acknowledge receipt of their comments submitted in response to this notice must submit a self-addressed, stamped postcard on which the following statement is made: ''Comments to Docket No. 95–CE–35–AD.'' The postcard will be date stamped and returned to the commenter.

Availability of NPRMs

Any person may obtain a copy of this NPRM by submitting a request to the FAA, Central Region, Office of the Assistant Chief Counsel, Attention: Rules Docket No. 95–CE–35–AD, Room 1558, 601 E. 12th Street, Kansas City, Missouri 64106.

Discussion

Sixteen accidents since 1975 involving Piper PA23 series airplanes where water-in-the-fuel was believed to cause engine stoppage prompted the FAA to issue AD 90–23–18, Amendment 39–6782 (55 FR 46787; November 7, 1990), and AD 92–13–04, Amendment 39–8274 (57 FR 24938;

June 12, 1992). AD 92–13–04 superseded AD 90–23–18 and currently requires preflight draining procedures on Piper Models PA23–150 and PA23–160 airplanes, and was issued to prevent rough engine operation or complete loss of engine power because of water contamination in the fuel. AD 92–13–04 exempts from its requirements airplanes with a dual fuel drain kit, part number (P/N) 765–363, installed in accordance with Piper Service Bulletin (SB) 827A, dated November 4, 1988. AD 90–23–18 required the installation of dual fuel drain kits and the installation of internal wedges in the fuel tanks before its effectiveness was suspended and eventually superseded by AD 92–13–04.

Even with the issuance of, and the owners/operators' compliance with, AD 92–13–04, the FAA continues to receive reports of fuel-related problems where the cause is believed to be water-in-the-fuel. Some of these reports specify incidents involving Piper Models PA23–235 and PA23–250 airplanes. AD 92–13–04 did not apply to these airplane models because the FAA believed that the baffled fuel tanks included with these airplane models would channel the water towards the drain instead of the low spot.

Floats and Fuel Cells (FFC) has issued Engineering Specification 2810–002, Revision A, dated March 21, 1995, which specifies procedures for installing external fuel ramps on Piper PA23 series airplanes.

After examining all information related to the incidents and service reports described above including the referenced service information, the FAA has determined that:

- The preflight draining procedures required by AD 92–13–04 are not adequate in eliminating water from the fuel on the applicable Piper Models PA23–150 and PA23–160 airplanes, and external fuel ramps should be installed on these airplanes;
- External fuel ramps should be installed on certain Piper Models PA23, PA23–235, and PA23–250 airplanes in order to eliminate water in the fuel;
- External fuel ramps should be installed on any affected airplane with a dual fuel drain kit, part number (P/N) 765–363, installed in accordance with Piper SB 827A, dated November 4, 1988;
- Any affected airplane with Piper Fuel Tank Wedge Kit, part number 599–367, incorporated in accordance with Piper SB 932A, dated August 30, 1990, should not have external fuel ramps installed until the fuel tank is replaced; and
- AD action should be taken to require the installation of these external fuel ramps in accordance with the instructions in FFC Engineering Specification 2810–002, Revision A, dated March 21, 1995.

Since an unsafe condition has been identified that is likely to exist or develop in other Piper Models PA23, PA23–150, PA23–160, PA23–235, and PA23–250 airplanes of the same type design, the proposed AD would supersede AD 92–13–04, Amendment 39–8274, with a new AD that would:

- Retain the preflight draining procedures required by AD 92–13–04 to require incorporating pilots' operating handbook (POH) revisions for Piper Models PA23, PA23–150, and PA23–160 airplanes that are not equipped with a dual fuel drain kit, part number (P/N) 765–363 (unless already accomplished). The POH revisions are included in Piper SB No. 827A, dated November 4, 1988;
- Require installing external fuel ramp assemblies on all the affected airplanes in accordance with FFC Engineering Specification 2810–002, Revision A, dated March 21, 1995; and
- Delay the compliance time for airplanes with Piper Fuel Tank Wedge Kit, part number 599–367, incorporated in accordance with Piper SB 932A, dated August 30, 1990, until a new fuel tank is installed.

The FAA estimates that 6,973 airplanes in the U.S. registry would be affected by the proposed installation, that it would take approximately 6 workhours per airplane to accomplish the proposed action, and that the average labor rate is approximately $60 an hour. Parts cost approximately $280 per airplane ($140 per tank X 2 tanks per airplane). Based on these figures, the total cost impact of the proposed AD on U.S. operators is estimated to be $4,462,720. This figure is based on the assumption that no affected airplane owner/operator has installed external fuel ramps. No fuel ramps have been distributed to the owners/operators of the affected airplanes.

In addition, incorporating the POH revisions as proposed would be required for approximately 2,046 airplanes in the U.S. registry. Since an owner/operator who holds a private pilot's certificate as authorized by sections 43.7 and 43.11 of the Federal Aviation Regulations (14 CFR 43.7 and 43.11) can accomplish this proposed action, the only cost impact upon the public is the time it takes to incorporate these POH revisions.

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

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

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Safety.

The Proposed Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

Authority: 49 USC 106(g), 40101, 40113, 44701.

§ 39.13 [Amended]

2. Section 39.13 is amended by removing Airworthiness Directive (AD) 92–13–04, Amendment 39–8274 (57 FR 24938; June 12, 1992), and by adding a new AD to read as follows:

The New Piper Aircraft, Inc.: Docket No. 95–CE–35–AD; Supersedes AD 92–13–04, Amendment 39–8274.

Applicability: The following model and serial number airplanes, certificated in any category:

Models	Serial No.
PA23, PA23–150, and PA23–160.	23–1 through 23–2046.
PA23–235.	27–505 through 27–622.
PA23–250.	27–1 through 27–7405476 and 26–7554001 through 27–8154030.

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

Compliance: Required with whichever of the following is applicable:

- For airplanes that do not have Piper Fuel Tank Wedge Kit, part number 599–367, incorporated in accordance with Piper Service Bulletin (SB) 932A, dated August 30, 1990: Within the next 100 hours time-in-service after the effective date of this AD, unless already accomplished; or
- For airplanes that do have Piper Fuel Tank Wedge Kit, part number 599–367, incorporated in accordance with Piper SB 932A, dated August 30, 1990: Upon installation of a new fuel tank, unless already accomplished.

To prevent water in the fuel tanks, which could result in rough engine operation or complete loss of engine power, accomplish the following:

(a) For all of the affected model and serial number airplanes, install external fuel ramps in accordance with the ACCOMPLISHMENT INSTRUCTIONS section of Floats and Fuel Cells (FFC) Engineering Specification 2810–002, Revision A, dated March 21, 1995.

(b) For all of the affected Models PA23, PA23–150, and PA23–160 airplanes that do not have a dual fuel drain kit, part number (P/N) 765–363, installed in accordance with Piper SB 827A, dated November 4, 1988, incorporate, into the Owners Handbook and Pilots' Operating Handbook, paragraphs 1 through 5 of the *Aircraft Systems Operating Instructions* that are contained in Part I of Piper SB 827A, unless already accomplished (compliance with superseded AD 92–13–04).

Note 2: Paragraphs 6 and 7 of the Handling and Servicing instructions that are contained in Part I of Piper SB No. 827A, dated November 4, 1988, are covered by AD 88–21–07 R1.

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

(d) An alternative method of compliance or adjustment of the compliance time that provides an equivalent level of safety may be approved by the Manager, Atlanta Aircraft Certification Office (ACO), Campus Building, 1701 Columbia Avenue, suite 2–160, College Park, Georgia 30337–2748. The request shall be forwarded through an appropriate FAA Maintenance Inspector, who may add comments and then send it to the Manager, Atlanta ACO.

Note 3: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the Aircraft Certification Office.

(e) All persons affected by this directive may obtain copies of the Engineering Specification 2810–002, Revision A, dated March 21, 1995, upon request to Floats & Fuel Cells, 4010 Pilot Drive, suite 3, Memphis, Tennessee 38118. Piper SB No. 827A, dated November 4, 1988, may be obtained upon request from the Piper Aircraft Corporation, Customer Services, 2926 Piper Drive, Vero Beach, Florida 32960. These documents may be examined at the FAA, Central Region, Office of the Assistant Chief Counsel, Room 1558, 601 E. 12th Street, Kansas City, Missouri 64106.

(f) This amendment supersedes AD 92–13–04, Amendment 39–8274.

Issued in Kansas City, Missouri, on September 13, 1995.

Gerald W. Pierce,

Acting Manager, Small Airplane Directorate, Aircraft Certification Service.

[FR Doc. 95–23215 Filed 9–18–95; 8:45 am]

BILLING CODE 4910–13–U

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 70

[AD–FRL–5298–1]

Clean Air Act Proposed Disapproval of Operating Permits Program; Commonwealth of Virginia

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed disapproval.

SUMMARY: EPA is proposing to disapprove the Commonwealth of Virginia's Operating Permits Program, which Virginia submitted in response to Federal requirements that States adopt programs providing for the issuance of operating permits to all major stationary sources and to certain other sources. EPA is proposing disapproval of Virginia's submittal because Virginia's program does not afford all persons who are entitled to seek judicial review of operating permits with the legal standing to obtain such review, does not assure that all sources required by the Clean Air Act (CAA) to obtain Title V permits will be required to obtain such permits, and does not contain an adequate provision for collection of Title V program fees.

DATES: Comments on this proposed action must be received in writing by October 19, 1995.

ADDRESSES: Comments should be submitted to Ray Chalmers, USEPA Region III; Air, Radiation, & Toxics Division; 841 Chestnut Building; Philadelphia, PA 19107.

Copies of the State's submittal and other supporting information used in developing the proposed disapproval are available for inspection during normal business hours at the following location: U.S. EPA Region III; Air, Radiation, & Toxics Division; 841 Chestnut Building; Philadelphia, PA 19107.

FOR FURTHER INFORMATION CONTACT: Ray Chalmers, 3AT23; U.S. EPA Region III; Air, Radiation, & Toxics Division; 841 Chestnut Building; Philadelphia, PA 19107. (215) 597–9844.

SUPPLEMENTARY INFORMATION:

I. Introduction

Title V of the CAA, 42 U.S.C. §§ 7661–7611f, requires that States develop programs for issuing operating permits to all major stationary sources and to certain other sources, that they submit those programs to EPA by November 15, 1993, and that EPA approve or disapprove each program within 1 year after receiving the submittal. The EPA's program review occurs pursuant to section 502 of the CAA and regulations promulgated at 40 Code of Federal Regulations (CFR) Part 70. The regulations promulgated at 40 CFR Part 70 define the minimum elements of an approvable State operating permits program and the corresponding standards and procedures by which the EPA will approve or disapprove and oversee implementation of State operating permits programs (see 57 FR 32250 (July 21, 1992)). Where a program substantially, but not fully, meets the requirements of section 502 of the CAA or of Part 70, EPA may grant the program interim approval for a period of up to 2 years. If EPA has not fully approved a program by 2 years after the November 15, 1993 date, or by the end of an interim program, it must establish and implement a Federal program.

Due in part to pending litigation over several aspects of the Part 70 rule promulgated on July 21, 1992, Part 70 is in the process of being revised. When the final revisions to Part 70 are promulgated, the requirements of the revised Part 70 will define EPA's criteria for the minimum elements of an approvable State operating permits program and the corresponding standards and procedures by which EPA will review State operating permits program submittals. Until the date on which the revisions to Part 70 are promulgated, the currently effective July 21, 1992 version of Part 70 shall be used as the basis for EPA review.

Virginia submitted a Title V program to EPA on November 12, 1993. The submittal included regulations, an Attorney General's opinion, a program description, permitting program documentation, and other required elements. On January 14, 1994, Virginia submitted a supplemental letter pertaining to enhanced monitoring. In a Federal Register notice published December 5, 1994 (59 Fed. Reg. 62324), EPA disapproved this program.[1] On January 9, 1995, Virginia submitted revised regulations and a revised Attorney General's opinion as amendments to its original program, and asked that EPA approve the revised program. On January 17, 1995, Virginia submitted an additional copy of the revised regulations (the version published in the Virginia Register). On April 18, 1995, EPA found Virginia's January 9, 1995 submittal to be administratively complete, pursuant to 40 CFR 70.4(e)(1). Finally, on May 17, 1995, Virginia again amended its program by submitting revised statutory language and an amended Attorney General's opinion.

The analysis contained in this document focuses on the major corrections required in Virginia's operating permit program submittals to enable Virginia's program to meet the minimum requirements of 40 CFR Part 70 and the CAA. The full program submittal, the Technical Support Document (TSD), providing additional analysis of Virginia's submittal, and other relevant materials providing more detailed information are available as part of the public docket.

II. Analysis of State Submittal

A. Statutes, Regulations and Program Implementation

Virginia's operating program submittal does not substantially meet the requirements of the CAA and of the implementing regulations at 40 CFR Part 70 because it: (1) Does not adequately afford persons the opportunity to seek judicial review of final permit decisions; (2) does not assure that all sources required by the CAA to obtain Title V permits will be required to obtain such permits; and (3) does not contain an adequate provision for collection of Title V program fees. These issues are discussed below, and in the TSD. In addition, this notice and the TSD specify other deficiencies which must be corrected before EPA can grant full approval to Virginia's operating permits program.

[1] The Commonwealth of Virginia filed an appeal of this rulemaking in the United States Court of Appeals for the Fourth Circuit (Case No. 95–1052).

1. Standing for Judicial Review

EPA is proposing to disapprove Virginia's Title V program because it does not adequately provide interested parties with adequate standing to obtain judicial review of final Title V permit decisions. As described in the December 5, 1994 final disapproval notice, EPA interprets section 502(b)(6) of the CAA and 40 CFR 70.4(b)(3)(x) as requiring that approvable Title V permit programs provide any party who participated in the public comment process on a permit action and who meets the threshold standing requirements of Article III of the U.S. Constitution with the opportunity to obtain judicial review of an operating permit in State court. (See 59 FR 62325). The Commonwealth's January 9, 1995, submittal did not correct the previously identified deficiency in Virginia's standing provisions. In particular, Virginia did not amend the standing provisions of Section 10.1–1318(B) of the Code of Virginia. Those provisions continue to extend the right to seek judicial review only to persons who have suffered an ''actual, threatened, or imminent injury * * *'' where ''such injury is an invasion of an immediate, legally protected, pecuniary and substantial interest which is concrete and particularized * * *'' Virginia's statute does not enable a party who meets the minimum threshold standing requirements of Article III of the U.S. Constitution to obtain access to Virginia's court system and therefore it fails to meet the minimum requirements for providing an opportunity for judicial review as required by section 502(b)(6) of the CAA and 40 CFR 70.4(b)(3)(x).

The Commonwealth's Attorney General has questioned the validity of EPA's interpretation of section 502(b)(6) of the CAA and, if that interpretation is valid, of the constitutionality of the CAA. EPA believes that its interpretation of section 502(b)(6) of the CAA is reasonable and is supported by the language of the CAA, its legislative history, and the goals Congress sought to achieve under Title V of the CAA. In addition, EPA believes that Title V of CAA and its related sanctions provisions do not violate the U.S. Constitution. (See 59 FR 62325–62327).

EPA must disapprove Virginia's program and cannot merely grant it interim approval on this issue because this deficiency is so significant that it prevents the entire program from substantially meeting the requirements of 40 CFR Part 70. If Virginia is permitted to narrowly preclude public commenters from exercising judicial review rights, one of the chief incentives for permit decision makers to fully consider public comments would be significantly reduced and the public comments process would thereby be rendered less meaningful. The guiding principle that EPA considers in all evaluations of approvability of interim programs is whether the proposed program can ensure the issuance of good permits. Only after a permit program is found to substantially meet the requirements of Part 70 can the criteria in 40 CFR § 70.4(d)(3) be applied to determine if the program is eligible for interim approval.

EPA cannot approve Virginia's operating permit program until Virginia amends *Va. Code* § 10.1–1318(B) to correct this deficiency.

2. Applicability Under the Operating Permits Program

EPA is also proposing to disapprove Virginia's submittal because it does not ensure the applicability of the Title V operating permit program to all sources subject to the program under 40 CFR 70.3. Virginia's regulations provide that the operating permit program applies to sources subject to certain listed air pollution control requirements. (See § 120–08–0501 and § 120–08–0601.) In these applicability sections the Commonwealth should have listed all the CAA requirements which trigger Title V applicability, as they are set forth at 40 CFR 70.3. Instead, Virginia lists, in several cases, its own air pollution control regulations, in which Virginia incorporates federal CAA § 111 and § 112 requirements. Virginia states in Rule 8–5, § 120–08–0501, and in Rule 8–6, § 120–08–0601, that sources are subject to its operating permits rule if they are subject to Virginia's regulatory provisions of Parts IV, V and VI as adopted pursuant to sections 111 and 112 of the CAA. To meet the requirements of 40 CFR 70.3, Virginia must revise § 120–08–0501 and § 120–08–0601 to state that sources are subject to the operating permits rule if they are subject to a standard, limitation or other requirement under sections 111 or 112 of the CAA.

EPA cannot approve Virginia's operating permit program until Virginia corrects the deficiencies discussed above.

3. Permit Fee Demonstration

EPA is also proposing to disapprove Virginia's submittal because it does not contain an adequate permit fee demonstration. Virginia's Rule 8–6, entitled ''Permit Program Fees for Stationary Sources,'' includes a formula to be used for calculating permit fees. Under this formula a base year fee

amount is to be increased each year by the amount of inflation as measured by the consumer price index for all urban consumers. This part of the formula meets the permit fee requirements of 40 CFR § 70.9.

However, in the formula Virginia defines the base year amount not as $25, which is the minimum required for EPA to presume a State fee to be adequate, as specified under 40 CFR § 70.9, but rather as ''the base year amount specified in § 10.1–1322(B) of the Virginia Air Pollution Control Law, expressed in dollars per ton.'' Section 10.1–1322(B) does not define a certain base year fee, but states only that ''The annual permit program fees shall not exceed a base year amount of twenty-five dollars per ton using 1990 as the base year, and shall be adjusted annually by the Consumer Price Index as described in § 502 of the federal Clean Air Act.'' For Virginia's program to be approvable, the fee assessment formula in Virginia Rule 8–6 must be revised to specify a base year fee amount of $25 per ton, with a base year of 1989 adjusted for inflation, as provided for under 40 CFR § 70.9. Also, § 10.1–1322(B) should be changed to specify a base year of 1989.

Virginia Rule 8–6 also includes a provision, in §§ 120–08–0604.D. and E., which allows Virginia to assess a fee of less than $25 per ton (1989 dollars) adjusted for inflation, if Virginia determines that it would collect more money than required to fund its Title V program if it assessed the full $25 per ton fee (1989 dollars), adjusted for inflation. If Virginia chooses in the future to collect a fee of less than $25 (1989 dollars), adjusted for inflation, its fee assessment would no longer meet the requirement for presumed adequacy under 40 CFR § 70.9. Accordingly, Virginia would trigger the requirements under 40 CFR § 70.9(b)(5) that it provide EPA with a detailed accounting that its fee schedule meets the requirements of 40 CFR § 70.9(b)(1).

Before the Commonwealth assesses a fee lower than the presumptive minimum of § 25 per ton (1989 dollars), adjusted for inflation, it must obtain EPA approval of such a fee. EPA would approve such a fee if Virginia submitted a detailed accounting showing that the fee would result in the collection of sufficient funds to run a fully adequate Title V program. This requirement for EPA approval of any fee lower than the presumptive minimum is consistent with the requirements of 40 CFR § 70.9, and is implied by § 120–08–0604.D. which states that ''Any adjustments made to the annual permit program fee shall be made within the constraints of 40 CFR § 70.9.''

4. Insignificant Activities

Section 70.4(b)(2) requires States to include in their operating programs any criteria used to determine insignificant activities or emission levels for the purposes of determining complete applications. Section 70.5(c) provides that an application for a Part 70 permit may not omit information needed to determine the applicability of, or to impose, any applicable requirement, or to evaluate appropriate fee amounts. Section 70.5(c) further states that EPA may approve, as part of a State program, a list of insignificant activities and emissions levels which need not be included in permit applications. Under Part 70, a State may approve as part of that State's program any activity or emission level that the State wishes to consider insignificant. Part 70, however, does not establish specific emission levels for insignificant activities, relying instead on a case-by-case determination of appropriate levels based on the particular circumstances of the Part 70 program under review.

In Appendix W of Rules 8–5 and 8–6 Virginia defines various specified types of emission units as insignificant for purposes of Title V permitting, and states that these units are not required to be identified in Title V applications. The Appendix also states that other unspecified types of units can be considered insignificant if their emissions or their size or production rate are below certain levels. These units must be listed in Title V applications, and their emissions, size, or production rate must be given, whichever is relevant, but no additional information must be supplied regarding them.

EPA has several concerns regarding Virginia's classifications of insignificant sources. One overall concern is that under Virginia Rule 8–5 and Appendix W the determination of whether or not a source is subject to the operating permit program can be done without taking into account emissions from units considered to be insignificant. If the total emissions from units subject to Title V requirements were just below the level which would trigger Title V program applicability, failure to take into account additional emissions from units which are exempt could result in a source avoiding Title V requirements when it should be subject to those requirements. EPA recommends that Virginia correct this deficiency by modifying the statements found in § 120–08–505D(1)(a)(2) and in Appendix W(I)(A)(4), which require that ''the emissions from any emissions unit shall be included in the permit application if the omission of those emission units from the application would interfere with the determination or imposition of any applicable requirement or the calculation of permit fees.'' The last portion of this statement should be modified to state ''if the omission of those emission units would interfere with the determination of Title V applicability, the determination or imposition of an applicable requirement, or the calculation of permit fees.''

EPA is also concerned that when Virginia defined emissions units as insignificant based on their emissions levels, Virginia used emissions levels which are too high. Specifically, EPA is concerned that Virginia defined as insignificant all emissions units with uncontrolled emissions of less than 10 tons per year of nitrogen dioxide, sulfur dioxide, and total suspended particulates or particulate matter (PM10), less than seven tons per year of volatile organic compounds, and less than 100 tons per year of carbon monoxide. Virginia defines ''uncontrolled emissions'' as emissions from a source when operating at maximum capacity without air pollution control equipment. Insignificant activity thresholds that are considered to be ''sound'' by EPA would fall in the range of 1 to 2 tons per year for criteria pollutants. EPA is also concerned that Virginia defined as insignificant all other pollutant emission sources (many of them hazardous emission sources) with emissions less than the section 112(g) de minimis levels set forth at 40 CFR § 63.44 or the accidental release threshold levels found at 40 CFR § 68.130. These levels are appropriate in many cases, but are too high in others. Accordingly, EPA believes that Virginia should modify this provision to indicate that sources emitting other air pollutants are considered insignificant if their emissions are below the lesser of the § 112(g) threshold levels set forth at 40 CFR § 63.44, the accidental release thresholds set forth at 40 CFR § 68.130, or 1000 pounds per year. EPA believes that the above criteria and other pollutant emission levels are sufficiently below the applicability thresholds for many applicable requirements to assure that no unit potentially subject to an applicable requirement would be omitted from a Title V application.

EPA is concerned that Virginia did not provide EPA with sufficient information to properly evaluate whether or not all of the activities

which Virginia included on its list of insignificant activities are appropriate. Of key importance to EPA in reviewing such lists is that no source subject to an applicable federal requirement should be included on the list, pursuant to 40 CFR § 70.5. Virginia did not provide a demonstration that the activities it listed are not likely to be subject to such requirements. Also important in reviewing such lists is that the emissions from the activities listed be truly insignificant, and Virginia did not provide EPA with information on the likely emissions of the activities listed. However, it is clear that Virginia has incorrectly listed as insignificant both ''comfort air conditioning'' and ''refrigeration systems,'' which are subject to stratospheric ozone protection requirements established by Title VI of the CAA. Virginia should remove both comfort air conditioning and refrigeration systems from the insignificant activities list.

EPA cannot fully approve Virginia's operating permit program until Virginia corrects the deficiencies discussed above.

5. Variance Provision

While not a disapproval issue, it should be noted that Virginia has the authority to issue a variance from requirements imposed by Virginia law. The variance provision at *Va. Code* § 10.1–1307.C. empowers the Air Pollution Control Board, after a public hearing, to grant a local variance from any regulation adopted by the board. EPA regards this provision as wholly external to the program submitted for approval under Part 70, and consequently is proposing to take no action on this provision of Virginia law. EPA has no authority to approve provisions of State law, such as the variance provision referred to, which are inconsistent with the CAA. EPA does not recognize the ability of a permitting authority to grant relief from the duty to comply with a federally enforceable permit, except where such relief is consistent with the applicable requirements of the CAA and is granted through procedures allowed by Part 70. EPA reserves the right to enforce the terms of the permit where the permitting authority purports to grant relief from the duty to comply with a permit in a manner inconsistent with the CAA and Part 70 procedures.

B. Provisions Implementing Other CAA Requirements

1. Authority and Commitments for Section 112 Implementation

Virginia requested that EPA grant Virginia ''delegation of authority upon approval of the operating permit program for all Section 112 programs except Section 112(r), prevention of accidental releases.'' Because EPA is disapproving Virginia's Title V submittal, Virginia's request for delegation has not been triggered.

Virginia demonstrated that it has in Va. Code § 10.1–1322.A. and Rule 8–5 the broad legal authority to incorporate into permits and to enforce most applicable CAA section 112 requirements. However, Virginia also indicated that it may require additional authority to conduct certain specific section 112 activities. Virginia supplemented its broad legal authority with a commitment to ''develop the state regulatory provisions as necessary to carry out these programs and the responsibilities under the delegation after approval of the operating permit program and EPA has issued the prerequisite guidance for development of these title III programs.'' Also, Virginia has the authority under § 120–08–0505.K. to require that an applicant state that the source has complied with CAA § 112(r) or state in the compliance plan that the source intends to comply and has set a schedule to do so.

EPA had until recently interpreted the CAA as requiring sources to comply with section 112(g) beginning on the date of approval of a Title V program regardless of whether or not EPA had completed its section 112(g) rulemaking. EPA has since revised this interpretation of the CAA as described in a February 14, 1995 Federal Register notice (see 60 FR 83333). The revised interpretation postpones the effective date of section 112(g) until after EPA has promulgated a rule addressing that provision. The rationale for the revised interpretation is set forth in detail in the February 14, 1995 interpretive notice.

The section 112(g) interpretive notice explains that EPA is still considering whether the effective date of section 112(g) should be delayed beyond the date of promulgation of the federal rule to allow States time to adopt rules implementing the federal rule, and that EPA will provide for any such additional delay in the final section 112(g) rulemaking. Unless and until EPA provides for such an additional postponement of section 112(g), Virginia would be required, if it were delegated authority to implement section 112(g), to be able to implement section 112(g) during the transition period between promulgation of the federal section 112(g) rule and adoption of implementing Virginia regulations.

2. Acid Rain Provisions

Virginia's program does not contain all provisions required relating to acid rain sources, but Virginia has committed to submit the required provisions shortly, and EPA find Virginia's commitment acceptable. Virginia's program properly requires ''affected sources'' to obtain operating permits, and Virginia defines an ''affected source'' as a source containing one or more ''affected units,'' which are themselves defined as ''a unit subject to any acid rain emissions reduction requirement or acid rain emissions limitation under 40 CFR Parts 72, 73, 75, 76, 77, or 78.'' However, Virginia has not defined as an ''applicable requirement'' any of these acid rain emissions reduction requirements or limitations. Therefore, Virginia's operating permits would not be required to include any of these requirements.

Virginia is aware of this deficiency and has committed to correct it. In Virginia's operating permits program submittal of January 9, 1995, Virginia committed to adopting an acid rain regulation by the latter half of 1995. Virginia stated that under this regulation it would issue acid rain sources operating permits which would include all requirements of the acid rain program. In a statement included in that submittal, Virginia's Attorney General also committed to provide EPA, when Virginia submits its acid rain regulation, with the required legal opinion regarding Virginia's legal authority to carry out the acid rain portion of the operating permits program.

III. Proposed Action and Implications

The EPA is proposing to disapprove the operating permits program contained in submittals from Virginia dated November 12, 1993, January 14, 1994, January 9, 1995, January 17, 1995, and May 17, 1995. If promulgated, this disapproval would constitute a disapproval under section 502(d) of the CAA (see generally 57 FR 32253–54). As provided under section 502(d)(1) of the CAA, Virginia would have up to 180 days from the date of EPA's notification of disapproval to the Governor to revise and resubmit the program.

If EPA finalizes this proposed disapproval, Virginia may become subject to sanctions under the CAA. Pursuant to section 502(d)(2)(A) of the CAA, EPA may, at its discretion, apply any of the sanctions in section 179(b) at any time following the effective date of

a final disapproval. The available sanctions include a prohibition on the approval by the Secretary of Transportation of certain highway projects or the awarding of certain federal highway funding, and a requirement that new or modified stationary sources or emissions units for which a permit is required under Part D of Title I of the CAA achieve an emissions reductions-to-increases ratio of at least 2-to-1. In addition, EPA is required by section 502(d)(2)(B) of the CAA to apply one of the sanctions in section 179(b), as selected by the Administrator, on the date 18 months after the effective date of a final disapproval, unless prior to that date Virginia has submitted a revised operating permits program and EPA has determined that it corrects the deficiencies that prompted the final disapproval. Moreover, if the Administrator finds a lack of good faith on the part of Virginia, both sanctions shall apply after the expiration of the 18-month period until the Administrator determines that Virginia has come into compliance. In all cases, if, six months after EPA applies the first sanction, Virginia has not submitted a revised program that EPA has determined corrects the disapproved program's deficiencies, a second sanction is required. Finally, if EPA has not granted full approval to Virginia's program by November 15, 1995, and Virginia's program at that point does not have interim approval status, EPA must promulgate, administer and enforce a Federal permits program for Virginia on that date.

EPA first disapproved Virginia's operating permits program in a Federal Register notice published on December 5, 1994, which became effective on January 5, 1995. As a result, EPA's authority to apply discretionary sanctions to Virginia arose on January 5, 1995, and the 18-month period before which EPA is required to apply sanctions also began on that date.

Consequently, following today's proposed disapproval EPA continues to have the authority to apply discretionary sanctions to Virginia and will be required to apply sanctions on July 5, 1996, unless by that date EPA determines Virginia has corrected each of the deficiencies that prompted EPA's original disapproval. Moreover, if today's proposed disapproval is finalized, EPA would be required to apply sanctions 18 months after the effective date of such action, unless by that date EPA determines Virginia has corrected each of the deficiencies that prompted EPA's disapproval and that were not the subject of the original final disapproval action.

IV. Proposed Action

EPA is proposing to disapprove the submittals made on January 9, 1995 and May 17, 1995 by the Commonwealth of Virginia to satisfy the requirements for the operating permits program required by Title V of the Clean Air Act for the reasons outlined in this notice.

V. Administrative Requirements

A. Request for Public Comments

The EPA is requesting comments on all aspects of this proposed disapproval. Copies of the State's submittal and other information relied upon for the proposed disapproval are contained in a docket maintained at the EPA Regional Office. The docket is an organized and complete file of all the information submitted to, or otherwise considered by, EPA in the development of this proposed disapproval. The principal purposes of the docket are: (1) To allow interested parties a means to identify and locate documents so that they can effectively participate in the disapproval process; and (2) to serve as the record in case of judicial review. The EPA will consider any comments received by October 19, 1995.

B. Executive Order 12866

The Office of Management and Budget has exempted this action from Executive Order 12866 review.

C. Regulatory Flexibility Act

The EPA's actions under section 502 of the CAA do not create any new requirements, but simply address operating permits programs submitted to satisfy the requirements of 40 CFR Part 70. Because this action does not impose any new requirements, it does not have a significant impact on a substantial number of small entities.

D. Federal Mandates

Under Section 202 of the Unfunded Mandates Reform Act of 1995 (''Unfunded Mandates Act''), signed into law on March 22, 1995, EPA must prepare a budgetary impact statement to accompany any proposed or final action that includes a Federal mandate that may result in estimated costs to State, local, or tribal governments in the aggregate; or to the private sector, of $100 million or more. Under section 205, EPA must consider the most cost-effective and least burdensome alternative that achieves the objectives of the rule and is consistent with statutory requirements. Section 203 requires EPA to establish a plan for informing and advising any small governments that may be significantly or uniquely impacted by the rule. EPA has determined that this proposed disapproval action of Virginia's Title V Operating Permits Program does not include a Federal mandate that may result in estimated costs of $100 million or more to either State, local, or tribal governments in the aggregate, or to the private sector. This Federal action disapproves pre-existing requirements under State or local law, and imposes no new Federal requirements. Accordingly, no additional costs to State, local, or tribal governments, or to the private sector, result from this action.

List of Subjects in 40 CFR Part 70

Environmental protection, Administrative practice and procedure, Air pollution control, Intergovernmental relations, Operating permits, and Reporting and recordkeeping requirements.

Authority: 42 U.S.C. 7401–7671q.

Dated: September 8, 1995.

W. Michael McCabe,

Regional Administrator, Region III.

[FR Doc. 95–23204 Filed 9–18–95; 8:45 am]

BILLING CODE 6560–50–P

---

40 CFR Part 81

[AD–FRL–5297–9]

Clean Air Act Reclassification; Pennsylvania—Liberty Borough Nonattainment Area; PM–10

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA is proposing to find that the Liberty Borough, Pennsylvania nonattainment area has not attained national ambient air quality standards (NAAQS) for particulate matter of nominal aerodynamic diameter smaller than 10 micrometers (PM–10) by the Clean Air Act (the Act) mandated attainment date for moderate nonattainment areas. The Act established an attainment date of no later than December 31, 1994 for areas classified as moderate nonattainment areas. This proposed finding is based on monitored air quality data for the PM–10 NAAQS during the years 1992–94. EPA is soliciting public comment on all relevant matters associated with this proposed action, including comment as to whether there are any mitigating facts or extenuating circumstances that it should consider in its review of the monitoring data used to propose to find that the area has not achieved the

NAAQS. All comments and information submitted, in writing, at the address and within the time frame specified below will be fully considered by EPA in determining its final action.

DATES: Comments must be received on or before October 19, 1995.

ADDRESSES: Comments may be mailed to Marcia L. Spink, Associate Director, Air Programs, Mailcode 3AT00, U.S. Environmental Protection Agency, Region III, 841 Chestnut Building, Philadelphia, Pennsylvania 19107. Copies of the documents relevant to this action are available for public inspection during normal business hours at the Air, Radiation, and Toxics Division, U.S. Environmental Protection Agency, Region III, 841 Chestnut Building, Philadelphia, Pennsylvania 19107 and at the Allegheny County Health Department, Bureau of Environmental Quality, Division of Air Quality, 301 39th Street, Pittsburgh, Pennsylvania 15201.

FOR FURTHER INFORMATION CONTACT: Thomas A. Casey, U.S. EPA Region III, (215) 597–2746.

SUPPLEMENTARY INFORMATION:

I. Background

A. Health and Welfare Effects of Particulate Matter

Based on studies of human populations exposed to high concentrations of particles (at times in the presence of SO_2) and laboratory studies of animals and humans, there are major human health concerns associated with particulate matter. These include deleterious effects on breathing and respiratory systems, aggravation of existing respiratory and cardiovascular disease, alterations in the body's immune systems against foreign materials, damage to lung tissue, carcinogenesis, and premature death. The major subgroups of the population that appear to be most sensitive to the effects of particulate matter include individuals with chronic obstructive pulmonary or cardiovascular disease, those with influenza, asthmatics, the elderly, and children. Particulate matter also soils and damages materials, and fine particles are a major cause of visibility impairment in the United States.[1]

B. Clean Air Act Requirements Concerning Designation and Classification

On November 15, 1990, the date of enactment of the 1990 Clean Air Act Amendments, PM–10 areas meeting the criteria of section 107(d)(4)(B) of the Act were designated nonattainment by operation of law. Once an area is designated nonattainment, section 188 of the Act outlines the process for classification of the area and establishes the area's attainment date. Pursuant to section 188(a), all PM–10 nonattainment areas were initially classified as moderate by operation of law upon designation as nonattainment. These nonattainment designations and moderate area classifications were codified in 40 CFR Part 81 on November 6, 1991 (56 FR 56694).

C. Clean Air Act's Requirements for Moderate PM–10 Nonattainment Areas

States containing areas which were designated as moderate nonattainment by operation of law under section 107(d)(4)(B) were to develop and submit State Implementation Plans (SIPs) to provide for the attainment of the PM–10 NAAQS. Those SIPs were to include the adoption and implementation of PM–10 reduction requirements which constitute reasonably available control measures, (RACM), including reasonably available control technology (RACT). Pursuant to section 189(a)(2) of the Act, those SIP revisions were to be submitted to EPA by November 15, 1991. The Commonwealth of Pennsylvania submitted this SIP revision (developed and adopted by the Allegheny County Health Department) on January 11, 1994. On April 11, 1995 (60 FR 18385), in a rulemaking separate from today's action, EPA proposed approval of the Commonwealth's SIP revision for the Liberty Borough moderate PM–10 nonattainment area. EPA received numerous comments on its proposed action, some in support and some in opposition, and has yet to take final action on that SIP revision.

D. Reclassification to Serious Nonattainment

EPA has the responsibility, pursuant to sections 179(c) and 188(b)(2) of the Act, of determining within 6 months of the applicable attainment date, whether PM–10 nonattainment areas have attained the NAAQS. Section 179(c)(1) of the Act provides that these determinations are to be based upon an area's ''air quality as of the attainment date'', and section 188(b)(2) is consistent with this requirement. EPA makes the determination of whether an area's air quality is meeting the PM–10 NAAQS based upon air quality data gathered at monitoring sites in the nonattainment area and entered into the Aerometric Information Retrieval System (AIRS). These data are reviewed to determine the area's air quality status in accordance with 40 CFR Part 50, Appendix K.

Pursuant to Appendix K, attainment of the annual PM–10 standard is achieved when the expected annual arithmetic mean PM–10 concentration is equal to or less than 50 micrograms per cubic meter ($\mu g/m^3$). Attainment of the 24-hour standard is determined by calculating the expected number of exceedances of the 150 $\mu g/m^3$ limit per year. The 24-hour standard is attained when the expected number of exceedances is 1.0 or less. A total of 3 consecutive years of non-violating air quality data is generally necessary to show attainment of the 24-hour and annual standards for PM–10. A complete year of air quality data, as defined in 40 CFR Part 50, Appendix K, is comprised of all 4 calendar quarters with each quarter containing data from at least 75 percent of the scheduled sampling days.[2]

Under section 188(b)(2)(A), a moderate PM–10 nonattainment area is reclassified as serious by operation of law if the Administrator finds that the area has failed to attain the NAAQS by the statutory attainment date. Pursuant to section 188(b)(2)(B) of the Act, EPA must publish a notice in the Federal Register identifying those areas that failed to attain the standard and the resulting reclassifications. EPA is fulfilling its responsibility for this requirement via the federal rulemaking process initiated by today's action.

E. Clean Air Act's Requirements for Serious PM–10 Nonattainment Areas

PM–10 nonattainment areas reclassified as serious under section 188(b)(2) of the Act are required to submit, within 18 months of the area's reclassification, SIP revisions providing for, among other things, the adoption and implementation of best available control measures (BACM), including best available control technology (BACT), for PM–10 and PM–10 precursors no later than four years from the date of reclassification. The SIP also must contain a demonstration that its implementation will provide for attainment of the PM–10 NAAQS no later than December 31, 2001. EPA has provided specific guidance on developing serious area PM–10 SIP revisions in an addendum to the General Preamble to Title I of the Clean Air Act. See 59 FR 41998 (August 16, 1994). These requirements are in

[1] Air Quality Criteria for Particulate Matter (External Review Draft), EPA–600/AP–95/001a–c, April 1995 (NTIS #: PB95–22–1727, –1735, –1743).

[2] EPA is currently under court order to review the NAAQS for particulate matter (*American Lung Association* v. *Browner*, No. 93–643 D. Ariz., October 6, 1994).

addition to the moderate PM–10 nonattainment area requirements for RACT/RACM.

II. Rationale for EPA's Proposed Action

By today's action, EPA is proposing to find that the Liberty Borough area did not attain the PM–10 NAAQS by the required attainment date of December 31, 1994. As discussed below, this proposed finding is based upon air quality data which revealed violations of the PM–10 NAAQS during 1992–1994. If EPA takes final action on this proposed finding, the Liberty Borough nonattainment area (comprised of the City of Clairton and the Boroughs of Liberty, Lincoln, Glassport, and Port Vue) located in Allegheny County, Pennsylvania) will be reclassified by operation of law as a serious nonattainment area for PM–10 under section 188(b)(2)(A) of the Act.

A. Ambient Air Monitoring Data

Table 1 lists each of the monitoring sites in the Liberty Borough area where the 24-hour PM–10 NAAQS has been exceeded during 1992–1994 and the concentration, in micrograms per cubic meter, on the day of the exceedance.

TABLE 1

Year and date	Lincoln (high-volume sampler) (μg/m³)	Lincoln (continuous sampler) (μg/m³)	Liberty (high-volume sampler) (μg/m³)
1992:			
1/28	.....	.....	175
12/15	186	.....	.....
1993:			
5/10	167	.....	.....
11/23	223	195	.....
1994:			
2/19	163	.....	.....
3/7	157	.....	.....

The monitors in the nonattainment area that recorded exceedances of the PM–10 NAAQS have operated on varying sampling schedules with varying data capture rates. EPA requires the adjustment of observed exceedances to account for incomplete data pursuant to 40 CFR Part 50 Appendix K. In the case of the Lincoln high-volume sampler, five exceedances of the 24-hour NAAQS were observed from 1992 through 1994.[3] Before adjusting for incomplete sampling, the number of exceedances per year for the three year period would be 1.7. After adjusting for incomplete sampling, the number of expected exceedances of the NAAQS at this site during the three year period was 2.2.

According to 40 CFR Part 50, the 24-hour NAAQS is attained when the expected number of days per calendar year with a 24-hour average concentration above 150 μg/m3 is equal to or less than one. In the simplest case, the number of expected exceedances at a site is determined by recording the number of exceedances in each calendar year, accounting for incomplete data, and then averaging them over the past three calendar years. Therefore from 1992–1994, the number of expected exceedances at the Lincoln high-volume sampler is 2.2. This estimation of expected exceedances indicates that the Lincoln site had not attained the 24-hour PM–10 NAAQS during 1992–1994.

Only one exceedance of the annual NAAQS has been recorded in the Liberty Borough area from 1992–1994. (The Lincoln high-volume sampler recorded a weighted-average concentration of 52.5 μg/m³ in 1994.) No station in the Liberty Borough area recorded an annual average concentration, averaged (as prescribed in Appendix K) from 1992–1994, which exceeded the annual NAAQS.

III. Proposed Action

By today's action, EPA is proposing to find that the Liberty Borough area did not attain the PM–10 NAAQS by December 31, 1994. As discussed above, this proposed finding is based upon air quality data which revealed violations of the PM–10 NAAQS during 1992–1994. If EPA takes final action on this proposed finding, the Liberty Borough nonattainment area will be reclassified by operation of law as a serious nonattainment area for PM–10 under section 188(b)(2)(A) of the Act.

IV. Request for Public Comment

EPA is requesting comment on all aspects of today's proposal, including, but not limited to: The PM–10 control requirements adopted to date by the County and the timing and status of their implementation, the compliance status and history of the sources subject to the PM–10 control requirements, the efforts made to date to meet the requirements, air quality data and trends as they relate to implementation of the control requirements, and weather system occurrances (meteorology). EPA is also soliciting comment as to whether there are any mitigating facts or extenuating circumstances that it should consider in its review of the monitoring data used to propose to find that the area has not achieved the NAAQS, including any relevant comparison of the data collected from the ambient monitors. EPA is soliciting comment as to the relevancy of such information in determining whether the area has achieved the NAAQS.

As indicated earlier in this notice, EPA will consider any comments received, in writing, by October 19, 1995.

V. Executive Order (E.O.) 12866

Under E.O. 12866, 58 FR 51735 (October 4, 1993), EPA is required to determine whether regulatory actions are significant and therefore should be subject to OMB review, economic analysis, and the requirements of the Executive Order. The Executive Order defines a ''significant regulatory action'' as one that is likely to result in a rule that may meet at least one of the four criteria identified in section 3(f), including, under paragraph (1), that the rule may ''have an annual effect on the economy of $100 million or more or adversely affect, in a material way, the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities.''

The Agency has determined that the finding of failure to attain proposed today would result in none of the effects identified in section 3(f). Under section 188(b)(2) of the Act, findings of failure to attain and reclassification of nonattainment areas are based upon air quality considerations and must occur by operation of law in light of certain air quality conditions. They do not, in-and-of-themselves, impose any new requirements on any sectors of the economy. In addition, because the statutory requirements are clearly defined with respect to the differently classified areas, and because those requirements are automatically triggered by classifications that, in turn, are triggered by air quality values, findings of failure to attain and reclassification cannot be said to impose a materially adverse impact on State, local, or tribal governments or communities.

VI. Regulatory Flexibility

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

[3] The Lincoln high volume sampler began operation in the Fall of 1992.

As discussed in section V of this notice, findings of failure to attain and reclassification of nonattainment areas under section 188(b)(2) of the Act do not in-and-of-themselves create any new requirements. Therefore, I certify that today's proposed action does not have a significant impact on small entities.

VII. Unfunded Mandates

Under sections 202, 203 and 205 of the Unfunded Mandates Reform Act of 1995 (Unfunded Mandates Act), signed into law on March 22, 1995, EPA must assess whether various actions undertaken in association with proposed or final regulations include a Federal mandate that may result in estimated costs of $100 million or more to the private sector, or to State, local or tribal governments in the aggregate.

EPA believes, as discussed earlier in section V of this notice, that the proposed finding of failure to attain and reclassification of the Liberty Borough nonattainment area are factual determinations based upon air quality considerations and must occur by operation of law and, hence, do not impose any federal intergovernmental mandate, as defined in section 101 of the Unfunded Mandates Act.

List of Subjects in 40 CFR Part 81

Environmental protection, Air pollution control, Intergovernmental relations, Particulate matter.

Authority: 42 U.S.C. 7401–7671q.

Dated: September 11, 1995.

W. Michael McCabe,

Regional Administrator, Region III.

[FR Doc. 95–23205 Filed 9–18–95; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

42 CFR Parts 441 and 447

[MB–046–P]

RIN 0938–AF42

Medicaid Program; Payment for Covered Outpatient Drugs Under Drug Rebate Agreements With Manufacturers

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

ACTION: Proposed rule.

SUMMARY: This proposed rule would specify requirements for State Medicaid agencies and conditions under which Federal payments would be made under Medicaid for covered outpatient prescription drugs. The rule would also specify the conditions for approval and renewal of rebate agreements with drug manufacturers participating in the Medicaid program.

The proposed rule would interpret sections 1902(a)(54), 1903(i)(10), and 1927 of the Social Security Act, as added by section 4401 of the Omnibus Budget Reconciliation Act of 1990, and amended by section 13602 of the Omnibus Budget Reconciliation Act of 1993, and section 601(b) of the Veterans Health Care Act of 1992. We consider this rule necessary to adequately implement the provisions of section 1927 of the Act.

DATES: Written comments will be considered if we receive them at the appropriate address, as provided in the ''Addresses'' section below, no later than 5:00 p.m. on November 20, 1995.

ADDRESSES: Mail written comments (an original and 3 copies) to the following address: Health Care Financing Administration, Department of Health and Human Services, Attention: MB–046–P, P.O. Box 7518, Baltimore, MD 21207–0518.

If you prefer, you may deliver your written comments (an original and 3 copies) to one of the following addresses: Room 309–G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, D.C., or C5–09–26, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

Due to staffing and resource limitations, we cannot accept comments by facsimile (FAX) transmission. In commenting, please refer to file code MB–046–P. Written comments received timely will be available for public inspection as they are received, beginning approximately 3 weeks after publication of this document, in room 309–G of the Department's offices at 200 Independence Ave., SW., Washington, D.C., on Monday through Friday of each week from 8:30 a.m. to 5:00 p.m. (telephone: (202) 690–7890).

If you wish to submit comments on the information collection requirements contained in this rule, you may submit written comments to: Office of Information and Regulatory Affairs, Attention: Laura Oliven, Office of Management and Budget, Room 3002, New Executive Office Building, Washington, D.C. 20503.

FOR FURTHER INFORMATION CONTACT: Estelle Chisholm, (410) 786–3286.

SUPPLEMENTARY INFORMATION:

I. Background

A. Overview of the Drug Rebate Provisions

Under section 1927 of the Social Security Act (the Act), manufacturers that have entered into a national rebate agreement must provide each State Medicaid program with rebate period payments (or other periodic rebate payments, as determined by the Secretary). The rebate must be calculated in accordance with sections 1927(b) and (c) of the Act, using manufacturing pricing data and State drug utilization information as outlined in the statute.

The requirements concerning rebate agreements apply to drugs dispensed and paid for under Medicaid on or after January 1, 1991. For manufacturers who entered into rebate agreements before March 1, 1991, section 1927(a)(1) of the Act provided for Federal financial participation (FFP) retroactively calculated as if the agreement had been entered into on January 1, 1991. For agreements that are entered into on or after March 1, 1991, Medicaid coverage and FFP begin, as specified in section 1927(a)(1), the first day of the rebate period that begins more than 60 days after the date the agreement is entered into. We are interpreting the term ''entered into'' to mean the date the agreement is postmarked by the U.S. Postal Service or other common mail carrier. We will not consider the date stamped by a postage meter to be a postmark.

Although the statute provides specific deadlines for manufacturers to sign rebate agreements, section 1927(a)(3) of the Act provides, in part, for payment of drugs not covered under rebate agreements if the Secretary determines that in the first calendar quarter of 1991 there were extenuating circumstances. Therefore, in light of the deadlines imposed by the statute for signing the agreement, and in accordance with the extenuating circumstances clause in section 1927(a)(3) of the Act, HCFA extended through April 30, 1991, the deadline for manufacturers to enter into Medicaid rebate agreements that are retroactive to January 1, 1991. Therefore, rebate agreements entered into on or after May 1, 1991, are effective on the first day of the calendar quarter that begins more than 60 days after the date the agreement is entered into.

The statute does not specify whether the drug provisions are applicable in areas other than the 50 States and the District of Columbia. However, in the

legislative history, the Congress specifically noted that the drug rebate provisions ''[r]equire drug manufacturers to comply with the rebate requirements in all States and the District of Columbia.'' (H. R. Conf. Rep. 964, 101st Cong., 2d Sess. 822 (1990).) Therefore, in accordance with our understanding of Congressional intent, we are applying the drug rebate requirements only to the 50 States and the District of Columbia.

Section 1115 of the Act contains provisions for State demonstration projects that are likely to assist in promoting the objectives of certain Federal programs, including the Medicaid program. Specifically, under the authority of section 1115(a)(1), the Secretary may waive compliance with the requirements of section 1902 of the Act for any State that is operating an experimental, pilot or demonstration project. Under section 1115(a)(2), the Secretary may also make payments notwithstanding restrictions under section 1903. In accordance with these provisions, a State operating under a section 1115(a) demonstration project waiver may have the requirements of section 1902(a)(54) of the Act, concerning compliance with applicable requirements of section 1927, waived. In addition to the extent that section 1927 requirements act as conditions under section 1903 for Federal matching funds to such a State, these conditions may be excused.

We note that section 1115(a) does not provide authority to waive or excuse requirements applicable to States other than the waiver State. Thus, there is no authority to waive inclusion of manufacturer sales within a waiver State from the calculation of best price or average manufacturer price applicable to other States.

Section 1927(j) of the Act specifies that the provisions of the drug rebate program do not apply to covered outpatient drugs dispensed by (1) health maintenance organizations (HMOs), including those organizations that contract to provide services to Medicaid recipients under section 1903(m) of the Act; and (2) hospitals that dispense covered outpatient drugs using drug formulary systems and bill the Medicaid program no more than the hospitals' purchasing costs for these drugs as determined under the State plan. Even though HMOs and certain hospitals are exempt from the requirements of the rebate program, section 1927(j) specifically states that its provisions should not be construed as providing that the amounts paid by these organizations should be excluded from the best price calculations. (Section V.B.2.a. of this preamble contains a discussion on best price.)

On February 15, 1991, we made available to drug manufacturers a national rebate agreement developed in response to section 1927 of the Act. Prior to that date, we held extensive discussions with representatives from States and drug manufacturers. These parties reviewed and commented on the proposed language of the national rebate agreement. We also provided information to the public regarding the national drug rebate agreement through a notice with comment period in the Federal Register on February 21, 1991 (56 FR 7049). The February 1991 notice reprinted the text of the national drug rebate agreement. We received a number of timely public comments in response to this notice.

A detailed discussion of the public comments and the Department's responses appear under section X. of this preamble. We have given these public comments full consideration and have incorporated certain provisions in this proposed rule based on that consideration. We are not amending the national rebate agreement at this time. We will amend the national rebate agreement in the future, as necessary, to conform the agreement with the regulations and to take into consideration public comments received on the February 21, 1991, notice that are not addressed in this rule and public comments that we receive on this proposed rule.

This proposed rule would interpret in regulations the amendments made by section 4401 of the Omnibus Budget Reconciliation Act of 1990 (OBRA '90), Public Law 101–508, enacted on November 5, 1990; section 601(b)(1) of the Veterans Health Care Act of 1992 (VHCA), Public Law 102–585, enacted on November 4, 1992; and section 13602 of the Omnibus Budget Reconciliation Act of 1993 (OBRA '93), Public Law 103–66, enacted on August 10, 1993, as discussed below.

B. Changes Made by the Omnibus Budget Reconciliation Act of 1990

Under the Medicaid program, States may provide coverage of prescription drugs as an optional service under section 1905(a)(12) of the Act. Section 1903(a) of the Act provides for FFP in State expenditures for these drugs.

Section 4401 of OBRA '90 added a Medicaid State plan requirement under section 1902(a)(54) of the Act to provide that: (1) if a State elects to cover outpatient prescription drugs, the State plan must provide that any formulary or similar restriction, except as provided in section 1927(d) of the Act, shall permit coverage of covered outpatient drugs of any manufacturer that enters into and complies with a rebate agreement under section 1927 of the Act, if the drugs are prescribed for a medically accepted indication; and (2) the State must comply with certain reporting and other coverage requirements specified in section 1927 of the Act.

Section 4401 of OBRA '90 also redesignated the existing section 1927 of the Act as section 1928 and added a new section 1927. New section 1927 provides that for payment to be made under section 1903 of the Act for covered outpatient drugs, the manufacturer must enter into and have in effect a rebate agreement with the Secretary of the Department of Health and Human Services (HHS) on behalf of the States (except that the Secretary may authorize a State to enter directly into agreements with manufacturers). (Section I.D. of this preamble contains a description of changes to sections 1902(a)(54) and 1927 made by section 13602 of the OBRA '93.)

Section 1927 of the Act specifies the requirements for the rebate agreements with manufacturers of covered outpatient drugs, the terms and length of the agreement, the requirements for States to provide State Medicaid drug utilization information to HCFA and the manufacturers, the requirements for manufacturers to provide pricing information to HCFA, the formulas to be used to determine the amount of the drug rebate, and the limitations on coverage of drugs. Section 1927 of the Act also contains provisions on termination procedures for agreements, and the imposition of civil money penalties on manufacturers that fail to comply with the requirements concerning pricing data submissions.

Section 4401 of OBRA '90 also amended section 1903(i) of the Act by adding a new paragraph (10) to provide for the denial of FFP in expenditures for covered outpatient drugs of a manufacturer dispensed in any State if, except as specified in section 1927(a) of the Act (whereby the Secretary may authorize a State to enter directly into agreements with a manufacturer), the manufacturer does not comply with the rebate requirements specified in section 1927; and, effective January 1, 1993, if the State does not provide for drug use review in accordance with section 1927(g) of the Act. (Section I.D. of this preamble contains a description of changes to section 1903(i)(10) made by section 13602 of OBRA '93.)

C. Changes Made by the Veterans Health Care Act of 1992

The VHCA amended section 1927 of the Social Security Act in several areas. This proposed regulation reflects the self-implementing amendments required under VHCA.

One major change required by VHCA affects the conditions that manufacturers must meet so that payment can be made under Medicaid for a manufacturer's covered outpatient drugs. Section 601(b)(1) of VHCA amended section 1927(a)(1) of the Act to provide that a manufacturer must meet the requirements of section 1927(a)(5) (with respect to drugs purchased by a covered entity on or after December 1, 1992) and section 1927(a)(6) of the Act (with respect to drugs purchased by the Department of Veterans Affairs (DVA) and certain other Federal agencies).

A manufacturer meets the requirements of section 1927(a)(5)(A) of the Act if it has entered into an agreement with the Secretary that meets the requirements of section 340B of the Public Health Service (PHS) Act with respect to covered outpatient drugs purchased by a covered entity on or after December 1, 1992. The term ''covered entity'' means an entity described in section 340B(a) of the PHS Act. In general, VHCA amended section 1927 of the Act to require that drug manufacturers enter into pharmaceutical pricing agreements with the PHS and offer discounts on covered outpatient drugs to PHS covered entities that are at least as great as the rebates (both basic and additional rebates) received by State Medicaid agencies.

A manufacturer meets the requirements of section 1927(a)(6) of the Act if it complies with the provisions of section 8126 of title 38 of the United States Code, including the requirement of entering into a master agreement with the Secretary of the DVA under such section. In general, effective January 1, 1993, a manufacturer must enter into a pharmaceutical pricing agreement (master agreement) with the DVA for all single source drugs, innovator multiple source drugs, biologicals, and insulin. Generally, beginning January 1, 1993, the prices that manufacturers charge Federal agencies listed in the master agreement may not exceed the annual Federal ceiling prices specified for such drugs.

In accordance with these amendments to section 1927(a) of the Act, a manufacturer must enter into a pharmaceutical pricing agreement with the PHS and, if necessary, the DVA in order for a manufacturer's drugs to be paid for under Medicaid. Manufacturers that do not enter into and comply with these agreements are subject to termination of the Medicaid national rebate agreement.

Section 1927(b)(4)(B)(ii) of the Act specifies that a manufacturer may terminate its rebate agreement for any reason. Section 601(b)(4) of VHCA amended section 1927(b)(4)(B) of the Act to provide that any such termination not be effective until the rebate period beginning at least 60 days after the date the manufacturer provided notice to the Secretary. Section 601(b)(4) of VHCA also added section 1927(b)(4)(B)(iv) of the Act, which provided that, in the case of a termination of a manufacturer, the Secretary will provide notice of the termination to the State not less than 30 days before the effective date of the termination.

D. Changes made by the Omnibus Budget Reconciliation Act of 1993

Section 13602 of OBRA '93 modified the Medicaid drug rebate program by amending sections 1902(a)(54), 1903(i)(10), and 1927 of the Act.

This section of the preamble contains a discussion of the amendments to the sections of the Act and how they differ from the original language under OBRA '90. Where applicable, effective dates are noted in the discussion.

Sections 13602(d)(1) and (2) of OBRA '93 specify two different effective dates of the OBRA '93 amendments. Section 13602(d)(1) provides that, except for changes made to sections 1902(a)(54) and 1927(d) of the Act, the OBRA '93 amendments are effective as if included in the enactment of OBRA '90. Under section 13602(d)(2) of OBRA '93, amendments to sections 1902(a)(54) and 1927(d) of the Act are effective with rebate periods (calendar quarters) beginning on or after October 1, 1993, without regard to whether or not regulations to carry out these amendments have been published by that date.

1. Payment for Covered Outpatient Drugs

Section 13602(b) of OBRA '93 amended section 1903(i)(10) of the Act to provide that FFP for covered outpatient drugs will be denied (l) unless there is a rebate agreement in effect under section 1927 for covered outpatient drugs or unless the drug is rated 1–A by the Food and Drug Administration, and (2) with respect to any amount expended for innovator multiple source drugs dispensed on or after July 1, 1991, if, under applicable State law, a less expensive multiple source drug could have been dispensed, but only to the extent that such amount exceeds the upper payment limit for such multiple source drug.

OBRA '93 amended section 1903(i)(10) of the Act to remove from this section the requirement for States to provide for drug use review as a condition to receive FFP. (A drug use review is still required under section 1927(g).) Former section 1927(e) of the Act, with respect to multiple source drugs, has also been added to section 1903(i)(10) and modified. This section now requires only that any amount above the upper payment limit be disallowed for an innovator multiple source drug if, under applicable State law, a less expensive multiple source drug could have been dispensed. As is the case with our current policy, this provision only applies to drugs subject to the Federal upper limits payment.

2. Formulary Provisions and Permissible Restrictions

Section 13602(c) of OBRA '93 amended section 1902(a)(54) of the Act to delete the reference that prohibits a State from maintaining a restrictive formulary. Section 1927(d)(1)(B)(iv) provides that a State may exclude a covered outpatient drug if the State has excluded coverage from its formulary in accordance with section 1927(d)(4). Section 13602(a)(1) of OBRA '93 added section 1927(d)(4) which provides that States may establish a formulary if the formulary meets the requirements specified in that section, as discussed below. States may continue to exclude or restrict drugs or classes of drugs specified in section 1927(d)(2). Previously, any State formulary or similar restriction must have permitted coverage, for all medically accepted indications, of a participating manufacturer's drugs except for those drugs or classes of drugs specified in the list of permissible restrictions in section 1927(d)(2).

a. Formulary Requirements. Section 13602(a)(1) of OBRA '93 added section 1927(d)(4) which provides that States may establish a formulary if it meets certain requirements, effective October 1, 1993. The formulary must:

(i) Be developed by an appropriate Governor-appointed committee consisting of physicians, pharmacists, and other appropriate individuals, or, at State option, the State drug use review board;

(ii) Except as specified in item (iii), include covered outpatient drugs, other than those drugs excluded from coverage or restricted under section 1927(d)(2), of manufacturers which have entered into and comply with the Medicaid drug rebate agreement;

(iii) Exclude only those drugs (with respect to the treatment of a specific disease or condition for an identified population) where the drug's labeling or its medically acceptable indication (based on appropriate compendia) does not have a significant, clinically meaningful therapeutic advantage, in terms of safety, effectiveness, or clinical outcome, over other drugs included in the formulary;

(iv) Have available to the public, a written explanation of the reasons for excluding drugs under item (iii); and

(v) Permit coverage of drugs that are excluded under item (iii) from the State's drug formulary (other than those drugs excluded from coverage in accordance with section 1927(d)(2)) and subject them to prior authorization consistent with the requirements in section 1927(d)(5).

This proposed rule does not address any further requirements that a formulary must meet. If we determine later that additional requirements should be imposed on States with regard to formularies, we will address them in a separate notice of proposed rulemaking.

b. List of Drugs Subject to Restriction. Section 1927(d)(1)(B) of the Act permits States to exclude or restrict drugs contained in the list of permissible restrictions in section 1927(d)(2) of the Act. Prior to OBRA '93, section 1927(d)(2) contained a paragraph (I) which meant that States could exclude or restrict drugs described in section 107(c)(3) of the Drug Amendments of 1962 (''DESI'' drugs) and those identical, similar, or related drugs (IRS drugs). OBRA '93 amended section 1927(d)(2) to eliminate paragraph (I). However, the removal of coverage restrictions from section 1927(d)(1)(B) does not mean that coverage is necessarily required in light of existing funding restrictions under section 1903(i)(5) and restrictions in the definition of a covered outpatient drug.

Thus, effective with rebate periods beginning on or after October 1, 1993, States cannot exclude or restrict these DESI/IRS drugs. This includes DESI/IRS drugs approved prior to 1962 that have not yet been approved under or subject to the DESI review process. If these drugs otherwise meet the criteria of a covered outpatient drug and are not subject to funding restrictions under section 1903 (i)(5) of the Act, States must provide coverage of these drugs and manufacturers must pay rebates on these drugs if they are dispensed and paid for by the State.

3. Terms of the Rebate Agreement

a. Periodic Rebates. Section 13602(a)(2)(A) of OBRA '93 amended sections 1927(b)(1)(A) and (b)(2)(A) of the Act and made technical changes to the original language under OBRA '90 as follows:

- The period of time used to calculate rebates was previously referenced as ''calendar quarter.'' OBRA '93 changed this term of reference to ''rebate period.'' However, this change does not alter the quarterly rebate period as previously established.
- OBRA '93 clarified the language in section 1927(b)(1)(A). This clarification supports the policy in the national rebate agreement that manufacturers will be responsible for rebates calculated for drugs dispensed after December 31, 1990 for which payment was made under the State Medicaid plan during a rebate period. Since the beginning of the Medicaid rebate program, Medicaid utilization data and rebates have been based on the date the State paid for the drug and not the date it was dispensed.

b. State Provision of Information. Section 13602(a)(2)(A)(ii) of OBRA '93 amended section 1927(b)(2)(A) of the Act to specify that States must report information to each manufacturer on the total number of units of each dosage form and strength and package size of each covered outpatient drug dispensed and paid for by the State. This change clarifies the language in section 1927(b)(2)(A), and supports the standard reporting format established by the Secretary and approved by the Office of Management and Budget that States must report drug utilization data to manufacturers using an 11-digit National Drug Code (NDC) number for each drug. Previously, section 1927(b)(2)(A) of the Act did not specify that States must report information on the package size, which represents the last two digits of the 11-digit NDC code.

4. Amount of Rebate

a. Revisions to Definition of Best Price. Section 13602(a)(1) of OBRA '93 amended section 1927(c)(1)(C) of the Act to ratify our interpretation that the definition of ''best price'' includes those prices available to providers and health maintenance organizations (HMOs). This interpretation of the definition of best price has been in effect since OBRA '90. Manufacturers must include in their best price calculation, for a single source or innovator multiple source drug, the lowest price available from the manufacturers during the rebate period to any wholesaler, retailer, provider, health maintenance organization, nonprofit entity, or governmental entity within the United States except for those entities specifically excluded by statute.

Section 13602(a)(1) of OBRA '93 also amended section 1927 of the Act to clarify the term ''free good'' to specify which free goods must be included in the best price calculation. Section 1927(c)(1)(C)(ii)(I) of the Act specifies that best price must include free goods that are contingent on any purchase requirement. Thus, only those free goods that are not contingent on any purchase requirements may be excluded from best price.

5. Additional Rebate for Single Source and Innovator Multiple Source Drugs

Section 13602(a)(1) of OBRA '93 amended section 1927(c)(2) of the Act regarding how additional rebates for single source and innovator multiple source drugs are calculated if the increase in the average manufacturer price (AMP) of the drug exceeds the increase in the Consumer Price Index-Urban (CPI-U). OBRA '93 deleted the requirement that effective January 1, 1994, additional rebates would be calculated using a weighted average manufacturer price (WAMP). Amended section 1927(c)(2) provides that additional rebates for single source and innovator multiple source drugs will continue to be calculated on a drug-by-drug basis, that is, the method in effect since January 1, 1991.

The additional rebate calculation utilizes the drug's ''base date AMP'' (the AMP of the drug when it was first marketed) and the ''base CPI-U'' (the CPI-U in effect when the drug was first marketed). Section 1927(c)(2) of the Act further clarifies ''base date AMP'' and ''base CPI-U'' for the calculation of the additional rebates as follows:

a. For Drugs Approved on or Before October 1, 1990. Base Date AMP—For drugs approved by the FDA on or before October 1, 1990, the base date AMP means the AMP for the calendar quarter beginning July 1, 1990. This base date AMP remains the same as the definition in the national rebate agreement. Consequently, the base date AMP remains the AMP reported for the July - September 1990 calendar quarter. OBRA '93 clarified our interpretations of section 1927(c)(2)(A)(ii) of the Act previously contained in language in the rebate agreement and in operating instructions provided to manufacturers, and, thus, there is no change in methodology. Therefore, the base date AMP is the AMP for the calendar quarter beginning July 1, 1990, without regard to whether or not the drug has been sold or transferred to an entity,

including a division or subsidiary of the manufacturer, after the first day of such calendar quarter.

Base CPI-U—The base CPI-U used for calculating the additional rebate amounts for drugs approved by the FDA before October 1, 1990 is also unchanged, that is, the base CPI-U in effect for September 1990.

b. For Drugs Approved After October 1, 1990. Base Date AMP—OBRA '93 changed the criteria for determining base date AMP for drugs approved by the FDA after October 1, 1990. However, as discussed in section VI.C. of this preamble, for rebate periods beginning on or after January 1, 1991 through September 30, 1993, the original policy in effect under OBRA '90 and explained in paragraph 5.a. of this section will continue to be used. That is, the base date AMP will continue to be the AMP for the first day of the first full month in which the drug was first marketed.

In accordance with the amended language of section 1927(c)(2)(B) of the Act, effective for rebate periods beginning on or after October 1, 1993 (as discussed in section VI.C. of this preamble), the AMP in effect for the first full rebate period after the day on which the drug was first marketed is the base date AMP and will be used to calculate the additional rebate.

Thus, for drugs approved by the FDA after October 1, 1990, but before October 1, 1993, there is the potential for the same drug to have different base date AMPs, that is, one AMP for the January 1, 1991 through September 30, 1993 period and one AMP for the period beginning October 1, 1993.

OBRA '93 amended section 1927(c)(2)(A)(ii) of the Act to clarify that the base date AMP in effect for both of these periods is to be determined without regard to whether or not the drugs have been sold or transferred to an entity, including a division or subsidiary of the manufacturer, after the first day of such rebate period. Thus, a manufacturer's base date AMP (whether for drugs approved by FDA prior to or after October 1, 1990) is drug-specific and should follow the drug regardless of which manufacturer has current legal title.

Base CIP–U—OBRA '93 also amended the criteria for determining the base CIP–U for drugs approved by the FDA after October 1, 1990. In accordance with the amended language of section 1927(c)(2)(A)(ii), effective for rebate periods beginning on or after October 1, 1993, the CIP–U for the month prior to the month of the first full rebate period on which the drug was first marketed is used to calculate the additional rebate as the base CIP–U.

In accordance with section 1927(c)(2)(A)(ii)(II) of the Act, the base CIP–U is the CPI in effect for the month prior to the month of the first full rebate period after the day on which the drug was first marketed. This change will be effective for rebate periods beginning on or after October 1, 1993.

For rebate periods beginning January 1, 1991 through September 30, 1993, the original policy in effect under OBRA '90 will be used. That is, the base CIP–U continues to be the CIP–U for the month before the month in which the drug was first marketed.

6. Requirements of the Prior Authorization Program

Except with respect to new drugs, OBRA '93 did not modify existing requirements on a State's ability to establish and maintain a program to subject drugs to prior authorization. The statute clarified in section 1927(d)(4) of the Act that a prior authorization program established by a State under section 1927(d)(5) is not a formulary subject to the requirements of section 1927(d)(4) (A) through (E).

7. Treatment of New Drugs

OBRA '93 eliminated all special coverage requirements for new drugs by deleting the former section 1927(d)(6) and deleting a reference to new drugs in sections 1902(a)(54), 1927(d)(1)(A) and 1927(d)(3) of the Act. Former section 1927(d)(6) provided that States could not exclude from coverage, subject to prior authorization, or otherwise restrict any new biological or drug approved by the FDA for 6 months after FDA approval.

Effective for rebate periods on or after October 1, 1993, States may exclude or restrict from coverage or prior authorize any new drugs approved by the FDA. New drugs approved by the FDA prior to October 1, 1993 will only receive the unrestricted coverage specified in former section 1927(d)(6) of the Act through September 30, 1993. Beginning October 1, 1993 the unrestricted coverage no longer applies to these new drugs.

8. Treatment of Pharmacy Reimbursement

a. Treatment of Pharmacy Reimbursement Limits. Section 13602(a)(1) of OBRA '93 redesignated section 1927(f) of the Act as section 1927(e), ''Treatment of Pharmacy Reimbursement Limits''. This section continues to specify that for the moratorium period of January 1, 1991 through December 31, 1994, a State cannot reduce its reimbursement limits or dispensing fees for certain covered outpatient drugs below the limits in effect as of January 1, 1991. For this provision to apply, States must have been in compliance with Federal regulations at 42 CFR 447.331 through 447.334.

OBRA '93 amended section 1927(e)(2) of the Act to clarify that if a State is not in compliance with the regulations at 42 CFR 447.331 through 447.334, the moratorium provisions do not apply to the State until it is in compliance with these regulations.

b. Effect on State Maximum Allowable Cost Limitations. Section 13602(a)(1) of OBRA '93 also added section 1927(e)(3) to clarify that the moratorium provisions do not affect State Maximum Allowable Cost (MAC) limitations in effect prior to or after the moratorium period. That is, as allowed under OBRA '90, States may continue to operate their MAC programs in effect prior to January 1, 1991, in accordance with the terms of that program, for example, adjusting limits and adding drugs within the requirements of the MAC.

9. Average Manufacturer Price

Section 13602(a)(2)(B)(i)(II) of OBRA '93 amended section 1927(k)(1) of the Act to clarify that the AMP for a rebate period is the average price paid to the manufacturer for the drug in the United States by wholesalers for drugs distributed to the retail pharmacy class of trade after deducting customary prompt pay discounts. The policy that AMP will be calculated after deducting customary prompt pay discounts is reflected in the national rebate agreement.

10. Limiting Definition of Covered Outpatient Drug

Section 13602(a)(2)(B)(ii) of OBRA '93 amended section 1927(k)(3) to clarify the limiting definition of what is not included in the definition of a covered outpatient drug. In addition to the criteria originally defined in section 1927(k)(3), a covered outpatient drug does not include the following two items:

- Any drug or product for which a NDC number is not required by the FDA. This category includes whole blood and blood components separated by physical or mechanical means.
- Any drug, biological, or insulin provided as part of, or as incident to and in the same setting as, services in an intermediate care facility for the mentally retarded (ICF/MR) (and for which payment is made as part of the service and not as direct reimbursement for the drug.)

11. Medically Accepted Indication

Section 13602(a)(2)(B)(iii) of OBRA '93 amended section 1927(k)(6) to further define the term ''medically accepted indication.'' OBRA '93 deleted the reference to the use of peer-reviewed medical literature and specified that the medical indication must be on the label or be supported by one or more citations included or approved for inclusion in any of the compendia described in section 1927(g)(1)(B)(i).

OBRA '93 amended section 1927(k)(6) to specify that the term ''medically accepted indication'' means any use for a covered outpatient drug which is approved under the Federal Food, Drug and Cosmetic Act or the use which is supported by one or more citations or approved for inclusion in any of the specified compendia. Those compendia have not changed and are the American Hospital Formulary Service-Drug Information, the American Medical Association Drug Evaluations, and the United States Pharmacopeia-Drug Information.

E. Organization of Remainder of Preamble

The following sections of the preamble explain the actual provisions of the regulations being issued at this time without a description of the history of the statute. In the remainder of the preamble, unless otherwise indicated, references to the statute should be read as the provisions as amended by both the VHCA and OBRA '93. The preamble is structured into six main sections which discuss all related drug covered rebate issues and policies: rebate agreements, drugs covered under the rebate agreement, limitations on drug coverage, reporting requirements, computation of drug rebates, and payment limitations for covered drugs. The balance of the preamble deals with other required regulatory sections, such as responses to comments and an impact analysis. The accompanying regulation text follows section XV. of the preamble.

II. Rebate Agreements

In general, section 1927(a)(1) of the Act provides that, in order for payment to be available under section 1903(a) of the Act for covered outpatient drugs of a manufacturer, the manufacturer must (1) have entered into and have in effect a national rebate agreement with the Secretary on behalf of the States; and (2) also enter into a pharmaceutical pricing agreement with PHS and, if necessary, with DVA (as discussed in Section I.B. of this preamble) for payment to be made under Medicaid for a manufacturer's covered outpatient drugs. The requirements for the rebate agreements are specified in section 1927(b) of the Act.

Section 1927(a)(1) also provides that the Secretary may authorize States to enter directly into separate agreements with manufacturers. For purposes of this rule, we are referring to separate agreements as either ''existing,'' that is, agreements that were entered into on or before the date of enactment of OBRA '90 (November 5, 1990); or ''new,'' that is, agreements that were entered into after the date of enactment of OBRA '90.

The Secretary's authority to approve separate State agreements is consistent with the statute and HCFA's understanding of Congressional intent to decrease program costs and maximize Medicaid savings. Section 1927(a)(1) of the Act gives the Secretary broad authority to authorize separate State agreements. There are no provisions in section 1927 that circumscribe the Secretary's authority to establish criteria for approving separate State agreements.

Thus, in accordance with the authority under section 1927(a)(1) of the Act, we would not approve a new agreement unless the manufacturer has entered into the national rebate agreement and the new agreement provides rebates at least as large as those required by the national agreement. (42 CFR 447.510) We believe these requirements are necessary to effectuate section 1927 of the Act and to uphold Congressional intent.

We would require that a manufacturer enter into the national rebate agreement as a condition of entering into a new State agreement, in order to ensure that Medicaid recipients in all 50 States and the District of Columbia have access to that manufacturer's drugs. In passing various provisions of section 1927, the Congress made it clear that Medicaid recipients be assured access to all medically necessary covered outpatient drugs. (H.R. Rept. No. 881, 101st Cong., 2d Sess. 96–98 (1990)). Without requiring that manufacturers enter into the national agreement, recipients could be denied access if a manufacturer only entered into separate agreements with several large States with a lucrative market for that manufacturer's drugs. Thus, access could be denied in other States.

We would require that a new State agreement provide rebates at least as large as those required by the national agreement because there would be little or no benefit to the Secretary in terms of savings to approve a new State agreement that provides less savings. Approving a new agreement that provides less savings would be contrary to the general understanding of Congressional intent to decrease program costs and maximize Medicaid savings.

The conditions that all existing agreements and new agreements between a State Medicaid agency and a manufacturer must meet in order to comply with the requirements in section 1927 of the Act are described below. The statute defines the entities considered manufacturers to which section 1927 applies. Section 1927(k)(5) of the Act defines the term ''manufacturer'' to mean any entity that is engaged in—

- The production, preparation, propagation, compounding, conversion, or processing of prescription drug products, either directly or indirectly by extraction from substances of natural origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis; or
- The packaging, repackaging, labeling, relabeling, or distribution of prescription drug products.

Under the statutory definition, the term ''manufacturer'' does not include a wholesale distributor of drugs or a retail pharmacy licensed under State law. For the reasons set forth below, we would clarify and interpret this statutory definition to require that the entity must possess legal title to the National Drug Code (NDC) number for a covered outpatient drug, insulin, or biological product. The NDC is a national, readily available numbering system maintained by the Food and Drug Administration (FDA) that identifies each drug by manufacturer, product, and package size. We believe this clarification is necessary to permit a practical means of identifying the manufacturer of the drug to determine which manufacturer is responsible for paying the rebate due under the statute to the State. This approach prevents duplicative manufacturer responsibilities for the drug.

In addition, we would further clarify and interpret the term to specify that if a corporation meets the statutory definition of manufacturer and possesses legal title to the NDC number, we would consider the term to include—

- Any corporation that owns at least 80 percent of the total combined voting power of all classes of stock or 80 percent of the total value of shares in all classes of stock in such entity (that is, a parent corporation);
- Any other corporation in which a parent corporation of the entity owns at least 80 percent of the total combined voting power of all classes of stock or 80 percent of the total value of shares

of all classes of stock in the other corporation (that is, a brother-sister corporation); and

• Any other corporation in which the entity owns at least 80 percent of the total combined voting power of all classes of stock or 80 percent of the total value of shares of all classes of stock in the other corporation (that is, a subsidiary corporation).

We would establish this definition of ''manufacturer'' because we believe that the statutory definition requires clarification to implement the provisions of OBRA '90 consistent with Congressional intent. As noted previously, section 1927(k)(5) of the Act defines a manufacturer, in part, as ''any entity'' engaged in the production, packaging or distribution of prescription drug products. We believe that when defining a manufacturer, the term ''entity'' should be interpreted to include any parent, brother-sister, or subsidiary corporation. Such an interpretation, in our opinion, comports with the Congress' desire to maximize recipient access to medically necessary drugs, while at the same time providing a more favorable drug purchasing arrangement for State Medicaid programs. (H. R. Conf. Rept. No. 964, 101st Cong., 2d Sess. 822, 832 (1990); H. R. Rept. No. 881, 101st Cong., 2d Sess. 996 (1990).)

The Congress, in passing the drug rebate provisions, made it clear that States that elect to cover prescription drugs must, except for certain restriction/exclusions allowed under the statute, for the most part, cover the drugs of a manufacturer that enters into and complies with a drug rebate agreement. In return for such coverage, a manufacturer would be responsible for providing a rebate to the State that would give the Medicaid program the benefit of those discounts that other large public and private purchasers receive. (*Id.*) We believe that it would be directly contrary to such intent for us to define manufacturer in a fashion that would permit a manufacturer (by forming a subsidiary corporation) to exclude some of its drugs from the drug rebate program.

A. Existing Agreements

Section 1927(a)(4) of the Act sets forth the conditions that an existing agreement must meet to be in compliance with the provisions of section 1927. Under section 1927(a)(4), existing agreements that were in effect between a manufacturer and a State Medicaid agency on November 5, 1990, will be considered to be in compliance with section 1927 of the Act until the end of the initial period specified in the agreement if (1) the State agrees to report any rebates paid under the agreement to HCFA; and (2) the agreement provides for a minimum aggregate 10-percent rebate of the State's total expenditures under the State plan for all of that manufacturer's drugs paid for by Medicaid in the rebate period. During the initial agreement period, manufacturers may calculate rebates in accordance with that existing agreement as long as these two requirements are met. (Because no manufacturer had existing agreements in all 50 States and the District of Columbia, and in light of the requirements of sections 1927(a) and 1903(i)(10) of the Act, we required all drug manufacturers with approvable existing agreements with State Medicaid agencies as of November 5, 1990, to enter into and comply with the national agreement to cover those States where manufacturers did not have existing agreements.)

As stated above, section 1927(a)(4) of the Act requires that existing individual State agreements provide for a minimum aggregate rebate of 10 percent of the State's total expenditures under the State plan for coverage of the manufacturer's drugs. However, given other provisions of the statute and the legislative history of OBRA '90, we do not believe that the Congress intended that the minimum aggregate rebate be calculated using State expenditures. Other provisions in section 1927 of the Act calculate rebates using manufacturer prices, and there is no evidence in the legislative history that the Congress intended existing rebates to be calculated using a different formula. In fact, the Conference Report specifies that manufacturer sales, not State expenditures, be used to calculate the minimum aggregate rebate. (H. R. Conf. Rept. No. 964, 101st Cong., 2d Sess. 822 (AMP), 832 (manufacturer sales) (1990).)

The House Conference Report, in discussing the House bill, specifically states that existing rebate agreements must be considered in compliance with the statute if the State can establish that ''the agreement can reasonably be expected to provide rebates at least as large as the rebates under this bill [which uses manufacturer prices].'' (H. R. Conf. Rept. 964, 101st Cong., 2d Sess. 822 (1990); *Id.* at 822 (Senate Amendment).) Similarly, the Conference agreement establishes a similar standard and specifies an aggregate rebate test using manufacturer pricing data. The Conference agreement provides that existing agreements should be considered in compliance with the statute if ''the amount of the rebate under the [existing] contract totals at least 10 percent of the manufacturer's sales to Medicaid in the State.'' (*Id.* at 832.) Therefore, to read the statute in its proper context, and to give effect to our understanding of Congressional intent, we have decided to use manufacturer prices to calculate the minimum aggregate rebate.

Furthermore, as noted previously, using State total expenditures conflicts with other rebate provisions that use manufacturer prices (referred to as average manufacturer prices (AMPs) and best prices) to calculate rebates. (Section V.B.2.a. of this preamble contains the definition of AMP.) A State's total expenditures include, among other items, wholesaler and retailer markup and dispensing fees. These additional charges are not included in the rebate calculations that base rebates on the AMP. Thus, using other than AMP as a percentage of a rebate test would result in an inequitable treatment of manufacturers participating in the rebate program. In light of the legislative history, we believe that the Congress intended that a similar formula based on manufacturer pricing data be used to calculate minimum aggregate rebates under section 1927(a)(4) of the Act.

Therefore, we have concluded that the 10-percent rebate test applies to the manufacturer's AMP (which represents the manufacturer's sale of the drug) and not other State components of drug expenditures. Accordingly, we would specify in our regulations at § 447.510(b)(1)(i) that, to calculate a State's total quarterly expenditures for a manufacturer's drugs for purposes of determining whether the minimum aggregate 10-percent rebate requirement for existing rebate agreements is met, the State must receive a minimum rebate of 10 percent of the AMP for the manufacturer's drugs. Actual rebates on specific drugs may be less than 10 percent as long as the aggregate rebate from that manufacturer for all of its covered outpatient drugs in that separate agreement meets the minimum 10-percent rebate.

An existing agreement must have provided for the minimum aggregate rebate as of November 5, 1990. If this minimum rebate condition was met, we believe it would be consistent with section 1927(a)(4) of the Act to permit States to modify an existing agreement to provide for a greater rebate. Therefore, under these regulations, States would be permitted to modify existing agreements if the State and the manufacturer are in agreement with all modifications and the terms of the agreement allow such modifications. Existing agreements would also be amended to add other drugs of the

manufacturer if the agreement continues to meet a minimum aggregate rebate of 10 percent of AMP. However, we do not believe it would be consistent with the statute or our understanding of Congressional intent to permit modifications to increase the length of the initial term since section 1927(a)(4) of the Act specifically references the initial agreement period.

In cases where an existing agreement did not have a stated percentage of rebate, we have required the State to submit to the HCFA regional office (RO) a written assurance from the manufacturer that the minimum 10-percent rebate, as calculated above, was met as of November 5, 1990. We would require in § 447.510(b)(2) that the rebates under an existing agreement also continue to meet the 10-percent threshold in order for payment to be made available under section 1903(a) of the Act for the manufacturer's covered outpatient drugs throughout the initial period specified in the agreement. We would monitor the savings figures, and, if this threshold is not met, we would consider the existing agreement as no longer in compliance with section 1927(a) of the Act. In this case, HCFA would notify the State that the manufacturer's drugs are subject to the rebate terms of the national drug rebate agreement.

The requirements for renewal of existing rebate agreements between States and manufacturers at the end of the initial period specified in the agreement are generally specified in section 1927(a)(4) of the Act. Under this section, a State/manufacturer agreement is renewable after the initial period specified in the agreement if the State establishes to HCFA's satisfaction that the agreement provides for rebates that are at least as large as the rebates required under the national rebate agreement, and the State agrees to report to HCFA any rebates received under the agreement. We would not approve the renewal of an existing agreement unless the manufacturer has entered into the national rebate agreement. As is the case for existing agreements in the initial period, the State is responsible for submitting to the HCFA RO, along with the agreement, a written assurance from the manufacturer that the agreement submitted for renewal meets the minimum rebate requirements described above.

If the actual rebates fail to be at least as large as those rebates required under the national agreement for the renewal period, the renewed agreement would not be considered to be in compliance with section 1927(a) of the Act. In this case, HCFA would notify the State that the manufacturer's drugs are subject to the rebate terms of the national agreement.

B. New Agreements

New rebate agreements are those individual rebate agreements between a manufacturer and a State that are entered into on or after November 6, 1990, and specifically authorized by HCFA. Section 1927(a)(1) of the Act provides that the manufacturer may enter into a rebate agreement with the Secretary on behalf of a State, or the Secretary may authorize a State to enter directly into a rebate agreement with a manufacturer, thus providing an alternative to the national rebate agreement.

In accordance with section 1927 of the Act, HCFA would authorize State Medicaid agencies to enter directly into new agreements with drug manufacturers. However, we would apply the requirements in section 1927(a)(4) to these new State manufacturer agreements, that is, the agreements must provide rebates at least as large as those required under the national rebate agreement, and the State must agree to report any rebates under the agreement to HCFA. Therefore, we would require in § 447.510(c)(4) that the State include with its agreement authorization request to HCFA a written assurance from the manufacturer that the agreement provides rebates that equal or exceed the rebate amounts specified in the national agreement.

We believe this additional verification of the rebate amounts specified in the new agreement would be necessary since these contracts can differ in form and content in each State. A written assurance from the manufacturer would be evidence that both parties certify that the rebate amounts under the new agreement meet or exceed the rebate amounts in the national agreement.

We would not authorize individual State agreements that provide for rebates less than those required under the national agreement. In our opinion, such agreements are contrary to our understanding of Congressional intent to maximize program savings while expanding access to covered outpatient drugs. Thus, since there is little or no additional benefit for either the States or HCFA to authorize these types of individual agreements, which would increase Medicaid drug costs without offsetting national rebate savings, we would not approve such agreements.

C. Length of Agreements

We would specify in § 447.512(a) that the initial period of an existing State/manufacturer agreement and a new State/manufacturer agreement is the period specified in the agreement, and that the national rebate agreement is effective for an initial period of at least 1 year. While we would not require a 1-year timeframe for the initial period in a new State/manufacturer agreement, we recommend its use to avoid administrative delays from HCFA reviewing new agreements with shorter timeframes. More frequent reviews add to unnecessary administrative costs and burdens for all parties involved.

Under this section we also would specify that the national agreement will be automatically renewed for successive periods of at least 1 year unless (1) HCFA terminates the agreement under the conditions specified in section 1927(b)(4)(B)(i) of the Act; or (2) the manufacturer terminates the agreement for any reason as permitted under section 1927(b)(4)(B)(ii) of the Act.

D. Termination of Agreements

1. Termination by HCFA

In accordance with section 1927(b)(4)(B)(i) of the Act, a rebate agreement may be terminated by the Secretary if the manufacturer violates the requirements of the agreement or for ''other good cause shown.'' HCFA has been delegated the Secretary's authority under section 1927(b)(4)(B) to provide for termination of a rebate agreement. We would interpret ''other good cause shown'' to be any violations of the provisions of the national rebate agreement, section 1927 or the related regulations, or the persistent failure to provide timely information on pricing and other required information or to pay timely rebates. HCFA would send a written notice of the decision to terminate the agreement to the manufacturer. HCFA would also notify State agencies of the termination. The termination would not be effective earlier than 60 days after the date a notice of the termination is sent to the manufacturer (§ 447.514(b)). If a manufacturer is dissatisfied with a termination decision made by HCFA, the manufacturer may request a hearing (as specified in section II.D.5. of this preamble). However, a request for a hearing would not delay the effective date of the termination.

2. Termination by the Manufacturer

In accordance with section 1927(b)(4)(B)(ii) of the Act, the manufacturer may terminate its rebate agreement for any reason. Section 601(b)(4) of VHCA amended section 1927(b)(4)(B) of the Act to provide that any such termination not be effective until the rebate period beginning at least

60 days after the date the manufacturer provides notice to the Secretary. A termination notice from a manufacturer is considered a request to end its participation in the national rebate agreement with the understanding that there is a delay before reinstatement (as discussed in section II.D.4. of this preamble).

We would provide in § 447.514(c)(1) that a manufacturer that wishes to terminate an agreement must provide to HCFA a written notice of intent to terminate at least 60 days before the beginning of the rebate period in which the termination will occur. We would specify that the effective date of a requested termination will be the first day of the first rebate period beginning at least 60 days after the manufacturer gives written notice requesting termination, or a later date if specified by the manufacturer. We would specify in § 447.514(c)(3) that the date of notice will be considered to be the postmark date of the U.S. Postal Service or common mail carrier.

If the manufacturer fails to terminate the agreement at least 60 days before the renewal date, the automatic renewal provisions of section 1927(b)(4)(A) would be effective and the agreement would not terminate until the rebate period following the renewal. For example, if a manufacturer intended to terminate the rebate agreement effective January 1, 1994, HCFA must have received the written notice on or before November 1, 1993. Otherwise, if HCFA received the notice on November 15, 1993, the termination date would be April 1, 1994 (the first day of the first rebate period beginning at least 60 days after receipt of the notice).

Any termination would not affect rebates due under the agreement before the effective date of the termination.

3. Nonrenewal of Rebate Agreement

To effectuate sections 1927(b)(4)(A) and (b)(4)(B)(ii) of the Act, we would require in § 447.514(c)(2)(i) that a manufacturer give written notice of its decision not to renew the rebate agreement (nonrenewal notice) at least 60 days before the end of the current agreement period. (We would consider the date a manufacturer gives written notice of its decision not to renew to be the date of the postmark of the U.S. Postal Service or common mail carrier (§ 447.514(c)(3)).) If HCFA receives a manufacturer's nonrenewal notice at least 60 days before the end of the agreement period, the nonrenewal would be effective on the ending date of the agreement period. This 60-day period would give HCFA the time needed to notify States that the manufacturer's drugs are no longer eligible for FFP under Medicaid.

If the manufacturer fails to meet this 60-day advance notice requirement, the agreement would be automatically renewed for another 1-year term. In this case, HCFA would deem the nonrenewal notice a termination notice because the manufacturer missed the nonrenewal deadline. Therefore, in accordance with the regulations at § 447.514(c)(2)(ii)(B), HCFA would terminate the rebate agreement effective the second calendar quarter of the renewed agreement period.

4. Reinstatements

Section 1927(b)(4)(C) of the Act provides that, if a rebate agreement is terminated, another agreement with the manufacturer (or a successor manufacturer) may not be entered into until a period of 1 calendar quarter has elapsed from the date of the termination, unless the Secretary finds good cause for an earlier reinstatement of the agreement. We would incorporate this provision in § 447.514(d) of our regulations. For example, if HCFA received a written notice on October 1, 1993, to terminate an agreement, the rebate agreement would be terminated on January 1, 1994, and a manufacturer could not enter into another agreement until April 1, 1994, unless HCFA finds good cause to do otherwise. An example of good cause might be if a manufacturer's drug is medically necessary to a significant number of Medicaid recipients and there is no therapeutic substitute available.

5. Opportunity for Appeal

Section 1927(b)(4)(B) of the Act provides that the Secretary must provide a manufacturer with a hearing concerning a termination of a rebate agreement if the manufacturer requests one. In accordance with this section of the Act, we would provide in § 447.514(b)(4) that, if a manufacturer is dissatisfied with a termination of a rebate agreement by HCFA, the manufacturer may appeal the termination under the administrative procedures specified in the contract provision in the rebate agreement. We believe the appeal procedures specified in the national rebate agreement afford manufacturers the due process rights to which they are entitled under section 1927 of the Act, since the process provides a written notification process, the right to appeal the termination and, if applicable, a hearing before a HCFA official or other party.

Section 1927(b)(4)(B)(i) of the Act also requires that the hearing not delay the effective date of the termination. Accordingly, we would provide in § 447.514(b)(4) that, while manufacturers have the right to an administrative hearing, such a hearing would not delay the effective date of the termination.

6. Notice to States

Section 601(b)(4) of VHCA added section 1927(b)(4)(B)(iv) of the Act, which provides that in the case of a termination of a manufacturer, the Secretary will provide notice of the termination to the States not less than 30 days before the effective date of the termination. In accordance with this section of the Act, we would provide in § 447.514(f) that HCFA will notify States of any termination from the drug rebate program at least 30 days prior to the effective date of the termination.

III. Drugs Covered Under the Rebate Agreement

A. Rebated and Non-Rebated Drugs

Sections 1927(k)(2) and (k)(4) of the Act specify the covered outpatient drugs that are subject to rebate agreements. Covered outpatient drugs are defined as (1) those drugs that may be covered as prescribed drugs under Medicaid under section 1905(a)(12) of the Act, are dispensed only upon prescription (except over-the-counter drugs), and that meet certain requirements specified in sections 1927(k)(2)(A)(i) through (iii) of the Act; (2) a biological product other than a vaccine that may be dispensed only upon prescription, is licensed under section 351 of the Public Health Service Act, and is produced at an establishment licensed under section 351 to produce such products; (3) insulin certified under section 506 of the Federal Food, Drug, and Cosmetic Act; and (4) ''over-the-counter'' drugs that are prescribed by a physician or other person authorized to prescribe under State law, if the State provides for coverage of these drugs as prescribed drugs under its approved State plan. We would add this definition to § 447.516(a) of our regulations.

We would require in § 447.516(b) that a manufacturer submit as part of its rebate agreement a listing of all of its drugs that fall within the definition of covered outpatient drugs in sections 1927(k)(2) through (k)(4) of the Act. We also would require use of National Drug Code (NDC) numbers to identify the drugs.

We would interpret ''covered outpatient drug,'' as defined in section 1927(k)(2) of the Act, to include all covered outpatient drugs for which that manufacturer holds legal title to the NDC number. The statutory definition

encompasses all FDA-approved prescription drugs and biologicals except for vaccines or drugs that fall within the limiting definition in section 1927(k)(3) of the Act (§§ 447.504 and 447.516(b)(2)). Manufacturers that have entered into the national rebate agreement have agreed to submit a listing of all covered outpatient drugs, not a partial listing. Therefore, in accordance with the statute and the provisions of the national rebate agreement, manufacturers that enter into a rebate agreement could not exclude any covered outpatient drug specified in section 1927(k) of the Act from its listing of covered outpatient drugs.

Even though States may choose to exclude or restrict certain drugs under section 1927(d) of the Act (as discussed in section IV.B of this preamble), the drugs may be covered in other States or covered by that State at a later date. Therefore, a manufacturer would be required to list by NDC number all of its covered outpatient drugs, regardless of whether its drugs are dispensed or covered by Medicaid programs in all States. In addition, HCFA would not allow a manufacturer to withhold its covered outpatient drugs from being subject to the rebate provisions, regardless of whether the drugs are sold by the manufacturer's subsidiaries or parent company, as discussed in section I.A. of this preamble.

In § 447.522(a), we would provide for an exclusion from the definition of covered outpatient drugs consistent with section 1927(k)(3) of the Act. Section 1927(k)(3) of the Act, as amended by section 13602(a)(2)(B)(ii) of OBRA '93, provides certain exclusions from the definition of covered outpatient drugs. This section specifies that covered outpatient drugs do not include ''any drug, biological product, or insulin provided as part of, or as incident to and in the same setting as, any of the following (and for which payment may be made under [Medicaid] as part of payment for the following and not as direct reimbursement for the drug): Inpatient hospital services; hospice services; dental services (except that drugs for which the State plan authorizes direct reimbursement to the dispensing dentist are covered outpatient drugs); physicians' services; outpatient hospital services; nursing facility services and services provided by an intermediate care facility for the mentally retarded; other laboratory and x-ray services; and renal dialysis'' (§ 447.522(a)).

The term ''covered outpatient drug'' also would not include any such drug, biological product, or insulin for which an NDC number is not required by the FDA that is used for an indication that is not ''medically accepted'' (§ 447.522(b)). A medically accepted indication is defined under section 1927(k)(6) of the Act, as amended by section 13602(a)(2)(B)(iii) of OBRA '93, as any use for a covered outpatient drug that is approved under the Federal Food, Drug and Cosmetic Act, or the use of which is supported by one or more citations included or approved for inclusion in any of the following compendia: The American Hospital Formulary Service-Drug Information, the American Medical Association Drug Evaluations, and the United States Pharmacopeia-Drug Information. We would incorporate this definition in § 447.504 of our regulations.

There are additional drugs and biologicals that do not fall within the definition of covered outpatient drugs set forth in section 1927(k) of the Act. These drugs are not subject to rebates, although Medicaid coverage may be provided under section 1905(a)(12) of the Act at State option, and FFP is available. Generally, these additional drugs and biologicals that do not fall within the section 1927(k) definition are discussed below and would be specified in § 447.522(c) through (g) of the regulations. We do not consider this a definitive list due to the vast nature of drugs and biologicals regulated by the FDA and the unique situations that exist for particular products. Drugs that fall outside of the scope of section 1927 of the Act would not be considered covered outpatient drugs and, therefore, would not be subject to rebate.

- Any drug, biological product, or insulin for which an NDC number is not required by the FDA would not meet the definition of a covered outpatient drug in section 1927(k) and, therefore, would not be subject to a rebate as a condition of FFP. This would include whole blood (collected from a single human donor) and blood components (which are the result of physical or mechanical separation either as part of the collection process or subsequent to the collection of whole blood).
- Medical items and supplies, such as syringes (except insulin-filled syringes), urine and blood glucose testing strips and devices, lancets, and inhalers (except pre-filled inhalers) do not meet the definition of covered outpatient drugs in sections 1927(k)(2) through (k)(4) of the Act and, therefore, would not be subject to a rebate as a condition of FFP.
- Certain nutritional products that are regulated as drugs would be covered under the rebate program. Parenteral products that are administered intravenously are approved as drugs by the FDA under section 505 of the Federal Food, Drug, and Cosmetic Act. These parenteral products that are approved as drugs, are administered intravenously, and meet the definition of a covered outpatient drug in accordance with section 1927(k) of the Act would be subject to a rebate as a condition of FFP. Parenteral products that are not administered intravenously are regulated as ''foods'' by the FDA and would not meet the definition of a covered outpatient drug.
- Enteral nutrition products that are not approved by FDA as a drug under sections 505, 506, or 507 of the Federal Food, Drug, and Cosmetic Act would not be considered covered outpatient drugs under section 1927(k)(2)(4) of the Act, and would not be subject to rebate.

HCFA has permitted States the option to cover enteral nutrition products that are not approved as a drug by the FDA, under Medicaid benefit categories other than prescription drugs. These categories include outpatient hospital services, home health services, clinic services, and rural health clinic services. The nutrient products may be covered in these settings as a medical supply. These supplies would not be considered covered outpatient drugs and, therefore, would not be subject to rebate.

- States have the option to cover under their Medicaid program investigational new drugs (IND) (for example, Treatment IND drugs, Parallel Track, and Group C cancer drugs). (State Medicaid programs often use the term ''experimental'' when referring to these types of drugs.) Since section 1927 of the Act made no changes to a State's previous ability to cover these drugs, FFP continues to be available for these drugs. However, because they do not meet the definition of covered outpatient drugs in sections 1927(k)(2) through (4) of the Act, they would not be covered under the drug rebate program or subject to a rebate.

B. Definitions of Drug Categories

As defined in section 1927(k)(7)(A)(iv) of the Act, ''single source drug'' means a covered outpatient drug that is produced or distributed under an original new drug application (NDA) approved by the FDA, including a drug product marketed by any cross-licensed producers or distributors operating under the NDA. (Section III.C.3. of this preamble contains the definition of original new drug application.) Section 1927(k)(7)(A)(i) of the Act defines ''multiple source drug'' as a covered outpatient drug for which there are two or more drug products that are—

- Rated as therapeutically equivalent by the FDA under its most recent publication of *Approved Drug Products with Therapeutic Equivalence Evaluations;*
- Are pharmaceutically equivalent and bioequivalent as determined by the FDA; and
- Are sold or marketed in the State during a calendar quarter.

Drugs are pharmaceutically equivalent if the products contain identical amounts of the same active drug ingredient in the same dosage form and meet compendial or other applicable standards of strength, quality, purity, and identity.

Drugs are bioequivalent if they do not present a known or potential bioequivalence problem, or if they do present such a problem, they are shown to meet an appropriate standard of bioequivalence. (This condition does not apply if FDA changes by regulation the requirement that in order for drug products to be rated as therapeutically equivalent, they must be pharmaceutically equivalent and bioequivalent.)

Sections 1927(k)(7)(A)(ii) and (iii) of the Act define ''innovator multiple source drug'' as a multiple source drug that was originally marketed under an original NDA approved by the FDA and ''noninnovator multiple source drug'' as a multiple source drug that is not an innovator multiple source drug. To clarify the statutory definition, we would further define multiple source drugs to distinguish the differences between an innovator multiple source drug and a noninnovator multiple source drug.

In accordance with our understanding of Congressional intent, we would define an ''innovator multiple source drug'' as a multiple source drug from 1938 to present that was originally marketed under an original NDA approved by the FDA. We would define a ''noninnovator multiple source drug'' as a multiple source drug that was marketed under an abbreviated NDA or any marketed, unapproved pre-1938 drug product for which the FDA has not made a final determination about its legal status. This would include (1) all products approved under an abbreviated NDA (authorized under the Drug Price Competition and Patent Term Restoration Act of 1984, Public Law 98–417), paper NDA under the FDA's former ''Paper NDA'' policy (54 FR 28873), or an application under section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act; and (2) any marketed, unapproved pre-1938 drug product that has not been evaluated under the new drug provisions of the Federal Food, Drug and Cosmetic Act. (§ 447.504)

C. Treatment of New Drugs

1. Elimination of New Drug Coverage Under OBRA '93

OBRA '93 eliminated all special requirements for new drugs by deleting the former section 1927(d)(6) of the Act. That section provided that a State may not exclude, subject to prior authorization, or otherwise restrict from coverage under the rebate program any new drug or biological approved by the FDA after the date of enactment of OBRA '90 (November 5, 1990) for a period of 6 months after the date of FDA approval. OBRA '93 also deleted the references to new drugs in section 1927(d)(1)(A) and (d)(3) of the Act.

Section 13602(d)(2) of OBRA '93 provided that amendments to section 1927(d) of the Act are effective with rebate periods beginning on or after October 1, 1993. That is, effective October 1, 1993, States may exclude or restrict from coverage or prior authorize any new drugs approved by the FDA. In accordance with section 13602(d)(2), new drugs approved by the FDA prior to October 1, 1993 may only receive the unrestricted coverage specified in former section 1927(d)(6) of the Act through the rebate period ending September 30, 1993. Beginning October 1, 1993 the unrestricted coverage no longer applies to these new drugs.

2. New Drug Coverage Provision in Effect for January 1, 1991–September 30, 1993

(Note: The discussions of sections 1927(d)(1), (3), and (7) throughout this section III.C.2. of the preamble pertain to any amendments made by OBRA '93.)

Prior to OBRA '93, section 1927(d)(6) of the Act provided that a State may not exclude, subject to prior authorization, or otherwise restrict from coverage under the rebate program any new drug or biological approved by the FDA after the date of enactment of OBRA '90 (November 5, 1990) for a period of 6 months after the date of FDA approval. Except as authorized in section 1927(d)(1) and (2) of the Act for the period of January 1, 1991–September 30, 1993, States must have covered these drugs with no restrictions for 6 months from the date of FDA approval, regardless of when the manufacturer began to market the drugs. We would incorporate these provisions in § 447.520(a) of our regulations. For purposes of these provisions, we did not consider a delay in the marketing of a new drug following FDA approval a cause for extending the 6-month period.

The mandatory coverage provisions of section 1927(d)(6) of the Act did not encompass those drugs that a State may exclude under sections 1927(d)(1) and (d)(2) of the Act. Sections 1927(d)(1) and (d)(2) provide that a State may exclude or otherwise restrict coverage of a covered outpatient drug if the drug is used to treat, for example, anorexia, weight gain, hair loss, or cough or cold symptoms. Section 1927(d)(2), when read in conjunction with sections 1927(d)(1) and 1927(k)(2) of the Act, circumscribes those covered outpatient drugs that must be covered by States under their State plan. In other words, the mandatory coverage provisions of section 1927(d)(6) did not affect those drugs that a State may exclude or otherwise restrict under sections 1927(d)(1) or (d)(2).

In addition, we would provide under § 447.520(c) of the regulations that coverage of new drugs between January 1, 1991 and September 30, 1993 for the first 6 months after approval by the FDA would not be available for manufacturers that did not have agreements in existence with HCFA for this 6-month time period, since section 1927(a) of the Act provides FFP only for covered outpatient drugs of manufacturers with rebate agreements. However, if the new drug is rated as 1–A, section 1927(a)(3) of the Act authorizes payment, at State option, for certain 1–A drugs not covered under a rebate agreement. (Section III.D.1 of this preamble contains a discussion of 1–A drugs.)

Before the enactment of OBRA '93, sections 1927(d)(1) and (d)(6) of the Act provided that a State may not subject a new drug to prior authorization during the 6-month period after FDA approval. If the State chose to cover a new drug or class of drugs that was listed in section 1927(d)(2) of the Act, it could not prior authorize a new drug within that category during the 6-month period. After the 6-month period, a drug that was considered a new drug could be subject to the prior authorization provisions of section 1927(d)(1) at State option. We would incorporate these provisions in § 447.520(b) of our regulations.

Before the enactment of OBRA '93, section 1927(d)(3) of the Act prohibited new drugs from being added to the list of drugs subject to restriction in section 1927(d)(2) during the 6-month period specified in section 1927(d)(6). After the 6-month period, new drugs could be added to the list, as discussed in section IV.B.2. of this preamble.

Before the enactment of OBRA '93, section 1927(d)(7) of the Act permitted a State to impose limitations on all

drugs in a therapeutic class, on the minimum or maximum quantities per prescription, or on the number of refills, provided such limitations are necessary to discourage waste. We believe that to effectuate Congressional intent, sections 1927(d)(6) and 1927(d)(7) of the Act must have been read in concert to discourage waste in the use of new drugs during the 6-month period after FDA approval. Section 1927(d)(7), in our opinion, permitted States to impose limitations on all drugs, including new drugs, in a therapeutic class, on the minimum or maximum quantities per prescription, or on the number of refills, provided such limitations were necessary to discourage waste.

We believe such an interpretation would be consistent with the statutory provisions in both section 1927(d)(6) and section 1927(d)(7). We believe the Congress mandated that States could not exclude from coverage, subject to prior authorization, or otherwise restrict a new drug for 6 months from FDA approval to ensure that medically necessary new drugs were made available to the general population. The limitations for waste in section 1927(d)(7) of the Act did nothing to discourage the proper prescribing, dispensing, and use of a new drug. They simply ensure that, for Medicaid recipients, the minimum supply of the drug is sufficient to be medically effective and economical and that the maximum supply of the drug discourages waste in the event the drug cannot be used (for example, because of allergic reactions, side effects, drug interaction, or other reasons of medical necessity). The foregoing would give effect to the provisions in both section 1927(d)(6) and section 1927(d)(7) and, thus, would uphold the intent of the Congress as set forth in the statute. (See section IV.C. of the preamble for a discussion of a State's attorney authority to impose limitations as amended by OBRA '93.)

3. Definition of Original New Drug Application (NDA)

Sections 1927(k)(7)(A)(ii) and (iv) of the Act reference the term ''original NDA'' in the definitions of ''innovator multiple source drug'' and ''single source drug.'' Under the national rebate agreement, a drug marketed under an original NDA, in addition to other criteria, may be classified as either a single source or an innovator multiple source drug. Neither the statute nor the rebate agreement, however, define the term ''original NDA.'' This term is also not defined in the Federal Food, Drug, and Cosmetic Act.

Because the statute does not provide specific guidance on this term, we would interpret it to comport with our understanding of the intent of the Congress. We would define in regulations at § 447.504 the term ''original NDA'' as an FDA-approved drug or biological application that received one or more forms of patent protection, patent extension under title II of Public Law 98–417, the Drug Price Competition and Patent Term Restoration Act, or marketing exclusivity rights granted by the FDA. This definition would include an NDA, an amended NDA, an antibiotic drug application (ADA), an amended ADA, a product license application (PLA), and an amended PLA.

Based on the statute, which requires larger rebates for single source and innovator multiple source drugs, we believe the term ''original NDA'' was included in sections 1927(k)(7)(A)(ii) and (iv) of the Act for the purposes of extracting larger rebates from those products that received some form of patent or marketing protection for a specific period of time. This form of protection could have been achieved through either some type of patent on the drug or some type of marketing exclusivity rights granted by the FDA.

Patent protection is generally granted for 17 years. Exclusivity rights generally run for a period of 3 to 7 years and are granted by the FDA for such innovations as new medical indications, new dosage strengths, new dosage forms, new regimens, or new routes of administration. Exclusivity rights can extend beyond the life of the patent and protect the manufacturer from competition in one or more specific market areas. Thus, the innovators of drug products with market protection often benefitted from a lack of competition and increased profits for a specific period of time. Therefore, innovators with market protection are required to pay larger rebates than noninnovators that produce generic drugs with no market protection. We believe the term ''original NDA,'' as proposed above, produces this effect.

The rebate classification system has raised questions among manufacturers regarding how to classify certain products. We believe some drugs that appear to meet the rebate agreement's definition of innovator multiple source drug are actually noninnovator multiple source drugs. The FDA may consider a previously approved drug product to be a new drug and require an NDA before marketing. However, in accordance with our understanding of these provisions, this drug may actually be a noninnovator. For example, under 21 CFR 310.509, the FDA does not generally recognize any parenteral drug product packaged in a plastic immediate container as safe and effective. Therefore, this type of drug product is considered a new drug within the meaning of section 201(p) of the Federal Food, Drug, and Cosmetic Act and requires an approved NDA as a condition for marketing. In this case, if no patent protection or marketing exclusivity rights were granted by the FDA for the covered outpatient drug of that manufacturer, we would consider it to be a noninnovator multiple source drug.

D. Covered Drugs of Manufacturers Without Rebate Agreements

1. Coverage of 1–A Rated Drugs

Prior to 1992, the FDA maintained a rating system under which drugs were rated based on various factors. Under that system, the FDA rating ''1–A'' signified the chemical type (1) and the therapeutic potential (A). The FDA, in its 1991 publication *Offices of Drug Evaluation Statistical Report,* defined the rating 1–A as follows:

- The chemical type ''1'' identifies the drug as a new molecular entity, that is, a drug for which the active moiety has not been previously marketed in the United States for use in a drug product, either as a single ingredient or as part of a combination product, or as part of a mixture of stereoisomers. The term ''new molecular entity'' is equivalent to ''new chemical entity''.
- The therapeutic potential type ''A'' is defined as a drug with important therapeutic gain. The drug may provide effective therapy or diagnosis for a disease not adequately treated or diagnosed by any marketed drug, or provide improved treatment of a disease through improved effectiveness or safety (including decreased abuse potential).

A 1–A drug may also be labeled ''1–A/AA''. The 1–A/AA designation means it is a 1–A drug that is generally being developed for AIDS and AIDS-related opportunistic infections and that the FDA has placed the drug on a fast track and will monitor it through the drug review process.

Section 1927(a)(3)(A) of the Act authorizes FFP for single source or innovator multiple source drugs rated by the FDA as 1–A that are furnished by manufacturers without rebate agreements if certain conditions are met. Under this section, Medicaid payments may be made if: (1) The State has determined that the availability of the drug is essential to the health of recipients under the approved State plan; and (2) the physician has obtained

approval for use of the drug before it is dispensed in accordance with a prior authorization program, or the Secretary has approved the State's determination regarding drug necessity to obviate the need for prior authorization (§ 447.518(b)). Necessity would be judged based on alternative therapies available and the probable outcome if a specific drug is not dispensed.

Even though section 1927(a)(3) of the Act authorizes HCFA to provide FFP for 1–A rated drugs under certain circumstances, States retain the option under sections 1902(a) and 1905 of the Act to choose which 1–A drugs they will cover under their approved State Medicaid plans.

The FDA recently changed its therapeutic classification system in which drugs were rated as either A, B, or C. As indicated in the FDA's *Staff Manual Guide*, Center for Drug Evaluation and Research, this three-tiered system has been replaced by a mutually exclusive two-tiered system in which the potential therapeutic classification of a drug product is either a Type P (Priority review, therapeutic gain) or a Type S (Standard review, substantially equivalent drug product). Type P is assigned to drugs that appear to represent a therapeutic gain over already marketed or approved drugs (formerly rated A or B). Type S is assigned to drug products that appear to have therapeutic qualities similar to drugs already approved or marketed (formerly rated C).

The Type P and S therapeutic classification system is effective for all NDAs approved on or after January 1, 1992. The classifications for NDAs approved prior to January 1, 1992, will remain unchanged, that is, these drugs will retain their A, B, or C therapeutic classification and 1–A drugs would continue to be covered by States as specified in this regulation. For purposes of section 1927(a)(3)(A) of the Act, we are inviting public comments on possible methods to identify 1–P-rated drugs that we could include as 1–A-drugs under this provision using the FDA's former classification system.

2. Coverage of Drugs During the First Rebate Period of 1991

Section 1927(a)(3)(B) of the Act provides for Medicaid payment for drugs not covered under rebate agreements if the Secretary determined that in the first rebate period of 1991 there were extenuating circumstances. On March 8, 1991, HCFA notified all State Medicaid Directors of its determination that extenuating circumstances did exist and that, for the first rebate period of 1991, outpatient prescribed drugs of manufacturers without rebate agreements were covered under Medicaid if they were included in the approved State Medicaid plan. States were not formally notified until March 15, 1991, of manufacturers participating in the rebate program. There was no practical way States could retroactively discontinue drug coverage on January 1, 1991, for drugs of nonparticipating manufacturers. However, as of April 1, 1991, FFP is available only for those covered outpatient drugs of manufacturers with rebate agreements.

Section 1927(a)(1) of the Act required that manufacturers enter into a rebate agreement by March 1, 1991, for payment to be available for their drugs under Medicaid for the January–March 1991 rebate period. As discussed earlier, HCFA also extended through April 30, 1991, the deadline for manufacturers to enter into rebate agreements that are retroactive to January 1, 1991.

IV. Limitations on Coverage of Drugs

Section 1927(d) of the Act, as amended by OBRA '93, permits States to place certain limitations on drugs that are covered under a rebate agreement. States may limit the coverage of drugs by: (1) Implementing a prior authorization program that complies with the requirements in section 1927(d) (5); (2) restricting or excluding from coverage drugs listed in section 1927(d) (2); (3) restricting the quantities of outpatient drugs per prescription and the number of refills under section 1927(d) (6); and (4) excluding coverage of the drug from its formulary in accordance with section 1927(d)(4). These limitations, that are proposed in the regulations at §§ 447.524 and 447.526, are explained below.

A. Prior Authorization

Section 1902(a)(54) of the Act provides that in the case of a State plan that provides medical assistance for covered outpatient drugs (as defined in section 1927(k) of the Act), the State must comply with the applicable requirements of section 1927 of the Act. Section 1927(d)(1)(A) provides that a State may subject any covered outpatient drug to prior authorization; that is, require approval of the drug before its dispensing for any medically accepted indication. The prior authorization system must meet two conditions specified under section 1927(d)(5) of the Act.

For drugs dispensed on or after July 1, 1991 section 1927(d)(5) of the Act permits a State to maintain a prior authorization program if the State responds by telephone or other telecommunication device to requests within 24 hours of a request for prior authorization. A State must, except for those drugs listed in section 1927(d)(2) of the Act, further provide for the dispensing of at least a 72-hour supply of the drug in emergency situations.

The provisions in section 1927 of the Act make no other changes to the State's ability to maintain or establish prior authorization programs. Thus, as specified in section 1927(d)(1) of the Act, States may subject to prior authorization any covered outpatient drug.

In passing these provisions, the Congress made it clear that Medicaid recipients should be assured access to all medically necessary covered outpatient drugs. (H. R. Rep. No. 881, 101st Cong., 2d Sess. 96–98 (1990).) Even though OBRA '93 added section 1927(d)(4) of the Act to allow States to establish formularies which meet specific requirements, section 1927(d)(4)(D) provides that the State plan must permit coverage of a drug excluded from the formulary (other than any drug excluded or restricted under section 1927(d)(2)) pursuant to a prior authorization program. In accordance with our understanding of Congressional intent, we believe that it is necessary to prevent States from using a prior authorization program as a proxy for a closed formulary beyond what the statute allows under the formulary provisions of section 1927(d)(4). In addition, we believe it is necessary to ensure that States respond to prior authorization requests within the timeframes specified in the statute. We believe these requirements are necessary to effectuate section 1927 of the Act and to uphold Congressional intent.

Prior authorizing drugs as a proxy for a closed formulary, beyond what the statute allows under the formulary provisions of section 1927(d)(4) without regard for medical necessity could result in recipients being treated with alternate therapies that may not be in their best interest. This could result in increased program costs if other medical services, such as inpatient hospital services, are necessary because a drug therapy is made less accessible under the State Medicaid program. Thus, a recipient's access to medically needed drugs could be unduly hampered if medical necessity is not used in a prior authorization program.

Therefore, we are proposing requirements to ensure that States utilize individuals with the appropriate level of medical expertise when determining which drugs are prior authorized and when deciding if the drug can be dispensed. Accordingly, we

believe it most appropriate that the level of expertise be reflected by the ability to prescribe/dispense drugs. We believe individuals with this knowledge would more likely be aware of negative consequences that could result if a specific drug is prior authorized or not approved for dispensing. Thus, the State Medicaid program and recipients would benefit from such a prior authorization system that considers medical necessity as its primary concern.

We note that this same level of expertise need not be present in those individuals responding to the prior authorization requests, as these persons would be acting in accordance with guidelines developed by those persons who place the drugs on prior authorization. However, as there may be requests for prior authorized drugs that do not fit into present guidelines, access to those persons responsible for putting drugs into a prior authorization program is needed.

Therefore, in accordance with section 1902(a)(54) of the Act, we would specify in these regulations at § 447.526(d) and (e) that:

- State staff who place drugs in a prior authorization system must be licensed to prescribe or dispense drugs in the State, for example, physicians or pharmacists, since these persons would have the medical knowledge necessary to determine criteria for prior authorization.
- State staff who respond to prior authorization requests are not limited to persons licensed to prescribe or dispense drugs as long as all decisions involving drugs subject to prior authorization are made—
  + In consultation with these licensed professionals; or
  + Under guidelines promulgated by such individuals as long as States provide access to licensed professionals in difficult or unusual cases.
- The State must establish a process to ensure recipients access to medically necessary covered outpatient drugs. We would not permit a State to use a prior authorization program as a means to deny covered outpatient drugs when medical necessity is shown.
- The State must provide annual written assurances to HCFA that the State's prior authorization program does not prevent recipients from gaining access to medically needed drugs.

Generally, we would allow States flexibility in implementing the statutory provisions relating to a 24-hour turnaround time for prior authorization requests and at least a 72-hour supply for emergency situations. For example, States may continue to prescribe the format for sending the request (for example, mail, telephone, or telefax). States may also continue to staff this function only during normal business hours, provided the requirement concerning a response to prior authorization requests within 24 hours of a request can be met.

However, to ensure access to medically necessary drugs, we would require States to structure their system so that, in emergency situations, a State's response is given to the dispenser or physician requesting the authorization before the emergency supply is exhausted. In these emergency situations, we would require the State to provide a mechanism so that a dispenser or physician can make a prior authorization request 24 hours before the supply is exhausted and a response returned by the State within that 24-hour period. We would require the State to allow a dispenser to provide a sufficient emergency supply (of at least 72 hours) until the prior authorization response can be returned to the dispenser. For example, the supply of a drug dispensed on Friday evening should not be exhausted before the prior authorization is requested on Monday morning and a response returned to the requester by the State on Tuesday morning (within 24 hours of a request).

We would allow States to develop a reasonable definition of emergency situations, as long as the definition does not prevent recipients from acquiring medically necessary covered outpatient drugs within the parameters set forth below. We would require in § 447.526(c)(2)(i) that States specify in their State plans the process that will be used to determine what constitutes an emergency situation. Emergency situations may involve immediate and severe adverse consequences or continuation of an immediate and severe adverse consequence if a covered outpatient drug is not dispensed when a prescription is submitted. We would not consider an emergency situation to exist if (1) the lack of a drug supply does not pose an immediate threat to the recipient, or (2) a drug must be prior authorized before it can be dispensed if there is no immediate threat to the recipient.

B. Exclusion or Restriction of Drugs

1. Drugs Subject to Restriction

Section 1905(a)(12) of the Act and regulations at 42 CFR 440.120 define prescribed drugs that may be covered by a State under its Medicaid program. Existing regulations under § 441.25 contain prohibitions on FFP for certain prescribed drugs. Except for covered outpatient drugs defined in section 1927 of the Act, these rules are not affected by the requirements for rebate agreements as a condition of FFP. This proposed rule would implement, in part, the provisions of section 1927(d)(2) of the Act, which specify the specific drugs or classes of drugs that States may exclude or restrict from coverage.

As noted previously in this preamble, section 1927(d)(1)(B) of the Act as amended by OBRA '93 specifies conditions under which a State may exclude or restrict coverage of an outpatient drug under a drug rebate agreement. A State may exclude or restrict a drug if—

- The prescribed use of the drug is not for a medically accepted indication;
- The drug is contained in the list of drugs subject to restriction under section 1927(d)(2) of the Act;
- The drug is subject to restrictions in a separate or existing agreement between a manufacturer and a State agency that has been authorized by HCFA under sections 1927(a)(1) of the Act or in effect in accordance with section 1927(a)(4) of the Act (§ 447.524(b)); or
- The State has excluded coverage of the drug from its formulary established in accordance with the requirements for formularies specified in section 1927(d)(4).

Section 1927(d)(2) limits a State's option to exclude or restrict drugs from coverage under the rebate program to the following drugs, classes of drugs, or their medical uses:

- Agents when used for anorexia, weight loss or weight gain.
- Agents when used to promote fertility.
- Agents when used for cosmetic purposes or hair growth.
- Agents when used for the symptomatic relief of cough or colds.
- Agents when used to promote smoking cessation.
- Prescription vitamins and mineral products, except prenatal vitamins and fluoride preparation.
- Nonprescription drugs.
- Covered outpatient drugs that the manufacturer seeks to require as a condition of sale that associated tests or monitoring services be purchased exclusively from the manufacturer or its designee.
- Barbiturates.
- Benzodiazepines.

We would allow States flexibility in specifying the drugs and medical uses that fall within these descriptions. We do not intend to further identify or define these drugs at this time. We would allow States to exclude or restrict drugs that fall within these descriptions. However, when a drug that is primarily

formulated to treat a medically accepted indication not included on the list set forth in section 1927(d)(2) of the Act is also prescribed for a medical use included in section 1927(d)(2), that use of the drug for the medically accepted indication outside of section 1927(d)(2) would not be excludable. For example, a drug that is primarily formulated to treat asthma or some condition other than coughs and colds should not be excluded for the treatment of asthma. However, a State could prior authorize the drug and exclude or restrict it if the drug is prescribed for a cough or cold in an individual case.

We would require in § 447.524(g) that a State amend its State Medicaid plan to include a list of those drugs or classes of drugs or medical uses under section 1927(d)(2) of the Act that the State is excluding or restricting from coverage. We would also require a State to describe in its plan limitations or conditions of coverage for these drugs. However, we would not require the State to list those drugs for which it requires prior authorization. We would require States to amend their State plans in this manner to ensure that both HCFA and the public are adequately informed of those drugs covered by various State plans.

2. Updating the List of Drugs Subject to Restriction

a. Adding Drugs to the List. In accordance with section 1927(d)(3) of the Act as amended by OBRA '93, the Secretary must periodically update, by regulation, the list of drugs, classes of drugs, or their medical uses subject to restriction under the rebate program if there is evidence of clinical abuse or inappropriate use. Section 1927(d)(3) provides that the Secretary must update the list on the basis of data collected by the State Medicaid agencies' surveillance and utilization review (SUR) programs. We would incorporate this provision in our regulations at § 447.524(d). As necessary, we will announce a proposed updated list in the Federal Register and allow public comment before the list is issued in final.

We request public comments with suggestions on how we should administer a process to determine when a drug, class of drug, or its medical use should be added to the list in section 1927(d)(2) of the Act when the item is subject to clinical abuse or inappropriate use. At a minimum, any suggestions made for the process must take into consideration that we must use SUR data to substantiate any proposal to add an item to the list. In accordance with section 1927(d)(3) of the Act, a SUR report submitted as supporting documentation would need to provide HCFA with the data necessary to make an objective analysis regarding clinical abuse or inappropriate use of an item.

While we currently have reporting requirements for SUR data, we would need to modify them to accommodate the additional information needed to update the list of drugs subject to restriction. These reporting requirements would be addressed in a separate document.

b. Deleting Drugs From the List. Section 1927(d)(3) of the Act provides that the Secretary must ''update'' the list of drugs subject to exclusion or restriction. In this proposed rule, we would interpret this provision to mean that drugs subject to clinical abuse or inappropriate use may be added to the list. However, we do not believe that section 1927(d)(3) allows the Secretary to delete drugs from the list. That list, set forth in section 1927(d)(2) of the Act, represents drugs that, as noted in the Senate Report, are ''commonly subject to exclusion or restriction by State Medicaid programs.'' (136 *Cong. Rec.*, S15658, daily ed. October 18, 1990) The tenor of that report, as with the statute, is that drugs may be added to the list, but that the categories already on the list will remain subject to State restriction.

An example to reinforce this point can be made with paragraph (H) under section 1927(d)(2) of the Act. Paragraph (H) refers to ''covered outpatient drugs that the manufacturer seeks to require as a condition of sale that associated tests or monitoring services be purchased exclusively from the manufacturer or its designee.'' If we were to conclude that we have the authority to remove any drug from the list if it were not subject to clinical abuse or inappropriate use (as noted in section 1927(d)(3) of the Act), and data were available demonstrating that a product was not subject to clinical abuse or inappropriate use, we would have to remove the drug from the list (regardless of any exclusive arrangement) and require all State Medicaid programs to cover the drug. This result would clearly conflict with the statute and with the legislative history. Accordingly, the drugs on the list would be statutorily mandated and could only be deleted from the list by amendments to the statute.

3. DESI and IRS Drugs

a. The DESI Program. Before enactment of the Federal Food, Drug, and Cosmetic Act of 1938, drugs could be marketed in the United States as long as a drug's label did not present false information regarding the drug's strength and purity. The Federal Food, Drug, and Cosmetic Act first established the requirement that a manufacturer has to prove the safety of a drug before the manufacturer could market it in the United States. In accordance with that statute, drugs marketed before the passage of the Federal Food, Drug, and Cosmetic Act were ''grandfathered'' so that manufacturers, if they do not change the representations on the drugs' labels, were allowed to continue to market them unless evidence was developed to indicate that they were not safe (referred to as pre-38 drugs). However, once a manufacturer changed the representation on a pre-38 drug's label, that drug was considered by the FDA to be a ''new drug'' and the manufacturer was required to prove that the drug was safe for its intended use.

In 1962, the Federal Food, Drug, and Cosmetic Act was amended to require that drugs sold in the United States be regulated more closely. Under the provisions of the Drugs Amendments of 1962 (Public Law 87–781), all new drugs must be shown by adequate studies to be both safe and effective before they can be marketed. This legislation also applied retroactively to all drugs approved as safe from 1938 to 1962 (referred to as pre-62 drugs). These pre-62 drugs were permitted to remain on the market while evidence of their effectiveness was reviewed. The program established under which the FDA would review the effectiveness of drugs approved between 1938 and 1962 was named the Drug Efficacy Study Implementation (DESI) program.

If the DESI review indicates a lack of substantial evidence of a drug's effectiveness for all of its labeled indications, the FDA will publish a Notice of Opportunity for a Hearing (NOOH) in the Federal Register concerning its proposal to withdraw approval of the drug for marketing. At that time, a manufacturer of that drug or identical, related, or similar (IRS) drugs has the opportunity to request a hearing and provide FDA with documentation of the effectiveness of the drug product before a final determination is made. Drugs for which a NOOH has been published are referred to as less than effective (LTE) DESI drugs. The IRS drug counterpart of a LTE DESI drug is also considered less than effective. (We note that the terms ''DESI drug'' and ''LTE DESI drug'' are not synonymous.)

If all the labeled indications of the product are found to lack substantial evidence of effectiveness, a withdrawal notice is published in the Federal Register withdrawing approval of the NDA for the product. At that time, shipping this product and any IRS drug product in interstate commerce after the

effective date of the withdrawal notice is unlawful.

If only some of the labeled indications of the product are found to lack substantial evidence of effectiveness, the manufacturer must delete those LTE indications from the drug's label. If a manufacturer does not comply with this requirement, the manufacturer's NDA can be withdrawn by the FDA. All manufacturers of IRS drug products must also revise their labeling and submit an application to the FDA to obtain approval for their product to be allowed to continue marketing their drug.

In accordance with section 1903(i)(5) of the Act, FFP is not available for LTE DESI/IRS drugs for which a NOOH is issued for all labeled indications. Under the drug rebate program, a drug is not considered a covered outpatient drug if a NOOH is issued for some or all labeled indications.

At present, drugs subject to the DESI review process are in various stages of review. The mandatory and optional State coverage requirements and FFP restrictions on these drugs are discussed in section IV.B.3.b. of this preamble. The term ''DESI/IRS drugs'' is used when discussing coverage of a DESI drug and its IRS counterparts.

b. Coverage of DESI/IRS Drugs Under the Medicaid Program. This section describes the general coverage, FFP requirements, and rebate requirements for DESI/IRS drugs. Detailed instructions on how to identify DESI drugs and the roles that HCFA, States, manufacturers, and the FDA play in this process have been sent to the manufacturers and States.

• Non-DESI/IRS Drugs or DESI/IRS Drugs Determined Safe and Effective. Non-DESI/IRS drugs (pre-38 drugs and post-62 drugs) and pre-62 DESI/IRS drugs that have undergone the DESI review process and have been determined by the FDA to be safe and effective for their labeled uses under sections 505 and 507 of the Federal Food, Drug, and Cosmetic Act meet the definition of a covered outpatient drug. Therefore, these drugs of a participating manufacturer must be covered under the drug rebate program and are, therefore, subject to a rebate and FFP.

• DESI/IRS Drugs under Review (No NOOH Issued). DESI/IRS (pre-62 drugs) of participating manufacturers which meet the definition of a covered outpatient drug that are undergoing the DESI review process but for which a NOOH has not been issued must be covered under the rebate program. These drugs include:

+ Drugs described in section 107(c)(3) of the Drug Amendments of 1962 and for which the Secretary has determined there is a compelling justification for its medical need, or is identical, similar, or related to such a drug; and

+ Drugs for which the Secretary has not issued a NOOH under section 505(e) of the Federal Food, Drug, and Cosmetic Act to withdraw approval of an application for such drug under such section because the Secretary has determined that the drug is less than effective for some or all conditions of use prescribed, recommended, or suggested in its labeling.

In other words, a State must cover DESI/IRS drugs of a participating manufacturer for which a NOOH has not been issued for some or all of the drug's labeled indications. FFP is available and the drugs are subject to a rebate. DESI/IRS drugs under this category do not include drugs that have been found to be safe and effective under the DESI review program.

• Less Than Effective (LTE) DESI/IRS Drugs for Some Indications. Section 1903(i)(5) of the Act does not prohibit FFP if a DESI drug is effective for at least one indication. A drug would meet this criterion if a NOOH has been issued for some, but not all, indications. These DESI/IRS drugs may be covered at State option and FFP is available.

For purposes of the rebate program, the definition of a covered outpatient drug in section 1927(k)(2)(A)(iii) of the Act specifically excludes those DESI/IRS drugs for which a NOOH has been issued because the FDA has determined that the drugs are less than effective for some or all of their prescribed recommended uses. However, when these drugs have an FDA-approved, labeled indication for which a NOOH has not been issued, the drug is considered a covered outpatient drug for that indication (and other medically accepted indications). Therefore, these drugs of participating manufacturers must be included in the drug rebate program for their approved indications (and other medically accepted indications) and are subject to a rebate and FFP.

• Less Than Effective (LTE) DESI/IRS Drugs for All Indications. Under section 1903(i)(5) of the Act, FFP is prohibited for DESI drugs for which a NOOH has been issued for all conditions of use prescribed, recommended, or suggested in its labeling. Therefore, if a State chooses to cover these LTE DESI/IRS drugs, FFP is not available. This prohibition was not changed by OBRA '90 and applies regardless of whether the manufacturer is appealing the NOOH for some or all of the drug's indications.

• Less Than Effective DESI/IRS Drugs Withdrawn from the Market. The FDA has determined this group of DESI/IRS drugs to be less than effective and published a NOOH and subsequent withdrawal notice in the Federal Register. Based on these findings, the manufacturer is required to discontinue the distribution of these drug products. However, because the FDA does not institute recalls of these drug products to the retail level, these products may still be available in pharmacies. In any event, under section 1903(i)(5), FFP is not available for these DESI/IRS drugs.

c. Reporting DESI/IRS Drugs. The rebate agreement requires that the manufacturer's list of covered outpatient drugs include the NDC numbers for all drugs currently marketed by the manufacturer. Manufacturers are also required to list the NDC number for a drug that it no longer markets because the manufacturer will be responsible for providing a rebate on the drug until the entire supply of the drug under an NDC has expired, the drug has been taken off the market, or for other reasons, the potential no longer exists that the covered outpatient drug may be dispensed under the manufacturer's NDC number. To comply with these requirements, manufacturers must include on their lists of covered outpatient drugs all DESI/IRS drugs.

Even though some drugs are not subject to the rebate program, manufacturers must report to HCFA the required information for all LTE DESI/IRS drugs. A change from one DESI category to another DESI category, as described in section IV.B.3.b. of this preamble, could change a drug's coverage under Medicaid. For example, LTE DESI/IRS drugs could be potentially covered at some point under the rebate program if the FDA reverses its decision on a NOOH. HCFA must have the baseline pricing data (for single source and innovator multiple source drugs) from October 1, 1990, and for all drugs, the DESI drug indicator, as well as other data, in the event they are covered at a later date.

A manufacturer is responsible for knowing the status of DESI/IRS drugs by reviewing DESI notices published in the Federal Register by the FDA. (See 52 FR 1663 and 1668, January l5, 1987.) Manufacturers must identify in their list of covered outpatient drugs which they submit to HCFA those DESI/IRS drugs that they produce that are the subject of a NOOH.

In accordance with section 1927(b)(3)(C)(ii) of the Act, any manufacturer with an agreement under section 1927 that knowingly provides false information is subject to a civil

money penalty in an amount not to exceed $100,000 for each item of false information. This provision also applies to any manufacturer that knowingly reports false information to HCFA regarding the status of a DESI/IRS drug for coverage purposes. In addition to civil money penalties, the manufacturer may also be subject to termination because it is not in compliance with section 1927 of the Act, the national rebate agreement, and regulations under § 447.534 that specify manufacturer reporting requirements.

C. Amount, Duration, and Scope of Services. Prior to the enactment of OBRA '90, States could establish amount, duration, and scope restrictions on Medicaid services, including prescription drugs. These restrictions could be based on such criteria as medical necessity and utilization control, or could be based on other factors so long as the amount of the services provided was sufficient to ''reasonably achieve its purpose'' (See section 1902(a)(10) of the Act and § 440.230 (Sufficiency of amount, duration, and scope)). States could impose prior authorization restrictions and also limit the number of prescription drugs that they covered through a formulary.

Section 1927 of the Act curtails a State's authority to exclude drugs from coverage and limited its authority to impose prior authorization requirements under section 1927(d)(5). However, the statute did not alter the State's authority to establish amount, duration, and scope restrictions, and, in fact, specifically recognized States' authority to impose additional restrictions on the quantities per prescription and the number of refills. Specifically, section 1927(d)(6) of the Act allows a State to impose restrictions on minimum and maximum quantities of outpatient drugs per prescription and on the number of refills within a therapeutic class to discourage waste. Section 1927(d)(6) also allows a State to impose these limitations and address instances of fraud or abuse by individuals in any manner authorized under the Act.

The legislative history of OBRA '90 indicates that this statutory provision was designed to enhance, not limit or replace, a State's authority to impose reasonable amount, duration, and scope restrictions. The House Report, adopted by the Conference Committee, states that ''States are not prevented from restricting the amount, duration, and scope of coverage of covered outpatient drugs consistent with the need to safeguard against unnecessary utilization.'' (H. R. Conf. Rept. No. 964, 101st Cong., 2nd Sess., 825, 832 (1990)) This statement supports the conclusion that the Congress did not intend to circumscribe a State's authority to impose amount, duration, and scope restrictions. Therefore, in regulations at § 447.524(e), we would specify that a State may continue to impose limitations on the minimum and maximum quantities of drugs per outpatient prescription and the number of prescriptions or dispensing fees allowed per month as it did before the enactment of OBRA '90.

A State, in accordance with section 1927(d)(6) of the Act, may impose coverage restrictions on package sizes of a drug when required to prevent waste. We do not believe that, given the general goals of the drug rebate provisions, Congress intended for States to pay for more expensive package sizes when less costly alternatives exist. Thus, we would permit States to impose coverage restrictions based on the relative economy, or the high cost, of a specific package size. For example, a State may exclude from coverage the unit dose packaging of a particular drug based on its cost; however, such restrictions may be imposed, given the formulary requirements of section 1927(d), only if the manufacturer packages the drug in other sizes which the State covers.

V. Reporting Requirements

Under section 1927(b)(2) of the Act as amended by OBRA '93, States are responsible for providing to the manufacturer Medicaid utilization data for a rebate period regarding the quantity of drugs that they have dispensed after December 31, 1990 for which payment was made under their State plan during a rebate period. Section 1927(b)(3) of the Act requires a manufacturer to supply to HCFA, for each rebate period, information concerning AMP and, as required, best price for its covered outpatient drugs. Rebates are calculated for each rebate period on the basis of this information, as explained in section VI. of this preamble.

A. State Reporting Requirements

Under section 1927(b)(2)(A) of the Act, the State Medicaid agency must provide to manufacturers with drug rebate agreements State drug utilization data regarding the total number of ''units'' of each dosage form, strength, and package size of the manufacturer's drug that were dispensed after December 31, 1990 and paid for under the State plan during a rebate period. In the regulations at § 447.530(a)(2), we would define ''unit'' as the lowest commonly identifiable amount of a drug for example, tablet or capsule for solid dosage form, milliliter for liquid forms, and gram for ointments or creams, as supplied to HCFA in accordance with instructions in the rebate agreement. The use of units with regard to State reporting requirements and rebate calculations is discussed throughout sections V. and VI. of the preamble.

To comply with the provisions of section 1927(b)(2)(A), we would specify in our regulations at § 447.530(b) that States provide Medicaid drug utilization data based on claims paid by the State Medicaid agency during a rebate period.

1. Pharmacy Coding, Oversight, and Audit

To comply with the provisions of section 1927(b)(2)(A) of the Act, and to facilitate uniform reporting, we would require in § 447.530(a)(1) that States report their utilization data by the 11-digit NDC number. We note that FDA's regulations at 21 CFR 207.35 refer to the NDC number as a 10-character code. This code can show leading zeros in any segment of the NDC number. However, for standardization purposes in the drug rebate program, we are using a consistent 11-digit code that reflects leading zeros and the maximum number of digits that can appear in each segment of the NDC code.

We are recommending that, in order to implement these provisions in the most efficient and cost-effective manner, State Medicaid agencies identify for pharmacies certain information, as discussed below, that will enable them to determine those drugs that are covered under a State plan. The State should make available to pharmacies information concerning the labeler codes of manufacturers with rebate agreements; drugs under section 1927(d) of the Act that are excluded or restricted from coverage and the limitations or conditions of coverage; and drugs that are subject to prior authorization.

For purposes of this regulation, the term ''pharmacy'' applies to any entity authorized by the State to dispense covered outpatient drugs in that State. Thus, these requirements will be binding on all dispensers of covered outpatient drugs to Medicaid recipients.

The State agency may establish its own policies to ensure accurate pharmacy coding. However, we would require the agency to establish and implement an oversight and auditing process to ensure proper pharmacy coding and reporting practices. We would also require States to establish and implement procedures for investigating allegations of erroneous utilization data at the pharmacy level by participating manufacturers or other

interested parties (§ 447.530(e) (2) and (3)). We would require State agencies to establish procedures to comply with section 1927(b)(2)(B) of the Act, which gives manufacturers the authority to audit State data. The agency would also be responsible for taking the actions necessary to ensure accurate coding (§ 447.530(e)(4)).

We believe these requirements regarding accurate pharmacy coding are necessary to effectuate OBRA '90 drug rebate provisions. Accurate pharmacy coding is a fundamental and critical component of the Medicaid drug rebate program under section 1927 of the Act. Without these requirements, pharmacies may use incorrect NDC numbers when billing the Medicaid State agencies, which could result in numerous problems.

Use of incorrect NDC numbers could have a detrimental effect that would carry through the entire drug rebate process. First, pharmacies could bill States for a brand name drug although a generic drug was dispensed, resulting in overpayments to pharmacies, increased drug costs, and erroneous utilization data. If pharmacies substitute the NDC numbers of one manufacturer for another, even if the drugs cost the same amount, the Medicaid utilization data would be flawed. Secondly, flawed data would cause the States to invoice manufacturers for erroneous rebates, resulting in over and under billing for rebates. Thirdly, erroneous data may increase the likelihood that manufacturers would dispute the data and withhold rebate payments to States. Thus, inaccurate pharmacy coding would increase a State's dispute resolution workload, delay rebate payments, and cause interest to accrue on unpaid amounts. The dispute resolution process is an expensive, lengthy, and resource-intensive process for all parties involved.

In addition to disputing the data, manufacturers may, in accordance with section 1927(b)(2)(B) of the Act, audit the drug utilization data provided (or required to be provided) by the State. A manufacturer could also request a State to audit a pharmacy, which is also expensive and resource intensive. Because of the magnitude of the problems and costs inaccurate pharmacy coding can cause, we believe the requirements discussed above are necessary to properly and efficiently effectuate the drug rebate program requirements in OBRA '90.

Therefore, we would require in § 447.530(e)(1) that the State must inform pharmacies that they are required to use accurate NDC numbers for the drugs dispensed in submitting their Medicaid claims and that payment can be denied for a drug that has been inaccurately coded by a pharmacy. States may consider inaccurate coding to be good cause for terminating provider agreements subject to applicable Federal and State laws. Also, under anti-fraud provisions, pharmacy claims with incorrect NDC numbers may subject these pharmacies to criminal or civil money penalties, as well as exclusion from the Medicare and Medicaid programs.

States must implement the requirements of § 447.530(e) within 60 days after publication of the final rule. We believe this timeframe is adequate for establishing procedures to ensure accurate pharmacy coding since we informed States of these requirements in mid-1991. We are aware that many States have since established procedures to ensure accurate pharmacy coding. States that do not ensure accurate pharmacy coding may be considered to be out of compliance with section 1927 of the Act and, therefore, subject to compliance proceedings. In addition to effectuating OBRA '90 drug rebate provisions, we believe these pharmacy coding requirements are essential to comply with section 1902(a)(30) of the Act. Section 1902(a)(30) generally provides that methods and procedures relating to the utilization and payment of services under the State plan safeguard against unnecessary utilization and to ensure that payments are consistent with efficiency, economy and quality of care.

In accordance with section 1927(b)(2)(B) of the Act, a manufacturer may audit the drug utilization data provided (or required to be provided) by the State. If the information indicates that utilization was greater or less than the amount previously specified, adjustments to the rebates must be made on the next quarterly report submitted by the State. All corrections must be applied to the quarter for which utilization data are adjusted. If the adjustments result in a manufacturer owing an additional rebate amount, the manufacturer must include that amount, plus interest, in the rebate payment for next rebate period.

Since the statute permits manufacturers to audit drug utilization data but does not authorize manufacturers to directly audit pharmacies, we would require States to have procedures to investigate manufacturers' allegations of erroneous utilization data produced at the pharmacy level. If the State agrees to such a request, it may apply a process that uses a sampling methodology to audit pharmacies in a targeted area where erroneous data are believed to be occurring, or by other means that will address the alleged problem. Given the large volume of Medicaid drug claims, we believe a targeted sampling of pharmacies and their claims is a reliable method to discover inaccurate coding and billing practices, especially when targeted for specific drugs. Doing otherwise could prove costly for States without providing a significant amount of additional information. If erroneous data are discovered, a State could expand the audit to determine the severity of inaccurate billing practices.

An audit may be performed at any time throughout the dispute resolution process. However, both parties must agree to the audit and develop mutually agreeable audit procedures. (Section V.F. of this preamble contains a discussion of dispute resolution.)

2. Format and Contents of Report

Section 1927(b)(2)(A) of the Act requires that the Secretary establish a standard reporting format that States must use to report drug utilization data to manufacturers and to HCFA. Using this standard reporting format, States must identify drugs by manufacturer to ensure that the proper rebates are paid. As indicated earlier, we selected the NDC number that identifies each drug by manufacturer, product, and package size as part of the standard reporting format to be used throughout the rebate program.

We have issued, through the rebate agreement and a notice published in the Federal Register on May 1, 1991 (56 FR 20006), the standard reporting format for States to use in reporting for the rebate period to HCFA and manufacturers. We have also issued subsequent letters to State Medicaid Directors containing instructions to provide additional guidance in using the reporting format. This standard reporting format includes the following information:

- State identification;
- Rebate period and year for which data apply;
- NDC number to identify labeler code, product code, and package size code;
- Total number of units paid for during the rebate period for each NDC;
- FDA registration name to provide a cross-check for the product code;
- Total amount of rebate that a State claims for each NDC;
- Number of prescriptions reimbursed by NDC;
- Rebate amount per unit and total reimbursement amount to verify manufacturer's payment; and

• A correction record flag to alert HCFA of a change or correction from a previous report.

These data elements will be updated through separate instructions as needed to further program objectives in this area. We would incorporate in the regulations at § 447.530(a) through (d) the basic reporting requirements and timeframes. HCFA instructions will provide guidelines for States to use when reporting utilization data.

3. Timeframe for State Reporting of Utilization Data

In accordance with section 1927(b)(2)(A) of the Act, we would require in § 447.530(c) that each State Medicaid agency report drug utilization data to HCFA and the manufacturer no later than 60 days after the end of each rebate period. The data for the first rebate period (January-March 1991) were originally due to HCFA and the manufacturer on May 30, 1991. However, since the Secretary had not developed a standard reporting format, we extended the May 30, 1991, deadline to July 30, 1991, for States to submit data to HCFA and the manufacturer. This delay resulted, in part, from a lack of either baseline and/or first rebate period data from many of the manufacturers, including the majority that joined the rebate program during the extension period to April 30, 1991. We believe the extension alleviated the need for States to send to HCFA and manufacturers multiple updates of corrected data, prevented disputes on partial data, and allowed for smoother implementation of the drug rebate program.

States should mail the utilization data to manufacturers in a form that will provide evidence of the date the data were received by the manufacturers. Manufacturers must pay rebates for each rebate period or provide a written notice of disputed utilization data by the 30th day after receipt of State utilization data. Evidence of the date received is important so that States can accurately determine when rebate payments are due, when interest begins accruing on any unpaid balances, and when the interest period begins for purposes of the dispute resolution process. (Section V.F.4. of this preamble contains a discussion of the interest provision.)

4. Effect of Timeliness of State Utilization Data on Payment of Rebates

Section 1927(b)(2)(A) of the Act provides that a State Medicaid agency shall report rebate period information on the drugs dispensed and paid for to each manufacturer not later than 60 days after the end of each rebate period and in a form consistent with a standard reporting format established by the Secretary. As noted previously in section V.A. of this preamble, we would specify in regulations that States provide Medicaid drug utilization data based on claims paid by the State during a rebate period. However, we believe circumstances could arise that prevent States from being able to generate Medicaid utilization information in the standard reporting format to meet this 60-day deadline. While the statute requires States to meet this 60-day requirement, we do not believe the statute relieves manufacturers from the obligation of paying rebates if States cannot meet the requirement. States do not have an incentive to submit late rebate claims to manufacturers since they are losing revenue by doing so. While processing late rebate claims may be an inconvenient administrative task for manufacturers, manufacturers have the advantage, in this case, by having access to these rebate funds which should have been paid to the State had the State submitted the data within the specified timeframe.

Thus, we realize that we must establish a maximum timeframe during which the manufacturer is bound to pay rebates on all drugs sold to Medicaid recipients. We would, therefore, establish a maximum time limit of 1 year from the end of a rebate period for States to bill a manufacturer for a rebate. However, if a State submits claims later than the required 60-day period, the State can only bill the manufacturer for the rebate amount that would have been due during the rebate period in which the State paid the drug claim. Consequently, we would specify in regulations at § 447.530(c) that the manufacturer is not required to pay a rebate on its drugs when a State does not submit its rebate period utilization data to the manufacturer within 1 year after the rebate period ended.

We believe this 1-year timeframe meets the needs of both States and manufacturers and is equitable because it parallels the maximum 1-year timeframe for providers' and States' responsibilities. Other Medicaid provisions allow a maximum timeframe of 1 year for pharmacies to submit claims and up to 1 year for States to pay claims (42 CFR 447.45(d)). A State would not lose rebates on those drugs for which it cannot compile the data within 60 days, and a manufacturer would not be held liable for rebates for an extensive period of time due to a State's failure to report utilization data within 60 days. As a general matter, HCFA will not find a State to be out of compliance if its utilization data are submitted to the manufacturer within this 1-year timeframe.

We consider any time period longer than 1 year after the rebate period ended to be extensive since this period could ultimately translate into a manufacturer being responsible for rebates for more than 3 years after the drug is dispensed. In accordance with § 447.45, pharmacies have up to 1 year to bill the State agency for drugs dispensed to Medicaid recipients, and States could take as long as 1 year to pay a drug claim. Thus, these two processing timeframes and the 1-year cutoff total 3 years. This 3-year time period also comports with general business principles. The Internal Revenue Service generally requires that records be maintained for 3 years unless they are involved in some type of action requiring their use. Manufacturers may not be able to substantiate rebate claims for more than 3 years after a drug is dispensed since they are not required to maintain records for more than 3 years. Adding more disputes to the resolution process for data where no records may exist is not, in our opinion, a cost effective or efficient manner of operating the drug rebate program. Thus, we believe this 1-year threshold for States to submit utilization data to manufacturers is reasonable and consistent with the drug rebate provisions of section 1927 of the Act and necessary to effectuate the OBRA '90 drug rebate provisions.

States that lose rebates required under section 1927 of the Act for failure to submit rebate period utilization data to manufacturers within 1 year after the rebate period ended may be considered out of compliance with section 1927. Therefore, HCFA could initiate a compliance action against a State if it fails to collect rebates to reduce the amount expended under their State plan for medical assistance (§ 447.530(c)).

5. Data Edits on State Utilization Data

As discussed in section V.A.2. of this preamble, States are required, under section 1927(b)(2)(A) of the Act, to submit drug utilization data to manufacturers in a format established by HCFA. Since the accuracy of the invoiced rebates is dependent upon the reliability of the State utilization data, we would require States to establish a system of edits to its Medicaid utilization information. These edits must be performed before the State submits it utilization data to the manufacturer. The data reports generated from these edits will not be disclosed to the manufacturer but will be used to verify the accuracy of the information disclosed. We believe this requirement is necessary to effectuate

the OBRA '90 drug rebate provisions and to prevent unnecessary disputes between States and manufacturers that delay the timely payment of rebates.

The types of edits described in this section are intended to verify the accuracy of the Medicaid utilization information by examining whether:

- The unit types claimed are appropriate for NDC number claimed;
- The units claimed match the amount paid by the State; and
- The amount paid by the State is an amount allowable for the NDC (for example, a brand name payment amount was not made for a generic drug or the opposite).

We believe that, by verifying the accuracy of such items described in this section before submitting the information to the manufacturer, the State will identify inconsistencies, correct them, and reduce the number of subsequent disputes. The State must submit the utilization data to the manufacturer within the timeframes contained in § 447.530(c), as described in sections V.A.3. and V.A.4. of this preamble, and only after the State has performed the types of edits described in § 447.530(f) and believes the data are accurate.

The requirement in § 447.530(f) for State edits on Medicaid utilization information would be effective 60 days following publication of the final rule. That is, State data submitted to manufacturers for that rebate period must have been verified through the use of system edits.

6. Use of Rounding Indicator

We also would establish the requirement in § 447.530(g) that States must identify by NDC number those drugs for which the number of units has been rounded by showing a rounding indicator for the number of units dispensed. States must include this information in their rebate period Medicaid utilization information submitted to the manufacturers. We have determined that this requirement is necessary since some pharmacies lack the ability to report decimal quantities in the Medicaid utilization information and, thus, in accordance with accepted industry standards, round up decimal quantities to the nearest whole unit. This practice can result in manufacturers being sent inflated utilization data or lead to disputes over the number of units billed.

We believe this requirement is necessary to effectuate the OBRA '90 drug rebate provisions and to prevent unnecessary disputes between States and manufacturers which delay the timely payment of rebates. We would, therefore, require States to indicate in the appropriate data field whether or not the number of units reported in the Medicaid utilization information has been rounded. This indicator will alert the manufacturer that a rounding adjustment factor has been applied to appropriately deflate the State's utilization data.

The requirement in § 447.530(g) for States to use the rounding indicator would be effective 60 days following publication of the final rule. That is, State data submitted to manufacturers for that rebate period must include the rounding indicator field and the number of units billed. We will provide separate instructions to the States and manufacturers regarding the use of the rounding indicator.

7. Rebate Tolerance Limits for Invoicing

Many States have informed us that the costs of preparing an invoice for drug rebates can often exceed the amount of a minimal rebate. For instance, some States have spent $50 preparing an invoice for a $5 rebate. We believe that if administrative costs are more than the rebates, the State should not expend its resources to collect a rebate that reduces State savings. Thus, to effectuate the OBRA '90 drug rebate provisions in the most efficient manner, we would establish a rebate tolerance limit for States to use in determining whether it should bill a manufacturer for a rebate when the administrative expense exceeds the rebate savings.

Generally, if the rebate amount due per labeler code is less than the administrative costs associated with preparing the invoice and collecting the rebate, the State should not invoice the labeler for that rebate amount. We have determined that a maximum tolerance of $50 per rebate period would be acceptable if State-supplied information establishes this as the reasonable cost of preparing a labeler's utilization data. In situations where the tolerance is applied, the State need not invoice the manufacturer, although it is free to establish its own tolerance below $50 and continue to submit utilization data above that tolerance. (We note that, in either event, the unit rebate amount must have been supplied by HCFA for all of that manufacturer's drugs in that rebate period and the State applied that unit rebate amount to its utilization data. If the manufacturer fails to supply pricing information for a drug, the unit rebate amount would be zero or missing from the HCFA pricing file. In this case, the tolerance would not apply.) Further, the State would not be at risk of loss of FFP on that portion of the uncollected rebates within the tolerance limits.

The State should maintain supporting documentation that identifies the instances when the tolerance levels were applied. We believe our policy promotes efficiency by allowing States the authority to pursue only those rebate amounts that exceed the States' administrative costs associated with those rebate amounts. Our policy also alleviates States' concern that they may be liable for the Federal share of those rebates that are within the tolerance limits.

B. Reporting Requirements for Manufacturers

Section 1927(b)(3)(A) of the Act requires manufacturers to supply drug pricing information to HCFA. In addition to pricing data, we would require manufacturers to complete and submit to States Form HCFA–304, the Medicaid Remittance Advice Report (RAR), within 30 days of receiving State Medicaid utilization information. The RAR has been approved by OMB prior to publication of this proposed regulation (OMB approval No. 0983–0676). The basis and timeframes for meeting this requirement, as well as what information is required on the RAR, are discussed below.

1. Timeframes for Reporting

Under the terms of the statute and the national rebate agreement, manufacturers must supply HCFA with a list of all covered outpatient drugs, the applicable baseline AMP, and, for single source and innovator multiple source drugs, best price within 30 calendar days of entering into the national rebate agreement. Manufacturers must update the list for each rebate period under the agreement to include AMP and, as appropriate, best price of drugs (both terms are discussed more fully below) and must report the update to HCFA no later than 30 days after the last day of each rebate period. We would incorporate these requirements in the regulations under § 447.534 (a) and (b).

In accordance with the dispute resolution process described in section V.F. of this preamble, and as set forth in regulations under § 447.536(b), we would require manufacturers to complete and submit to States the RAR within 30 days of receiving a State's Medicaid utilization information. We believe this requirement is necessary to effectuate the drug rebate provisions in OBRA '90, and to aid in the timely resolution of disputes and the timely payment of rebates.

2. Content of Reporting

a. Manufacturer Reporting Requirements to HCFA. Section

1927(b)(3)(A)(i) of the Act requires that the manufacturer's list of covered outpatient drugs submitted under the rebate agreement must be updated by the manufacturer on a rebate period basis to include the AMP and, for single source drugs and innovator multiple source drugs, the manufacturer's best price.

(1) Definition of Average Manufacturer Price (AMP). As stated earlier, under section 1927(k)(1) of the Act, AMP means, with respect to a rebate period, the average unit price paid to the manufacturer for the drug in the States by wholesalers for drugs distributed to the retail pharmacy class of trade after deducting customary prompt pay discounts. We would incorporate the definition of AMP in § 447.534(c). Under this definition, sales that a manufacturer makes to other than the retail class of trade must be excluded. Thus, sales where the buyer relabels or repackages the drug with another NDC number and sales through wholesalers where the manufacturer pays a chargeback for sales to an excluded buyer, such as a hospital, would not be considered sales to the retail class of trade.

We would also exclude from this definition direct sales to hospitals, health maintenance organizations and to distributors where the drug is relabeled under that distributor's NDC number because these entities are not considered the retail pharmacy class of trade. We would also exclude Federal Supply Schedule (FSS) prices from the calculations of AMP since the statute does not include FSS and FSS does not represent a retail level of trade.

We have interpreted AMP to include cash discounts and all other price reductions and customary prompt pay discounts (other than rebates under section 1927 of the Act) that reduce the actual price paid. This definition comports with the statute and HCFA's understanding of Congressional intent as set forth in the legislative history. (H.R. Conf. Rept. No. 964, 101st Cong., 2nd Sess. 825 (1990).)

The manufacturer must calculate AMP as a weighted average price for all of its package sizes for each covered outpatient drug sold during that rebate period but only report a single AMP for the weighted average. AMP must be calculated as net sales divided by number of units sold, excluding goods or any other items given away that are not contingent on any purchase requirements. For bundled sales, the allocation of the discount is made proportionately to the dollar value of the units of each drug sold under the bundled arrangement. In this context, bundled sale refers to the packaging of drugs of different product codes where the condition of rebate or discount is that more than one drug is purchased, or where the resulting discount or rebate is greater than that which would have been received had the drug products been purchased separately. Because we are defining the AMP to include cash discounts allowed and all other price reductions, we would require in § 447.534(c)(5) that the manufacturer adjust the AMP for a rebate period if cumulative discounts or other arrangements subsequently adjust the prices actually realized.

(2) Definition of Best Price. We have interpreted ''best price,'' as defined in section 1927(c)(1)(C) of the Act, to mean, with respect to single source and innovator multiple source drugs, the lowest price at which the manufacturer sells the covered outpatient drug to any purchaser (as discussed later in this section of the preamble) in the United States (excluding the Territories). We would further interpret best price at § 447.534(d) to mean the lowest price in any pricing structure (including capitated payments) in the same rebate period for which the AMP is computed.

The best price must include cash discounts, free goods that are contingent on any purchase requirements, volume discounts, and rebates other than rebates under section 1927 of the Act. Best price must be determined on a unit basis without regard to special packaging, labeling, or identifiers on the dosage form or product or package, and will not take into account prices that are nominal in amount (that is, less than 10 percent of AMP). Unlike AMP, the best price is the single lowest price of the drug at the product code level during the rebate period and is not a weighted average.

For bundled sales, the allocation of the discounts is made proportionately to the dollar value of the units of each drug sold under the bundled arrangement. We would require the manufacturer to adjust the best price for a rebate period if cumulative discounts, rebates, or other arrangements subsequently adjust the prices actually realized. We believe this is consistent with our understanding of the statute and the Congress' desire that the Medicaid program benefit from the same discounts available to other bulk purchasers.

OBRA '93 amended section 1927(c)(1)(C) of the Act by adding to the definition of ''best price'' providers and health maintenance organizations (HMOs) as entities included in the best price calculation. This reflects our existing policy in this area as the result of OBRA '90. The best price reflects any price of a manufacturer except those prices specifically exempted by the law. For purposes of best price we interpret ''provider'' to mean a physician, hospital and other health maintenance organizations or entities that treat individuals for illnesses and injuries or provide services or items in the provision of health care.

OBRA '93 amended section 1927(k)(3) to specify that any drug, biological, or insulin excluded from the definition of covered outpatient drug as a result of section 1927(k)(3) must be treated as a covered outpatient drug for the purpose of determining the drug's best price. That is, any prices offered to the entities listed in section 1927(k)(3) of the Act must be included in a manufacturer's best price calculation even though drugs provided as part of these settings are not considered covered outpatient drugs.

Because of legislative changes, best price varies over time regarding the prices that are included and excluded from its definition. To identify these variances, we have separated them into the specific time periods.

(a) *Best Price Definition Effective January 1, 1991–October 27, 1991 and July 1, 1992–September 30, 1992.* For these periods, best price includes prices to wholesalers, retailers, providers, HMOs, nonprofit entities or governmental entities within the States (excluding depot prices and single-award contract prices of any agency of the Federal Government). ''Depot prices'' mean prices available to any depot of the Federal Government for purchase of drugs from a manufacturer through the depot system of procurement, irrespective of whether the drug products physically flow through the depot. ''Depot'' means any Federal warehousing facility and distribution arrangement whether: (1) Government owned and operated; (2) government owned and privately operated; or (3) privately owned and operated. The Department of Defense's (DOD's) Electronic Commerce Initiative (ECI), which is an electronic ordering system that ships drugs directly to Federal Government medical facilities that were previously shipped through the depot system, is included in this definition. ''Single-award contract prices'' mean prices under a contract between the Federal Government and a manufacturer resulting in a single supplier for a covered outpatient drug within a class of drugs.

Given the definition of best price provided in section 1927(c)(1)(C) of the Act, it is our opinion that the FSS prices must be included in the best price calculation for these periods, since FSS

prices are neither depot nor single award prices, which are the only statutory exclusions relative to best price. Since prices for drugs and biologicals that are either paid by the DVA or in contracts administered by the DVA are listed in the FSS, these prices must also be included in the best price calculation for these periods.

(b) Best Price Definition Effective October 28, 1991–June 30, 1992. For this period, best price includes prices to wholesalers, retailers, providers, HMOs, nonprofit entities, governmental entities within the States (excluding depot prices and single-award contract prices of any agency of the Federal Government). The Department of Veterans Affairs Appropriations Act (Public Law 102–139), enacted on October 28, 1991, provides that effective October 28, 1991, through either June 30, 1992, or the date of enactment of other DVA drug price legislation, whichever is earlier, prices for drugs and biologicals paid by the DVA, and drugs and biologicals sold under contracts administered by that Department that are listed in the FSS, shall not be considered in the Medicaid drug rebate calculation. Therefore, for the period October 28, 1991, through June 30, 1992, the definition of best price excludes FSS prices for drugs and biologicals paid by the DVA and drugs and biologicals sold under contracts administered by that Department that are listed in the FSS. (Note: In accordance with this legislation, manufacturers must reflect any sales of drugs or biologicals to the DVA or of drugs and biologicals sold under contracts with that Department that are listed in the FSS during the period of October 1, 1991, through October 27, 1991, in their best price for the fourth quarter of 1991 and again beginning in the rebate period starting July 1, 1992.)

(c) Best Price Definition Effective October 1, 1992. Beginning October 1, 1992, best price includes prices to wholesalers, retailers, providers, HMOs, nonprofit entities or governmental entities within the States (excluding depot prices and single award contract prices of any agency of the Federal Government). The Veterans Health Care Act broadened the exclusions from best price effective October 1, 1992. Section 601(a) of VHCA amends section 1927(c)(1)(C) of the Act to exclude from best price any prices charged on or after October 1, 1992, to the Indian Health Service, the DVA, a State home receiving funds under section 1741 of title 38 of the United States Code, the Department of Defense, the Public Health Services, or a covered entity described in section 1927(a)(5)(B) of the Act; any prices charged under the FSS of the General Services Administration; or any prices used under a State pharmaceutical assistance program. Best price excludes depot prices and single-award contract prices of any agency of the Federal Government.

(3) Requirements for the List of Covered Outpatient Drugs. We would require that the manufacturer's list of covered outpatient drugs include the NDC numbers for all drugs currently marketed by the manufacturer and continue to list the NDC numbers for drugs that are no longer marketed until such time as it is no longer possible for a State Medicaid agency to properly make payment for the drug and report this payment to the manufacturer. We would require that a manufacturer continue to list an NDC number for a drug that it no longer markets because the manufacturer will be responsible for providing a rebate on the drug until the entire supply of the drug under an NDC has expired, the drug has been taken off the market, or, for other reasons, there no longer exists the potential that the drug may be dispensed under the manufacturer's NDC number (for example, the FDA recalls the drug or reverses its approval on an approved NDA). In addition, since the manufacturer must pay the rebate on State utilization data for up to 1 year after the rebate period in which the data are submitted (as discussed in section V.A.4. of this preamble), the manufacturer must continue to report the data during this period. A rebate would be calculated on drugs that are no longer marketed using the AMP and best price from the last rebate period reported for those drugs (§ 447.534(b)).

In accordance with the provisions of the rebate agreement and the May 1, 1991, Federal Register notice (56 FR 20006), and to implement the drug rebate provisions of OBRA '90, we would require the manufacturer to supply the following information:

- NDC number with labeler code, product code, and package size code;
- Period covered for rebates (rebate period and year);
- Product FDA registration name;
- Drug category of single source, innovator multiple source, or noninnovator multiple source;
- DESI drug indicator;
- FDA therapeutic equivalence explanation code;
- Unit type;
- Units per package size;
- Average manufacturer price (AMP);
- Base date AMP;
- Best price;
- FDA approval date;
- Date drug entered market;
- Drug termination date;
- Drug type (Rx/OTC indicator);
- Rounding adjustment factor; and
- Correction record flag.

The above information is needed to meet the requirements set out in section 1927 of the Act. To calculate the rebate amounts required for each manufacturer under section 1927(c) of the Act, we need specific information to identify the manufacturers, drugs, prices, number of units sold, and the time period covered. The drug category is used to determine which rebate calculation to apply. The FDA approval date and the date the drug entered the market are necessary to determine baseline AMP for drugs approved by the FDA after October 1, 1990. The drug termination date is necessary to avoid making payment for a drug that is no longer on the market. The FDA registration name, DESI drug indicator, FDA therapeutic equivalence code, and the drug type indicate whether the drug meets the definition of a covered outpatient drug in sections 1927(k)(2) and (4) of the Act, and allow States to properly exclude drugs under section 1927(d)(2) of the Act. The rounding adjustment factor is supplied for drugs sold in decimal quantities and is used by a State when the quantity of a drug has been rounded up. The correction flag signals that the record contains corrected information from a previous submission.

(4) Rounding Adjustment Factor. We would establish a requirement that manufacturers include a rounding adjustment factor for those drugs sold in decimal quantity sizes, for example, a 1.4 gram of ointment. We have determined that this requirement is necessary to effectuate the OBRA '90 drug rebate provisions because, as described in section V.A.6. of this preamble, some pharmacies lack the capability to report decimal quantities of drugs to the State agencies. In this situation, the pharmacy rounds the utilization data upward so that a 1.4-gram tube is reported as a 2-gram tube. Rounding up is the pharmacy industry standard and is a common practice in all States that round decimal quantities of drug utilization data. Since, in this case, the rebate amount is calculated on a unit basis of grams, the manufacturer may be invoiced for an excessive rebate amount. Thus, the use of a rounding adjustment factor can reduce the amount of disputes for decimal quantity packages. Therefore, we would require manufacturers to provide a rounding adjustment factor for each of their rebate period pricing data submitted to HCFA for those drugs sold in decimal quantities.

As described in section V.A.6. of this preamble, we would also require States to identify for manufacturers those utilization data by NDC number that have been rounded. Therefore, HCFA will submit the rounding adjustment factors to the States with the rebate period unit rebate amount information. This will enable States that round decimal quantity packages to apply the rounding factor to its data before submitting utilization data to the manufacturer. Such data will help ensure that rebates are an accurate reflection of the units paid during a rebate period.

We will issue specific program instructions to States and manufacturers regarding the use of the rounding adjustment factor.

The requirements for reporting the rounding adjustment factor for manufacturers and the requirements for States to identify rounded utilization data with the rounding indicator, as described in section V.A.6. of this preamble, would be effective 60 days following publication of the final rule. That is, the rebate period pricing data submitted to HCFA by manufacturers for that rebate period must include the rounding adjustment factor for those applicable NDCs. We believe this allows sufficient time for manufacturers and States to implement the rounding requirements.

As stated earlier, section 1927(b)(3)(A)(i) of the Act requires that the manufacturer's list of covered outpatient drugs submitted under the rebate agreement be updated by the manufacturer on a rebate period basis to include the AMP and, for single source drugs and innovator multiple source drugs, the manufacturer's best price. We will issue program instructions to manufacturers to update the data elements, as needed, to further program objectives in this area.

b. Manufacturer Reporting Requirements to States. We would require manufacturers to complete and submit to States Form HCFA–304, the Medicaid Remittance Advice Report (RAR). The RAR has been approved by OMB prior to publication of this proposed regulation (OMB approval No. 0938–0676). The RAR is a mandatory form that provides a uniform format for manufacturers to report the remittance of rebate payments to States, adjustments to previous rebate period payments, and disputed rebate amounts. The RAR is available in two formats, electronic and paper, depending on the preference of the manufacturer. Each participating manufacturer would be required to complete and submit the RAR to States within 30 days of receiving State Medicaid drug utilization information. In addition to reporting regular rebate period rebates and disputed amounts, manufacturers would use the RAR on an unscheduled basis when the States need the RAR to process adjustments to prior periods. The regulations pertaining to the RAR are found in §§ 447.534(f) and 447.536(b).

HCFA developed the RAR in response to a need for improved data exchange between manufacturers and States. In order to develop the RAR to meet the needs of both manufacturers and States, HCFA convened several dispute resolution conferences beginning in February 1992. These conferences were attended by groups representing manufacturers, pharmacists, States and HCFA. HCFA received suggestions from these groups to help develop a uniform reconciliation report to improve data exchange between manufacturers and States, to enable States to verify rebate payments, and to provide a vehicle for manufacturers to identify specific disputed amounts. HCFA considered these suggestions in preparing the final version of the RAR.

The RAR will function as a reconciliation report with the intent of reducing disputes by standardizing data exchange and improving communication between manufacturers and States regarding Medicaid utilization data, rebates, adjustments, and disputes. For these reasons, we have determined that the requirement for the completion and submission of the RAR is necessary to effectuate the OBRA '90 drug rebate provisions and to provide for the efficient administration and function of the Medicaid drug rebate program as required under section 1927 of the Act.

The RAR includes the following information:

- Manufacturer name;
- Labeler code;
- Manufacturer address;
- Name of manufacturer contact person;
- Telephone number of contact person;
- Facsimile (FAX) number of contact person;
- State;
- Rebate period and year for which the information applies;
- Invoice number, if State provided one;
- NDC number;
- Product name;
- Rebate amount per unit;
- Units invoiced;
- Rebate amount invoiced;
- Rebate amount paid;
- Adjusted rebate per unit, if applicable;
- Adjustment code, if applicable;
- Credit/debit indicator, if applicable;
- Adjusted invoice amount, if applicable;
- Units disputed, if applicable;
- Dispute code, if applicable;
- Withheld invoice amount, if applicable;
- Total rebate amount invoiced;
- Total rebate amount paid;
- Total adjusted invoice amount, if applicable; and
- Total withheld invoice amount, if applicable.

These data elements will be updated, as needed, through separate instructions to further program objectives in this area. We would incorporate the basic reporting requirements and timeframes in our regulations at § 447.534(f).

We believe the above information is needed for the State to identify and verify rebates per NDC and reconcile any disputed amounts as a result of the requirements set forth in section 1927 of the Act and these regulations. We further believe the information is necessary for HCFA to more accurately monitor the operation of the drug rebate program. To verify the rebate amounts paid as calculated under section 1927(c) of the Act, or to reconcile any disputed amounts, it is essential that the information contained in the RAR identify the manufacturers, drugs by NDCs, rebate amounts per units, units invoiced, rebate amounts invoiced, and rebate amounts paid, as well as any adjusted rebate amounts, reasons for any adjustments, units disputed, reasons for any disputed amounts, and any withheld invoice amounts, if applicable. We would also require that manufacturers separately report supporting documentation if a State requests it to verify the information contained on the RAR.

c. Prior Period Adjustments. A prior period adjustment is a change in the unit rebate amount based on a manufacturer's revised AMP or best price data for a prior rebate period after that rebate period's pricing data has been submitted to HCFA. HCFA uses the manufacturer's pricing data to generate the unit rebate amount for each 9-digit NDC which States use to calculate rebate amounts due from manufacturers. Any changes to a manufacturer's AMP or best price result in changes to the unit rebate amount and rebates due from the manufacturer. Thus, prior period adjustments are necessary to correct rebate amounts that are owed by manufacturers or credits due to manufacturers.

We would establish a time limitation of 3 years during which prior period adjustments will be generated based on

revised AMP or best price data from manufacturers. Therefore, we would require manufacturers to report changes to AMP or best price for 3 years after the rebate period to which the data pertains (§ 447.334(h)). No prior period adjustments will be generated for a quarter more than 12 quarters prior to the current quarter. For example:

(1) No prior period adjustment pertaining to the rebate period ending December 31, 1991, may be generated after December 31, 1994.

(2) All prior period adjustments pertaining the rebate period ending June 30, 1992, must be generated prior to July 1, 1995.

We believe this 3-year timeframe is reasonable since it is consistent with the record retention requirements we would establish under § 447.534(g)(1). That is, we would require manufacturers to retain records (written or electronic) for 3 years after the date the manufacturer reports its rebate period AMP or best price. This 3-year time-frame also comports with the requirements for the maintenance of records on State Medicaid expenditures imposed on States. (See section V.C. of the preamble for a discussion of the record retention requirements.)

The 3-year timeframe during which manufacturers must report changes to AMP or best price parallels the record retention period and the possible corrective actions from audits during this 3-year period. During this timeframe, a manufacturer's records on the drug rebate program could be audited with findings that result in an adjustment of pricing information and rebate payments. Thus, any changes to AMP or best price should also be required during this 3-year timeframe.

After States receive prior period adjustments from HCFA on the quarterly pricing file, States should calculate the difference between the original and revised unit rebate amounts and adjust the rebate amounts due from or credited to manufacturers.

We note that changes to the unit rebate amount from prior period adjustments cannot be disputed by manufacturers nor handled through the normal dispute resolution mechanism because this information is reported by manufacturers to HCFA. Any discrepancies in the unit rebate amounts should be reported to HCFA for clarification and resolution. HCFA will review all pricing information changes that result in a revised unit rebate amount.

C. Recordkeeping Requirements

1. AMP and Best Price Calculations

Section 1927(b)(3)(B) of the Act gives the Secretary the authority to survey a manufacturer's records and data to verify the pricing information reported under section 1927(b)(3)(A) of the Act. To facilitate such surveys, we would require under § 447.534(g) that a manufacturer must retain for 3 years from the date the manufacturer reports that rebate period's data, all records (written or electronic) of the data and any other materials from which the calculations of the AMP and best price were derived. A manufacturer must retain records beyond the 3-year period if audit findings related to the AMP and best price have not been resolved. In addition, if the manufacturer makes reasonable assumptions in its calculations of AMP and best price, the manufacturer must also maintain a written or electronic record outlining these assumptions. We will consider reasonable assumptions to include: that the AMP can never be zero or a negative number; that the methodology used to determine basedate AMP, as well as AMP and best price, is used consistently for all rebate period calculations; and that accounting methods are in accordance with generally acceptable accounting principles and conform to the manufacturer's tax reporting accounting policies.

We would require manufacturers to maintain records for 3 years since this time period is necessary to verify the accuracy of information received. Also, the 3-year time period comports with the requirements for the maintenance of records on State Medicaid expenditures imposed on States. Regulations at § 433.32 require that States retain records for 3 years from the date of submission of a final expenditure report for FFP. Therefore, we believe that manufacturers should also maintain records for this same timeframe, in the event that manufacturers' records on the drug rebate program are audited and the audit results in an adjustment of pricing information and rebate payments.

2. Dispute Resolution Process and RAR

The dispute resolution process described in section V.F. of this preamble and § 447.536 would require that both States and manufacturers maintain supporting documentation at various stages of the dispute resolution process. For example, manufacturers and States must maintain supporting documentation for certain types of disputes indicated on the RAR, data inconsistencies, and agreements reached between both the manufacturer and State in settling a dispute. States must also maintain documentation if States choose to cease the dispute resolution process based on the cost effectiveness thresholds. Thus, in § 447.534(g)(2) we would require both States and manufacturers to keep all supporting documentation required under the dispute resolution process and in conjunction with the RAR for a 3-year period from the date the dispute is resolved between the manufacturer and the State.

As discussed in section V.C.1. of this preamble, States are required to maintain records on State Medicaid expenditures for 3 years from the date of submission of a final expenditure report for FFP. The final expenditure report for FFP must contain any rebate payment adjustments as a result of the final dispute settlement (§ 447.534(g)(2)).

We would require manufacturers to maintain supporting documentation for this 3-year period under our general rulemaking authority since this requirement comports with the State maintenance of record requirements and is necessary to effectuate the provisions of OBRA '90 and the dispute resolution process.

D. Confidentiality of Reported Information

In accordance with section 1927(b)(3)(D) of the Act (as amended by VHCA), we would specify in § 447.540(a) that manufacturer-specific pricing information disclosed by the manufacturer in connection with the rebate agreement is confidential and, notwithstanding other provisions of law (including the Freedom of Information Act (FOIA), 5 U.S.C. 552), must not be disclosed by the Secretary of HHS, the Secretary of Veterans Affairs, the State Medicaid agency or its contractors in a form that reveals the manufacturer or wholesaler, or prices charged by the manufacturer or wholesaler, except as necessary for:

- The Secretary to carry out the provisions of section 1927 of the Act;
- The Comptroller General to review the information provided; and
- The Director of the Congressional Budget Office to review the information provided.

Based on this explicit confidentiality language, HCFA is prohibited from disclosing specific manufacturer data that identify the base date AMP, AMP, best price, unit rebate amount, or the total rebate amount claimed. We believe that it is reasonable to expect that disclosure of any of these data would lead to the identity of a manufacturer and its prices. We do not believe,

however, that this prohibits us from releasing data in a non-manufacturer specific or aggregate form, such as that required in section 1927(i) of the Act, which describes the information to be included in the Secretary's annual report regarding the operation of the drug rebate program. Under this section, the Secretary must include in the annual report such information as the total value of rebates received and the number of manufacturers providing such rebates, and the effect of inflation on the value of rebates required under the drug rebate program.

While we are not precluded from releasing AMP and best price to the States (inasmuch as the confidentiality provisions of section 1927(b)(3)(D) of the Act contemplate such release), we have determined that supplying the specific unit rebate amount to the States, as opposed to other pricing data, will give States sufficient information to invoice and verify rebate payments.

States are prohibited from releasing any manufacturer-specific pricing data supplied by HCFA in relation to the drug rebate program. States are also prohibited from releasing these data to individual pharmacists or pharmacy groups. However, release of a State's utilization data, excluding manufacturer-specific pricing data, is permitted to the extent it is allowed under Federal or State confidentiality laws.

These confidentiality provisions will remain in full force and effect on the States and HCFA, regardless of the nonrenewal or termination of the rebate agreement. The statute does not specify that the confidentiality provisions are limited to the period when an agreement is in effect.

E. Penalty for Failure to Report Information or for Reporting False Information

Section 1927(b)(3)(B) of the Act provides that the Secretary may survey wholesalers and manufacturers that directly distribute their covered outpatient drugs, when necessary, to verify manufacturer prices reported to HCFA. The Secretary may impose a civil monetary penalty in an amount not to exceed $100,000 on a wholesaler, manufacturer, or direct seller of a covered outpatient drug if the wholesaler, manufacturer, or direct seller refuses a request for information about charges or prices by the Secretary in connection with a survey or knowingly provides false information. The provisions of section 1128A of the Act regarding civil monetary penalties (except for subsections (a) (with respect to amounts of penalties or additional assessments) and (b)) apply to the imposition of these penalties in the same manner as such provisions apply to a penalty or proceeding under section 1128A(a).

If a manufacturer fails to provide the required information on AMP and best price or the list of covered outpatient drugs, the amount of the civil money penalty is $10,000 for each day beyond the due date that the information is not provided. We have included the list of covered outpatient drugs as a required item because we believe it is a necessary component of the pricing information required by the statute. The corresponding drug identifiers provided by the list of covered outpatient drugs, such as NDC numbers, names, and package sizes, are needed to accurately verify the pricing information of the vast number of drugs on the market. If all of the required information is not reported within 90 days of the required timeframe, HCFA is authorized to suspend the drug rebate agreement after the end of that 90-day period and continue the suspension until the information is provided. The suspension period must not be for less than 30 days. A manufacturer will continue to be responsible for rebates on drugs covered during the period the agreement was not suspended.

Any manufacturer with an agreement, that knowingly provides false information, will be subject to a civil money penalty in an amount not to exceed $100,000 for each item of false information. These penalties are in addition to other penalties prescribed by law. The provisions of section 1128A (other than subsections (a) and (b)) apply to a civil money penalty under this paragraph in the same manner as such provisions apply to a penalty or proceeding under section 1128A(a). We would incorporate these provisions under § 447.542.

F. Dispute Resolution for Medicaid Utilization Information

1. Background

As required under section 1927(b)(1) of the Act, a manufacturer must provide to each State a rebate for covered outpatient drugs within 30 days after receipt of the State utilization information. For purposes of the Medicaid drug rebate program, and, as set forth in section II.(b) of the national rebate agreement, the manufacturer is responsible for timely payment of the rebate amounts within 30 days of receiving, at a minimum, information, by NDC number, on the number of units reported by the State. Additionally, section V.(b) of the national rebate agreement sets forth broad guidelines for a dispute resolution process for States and manufacturers to follow in cases where the manufacturer believes the State utilization data are erroneous. We would clarify these guidelines and timeframes for dispute resolution in these regulations.

The resolution of disputes has been a source of concern for manufacturers and States alike. The type of process needed to resolve disputes over utilization data is unique to the drug rebate program under Medicaid. Because these disputes often do not involve legal issues but can be resolved by exchange of information and refinement of data collection methods through discussions between the principals, the process must provide a full opportunity for such resolution before any proceeding before a hearing officer (the method commonly used to resolve other types of disputes). There are no existing regulations, under either the Medicaid or Medicare program, that can be applied to this dispute process. Likewise, there are no regulations that could be used as a model for developing the dispute resolution requirements.

Recognizing the need for improvements in this area, HCFA convened a meeting in February 1992 on dispute resolution with members of organizations representing manufacturers, pharmacists, and States. At that meeting, we discussed the concerns of the participants relating to dispute resolution. A workgroup was formed from the conferees to explore ways in which HCFA could develop a uniform set of guidelines for States and manufacturers to follow in the resolution of disputes.

In May 1992, the conferees reconvened and recommendations of the workgroup were discussed. As a result of the meetings and suggestions received from participants, HCFA decided to provide more detailed requirements in the area of dispute resolution. In part, we have established a two-phase process for settling disputes. Phase I involves the manufacturer and State working jointly to resolve the dispute. Phase II involves using the State hearing process or an arbitrator or mediator to help resolve the dispute. We would identify specific steps and timeframes within each phase for the resolution of disputes and have incorporated them into our regulations at § 447.536. We believe these requirements are necessary to effectuate the drug rebate provisions of OBRA '90, and to ensure that rebates are paid in a timely manner.

Under phase I of the process, there is a 240-day timeframe after the State receives the manufacturer's RAR for the

States and manufacturers to seek resolution of the dispute through exchange of information and informal negotiation. If both parties cannot reach a resolution within this timeframe, they must take one of several actions described in Step 4 of phase I or proceed to phase II of the dispute resolution process.

Under phase II of the process, the State must schedule a hearing to settle the dispute. Proceeding to phase II to settle disputes is generally done after all steps in phase I have been completed. However, either a State or a manufacturer may proceed to phase II if either party has not fulfilled its obligations under any step in the first phase of the process. For example, the manufacturer may request that the State schedule a hearing at any stage of the dispute resolution process if the State fails to perform required phase I actions within the specified timeframes. Conversely, the State may schedule a hearing at any stage of the process if the manufacturer fails to perform required phase I actions within the specified timeframes, and/or request HCFA, through the HCFA Regional Office (RO), to terminate the manufacturer's national rebate agreement.

We believe the timeframes established for each of the steps in the first and second phases of the dispute resolution process are reasonable for both States and manufacturers based on our experience to date with the drug rebate program, and based on feedback from States and manufacturers in compiling such data and working with the original dispute resolution process under the national rebate agreement. The timeframes established in these proposed regulations were extensively discussed with the workgroup participants for the dispute resolution process. We believe that delaying the payments of rebates due to a more time-consuming dispute resolution process would harm both States and manufacturers. Rebates are needed on a predictable basis to reduce State expenditures for drugs and to allow States to estimate future budgeting for drug spending based on expected rebates. Longer timeframes could result in the manufacturer being liable for substantial amounts of interest accruing on disputed data.

Therefore, to effectuate the OBRA '90 drug rebate provisions and to ensure that rebates are paid in a timely manner, we would require manufacturers and States to comply with the process and timeframes outlined in this section of the preamble beginning with disputes associated with data for the rebate period occurring 60 days following publication of the final rule. We believe this timeframe is sufficient since both manufacturers and States have had extensive experience in handling a variety of disputes since 1991. Disputes in existence prior to this rebate period would not be subject to the dispute resolution requirements of the final rule, as in some cases the applicable timeframes will already have passed. However, we expect such disputes to be resolved as quickly as possible or the State hearing process, as specified in the initial rebate agreement, to be made available to the manufacturer by the State.

While current State law may not include manufacturers as ''providers'' under State Medicaid programs, for purposes of these proposed regulations, we would require States to provide a hearing which we anticipate will involve the same procedure as provider hearings. There are no specific Federal requirements that govern this hearing process. In these regulations, we would not establish any new requirements or criteria for this process, except for the overall timeframe for the conduct of the hearing.

2. Identifying and Resolving Data Inconsistencies Prior to Phase I of the Dispute Resolution Process

In general, within prescribed timeframes after a State submits to a manufacturer the Medicaid utilization information, the manufacturer must review the data and pay a rebate on the undisputed portion. The disputed portion of the data must be resolved through the dispute resolution process. However, to prevent both phase I and phase II of the process from being used to handle disputes involving data inconsistencies, we would require both States and manufacturers to take certain actions, as discussed below, to resolve data inconsistencies before they initiate phase I of the dispute resolution process. We would consider data inconsistencies to be data errors unrelated to actual utilization, such as incorrect NDC numbers, unit types, or decimal positions (§ 447.536(a)).

The dispute resolution process is a costly and time-consuming activity for all parties, delays the payment of rebates for disputed data, and causes interest to accrue on disputed amounts. Therefore, to effectuate the drug rebate provisions of OBRA '90 and to ensure the timely payment of rebates, we would require in § 447.536(a) that manufacturers attempt to identify and resolve State Medicaid utilization data inconsistencies with the State no later than 30 days after receipt of the data. We believe that requiring States and manufacturers to resolve data inconsistencies during the 30-day period before a manufacturer must pay a rebate on the undisputed data will result in timely rebates being paid for a larger percentage of State utilization data and reduce the volume of data involved in disputes. Thus, administrative costs incurred from the dispute resolution process would be reduced for both States and manufacturers.

Examples of data inconsistencies that manufacturers must screen for are items such as:

- Incorrect unit types;
- Reported NDC numbers failing to match manufacturer's NDC numbers; and
- Incorrect decimal position in units reported.

If, in any rebate period, a manufacturer discovers discrepancies in a State's utilization data, the manufacturer must distinguish between disputes that will require further resolution and data inconsistencies before initiating phase I of the dispute resolution process. If data inconsistencies are detected, a manufacturer must contact the State, identify the inconsistencies, and propose possible corrective actions. Examples of an attempt by the manufacturer and State to resolve these data inconsistencies could involve:

- Verifying that unit types are appropriate for the product;
- Examining the data to verify that the total number of units is appropriate for the amount paid; and
- Matching State-reported NDCs to the manufacturer's NDCs.

If an agreement is reached and the data inconsistencies are resolved, both the State and manufacturer must maintain written documentation of the resolution. The manufacturer must record the resolution of data inconsistencies on the RAR. If these preliminary attempts to resolve the data inconsistencies fail, the manufacturer and State must initiate phase I of the dispute resolution process as described below.

3. Steps in the Dispute Resolution Process

a. Steps in Phase I of the Dispute Resolution Process. Phase I of the dispute resolution process is divided into four steps. These steps describe the actions that manufacturers and States must take and specify the timeframes within which the actions must be completed. The HCFA RO will monitor the dispute resolution process, and problems that occur in the process

should be referred to the appropriate RO.

Step 1: Manufacturer Submits RAR to State (To be completed within 30 days after the manufacturer receives State utilization information)

In the event a manufacturer discovers a discrepancy in the Medicaid utilization information that the manufacturer and the State are unable to resolve within the 30-day timeframe, as discussed in section V.F.2. of this preamble, the manufacturer must complete the following actions:

- Pay the rebate on undisputed data and provide written notice of any discrepancies by submitting the RAR to the State Medicaid agency. The manufacturer may, at this time, pay rebates on the disputed portion of the data;
- Ensure that the RAR is postmarked by the United States Postal Service or common mail carrier no later than 30 days after receipt of State data; and
- Identify on the RAR, among the other requirements of that form, the reason(s) why the data are disputed, by NDC number, and, if the entire amount of the rebate is not paid, why the disputed portion of the rebate is withheld.

We would require the manufacturer to submit supporting documentation with the RAR for certain types of disputes, as indicated on the RAR. The manufacturer must submit supporting documentation for other types of disputes if a State requests it to verify information contained on the RAR. This support will allow the State to verify the dispute and submit relevant information in the next step to move towards a resolution.

Interest begins to accrue on the withheld portion of rebates for disputed data on the 31st day after the manufacturer receives State data. Interest ceases to accrue only when payment is made for both rebates and accumulated interest, or an excess payment is refunded, consistent with the resolution of the dispute.

Step 2: State Responds to Manufacturer Regarding Disputes Identified on RAR (To be completed within 90 days after the State receives the manufacturer's RAR).

Within 90 days after the State receives the manufacturer's RAR, the State must complete two actions. First, the State must contact the manufacturer to discuss, by NDC number, the items disputed and the reasons why the manufacturer is disputing the items. Second, the State must present its preliminary response on the items identified on the RAR as being in dispute. Both the State and manufacturer must maintain documentation of the items disputed and the State's preliminary response to the manufacturer.

Step 3: Exchange of Data and Negotiations Between Manufacturer and State (To be completed within 150 days after the State receives the manufacturer's RAR).

Within 150 days after the State receives the manufacturer's RAR, the State must take definitive steps, as discussed below, to resolve the disputed items. If State confidentiality laws allow, we would require that the State provide the manufacturer with zip code or pharmacy-level data, a sampling of pharmacy claims, or historical trends data on such items as the manufacturer may have found in dispute. We would require the State to provide the manufacturer with the same type of data that the manufacturer used to dispute the rebate payment. That is, if the manufacturer based its dispute on pharmacy-level data, the State must provide pharmacy-level data to enable the manufacturer to analyze and compare the two sources in an effort to resolve the discrepancies. We would define zip code-level data or pharmacy-level data as a report by NDC number for a particular covered outpatient drug dispensed by pharmacies within a particular zip code or dispensed by a particular pharmacy respective to Medicaid recipients.

We believe these requirements for data exchange between States and manufacturers are necessary to effectuate the OBRA '90 drug rebate provisions and to resolve disputes in a timely manner. Without additional like data to substantiate or refute disputes, neither party may be able to resolve the discrepancies and, thus, further delay the payment of rebates and increase the amount of interest accruing on disputed rebates. Further, if the State disagrees with the manufacturer on the disputed items, the State must provide the manufacturer with this further breakdown of data or other reasons to support its position. Otherwise, the process may reach an impasse if the State and the manufacturer have no basis to resolve the underlying dispute.

Both the State and the manufacturer must ensure that any exchange of data protects the confidentiality requirements of section 1927(b)(3)(D) of the Act. Specifically, the statute prohibits disclosure by the State of any information that would disclose the identity of the manufacturer or the prices of the manufacturer's drugs.

Furthermore, if State confidentiality laws prohibit the release of certain data, such as pharmacy specific data, the State may require the manufacturer to supply to the State the data on which it based its dispute. If the manufacturer supplies the State with like data in this situation, we will consider the manufacturer to have satisfied this data exchange requirement and to be in compliance with the requirements under this step of phase I of the dispute resolution process.

Step 4: Post-Negotiations Decision (To be completed within 240 days after the State receives the manufacturer's RAR) Within 240 days after the State receives the manufacturer's RAR, the negotiations between the State and the manufacturer must be completed and one of the following options must be chosen and acted upon:

- The State may decide to cease the dispute resolution process based on its cost-effectiveness determination as described in section V.F.6 of this preamble. However, the State maintains the discretion to continue the dispute resolution process for disputed amounts that fall below the thresholds. Further, the State must maintain adequate documentation to support its determination to discontinue the dispute based on cost-effectiveness or maintain adequate documentation that clearly describes any settlement reached with a manufacturer.
- The State and the manufacturer may agree to a settlement based on the State's Medicaid utilization information.
- The State and the manufacturer may agree to a settlement based on valid documentation that other data were more representative of the actual Medicaid utilization.
- If none of the above settlements are reached, the State and manufacturer must proceed to phase II of the process to settle the dispute.

b. Phase II of the Dispute Resolution Process. Phase II of the dispute resolution process is initiated when the dispute is not resolved in step 4 of phase I, or when either party does not comply with the requirements under any of the phase I steps and either the manufacturer or State wants to proceed to phase II. In either case, under phase II the State must schedule a hearing within 30 days from the end of the phase I process, or within 30 days from the date the manufacturer or the State chooses to proceed to phase II due to noncompliance. We would require that the hearing be conducted no later than one year from the 240th day after the State receives the manufacturer's RAR (§ 447.536(d)). The State and the manufacturer could continue to attempt to settle the dispute between themselves before the hearing is conducted. However, we would require that the hearing be scheduled and conducted, if

still necessary, within the one-year timeframe.

In lieu of a State hearing, the State and the manufacturer may agree to arbitration or mediation to settle the dispute. In this case, we would require the State to maintain documentation that clearly describes the agreement with the manufacturer to settle the dispute through arbitration or mediation rather than a State hearing (§ 447.536(e)).

After the dispute is resolved, the disputed amount plus the rate of interest, as set forth in section 1903(d)(5) of the Act, must be paid or credited on the entire balance by the manufacturer or the State no later than the due date of the next rebate period payment. As noted in section V.F.4 of this preamble, interest would begin to accrue 38 calendar days from the date the State mails its Medicaid utilization information to the manufacturer. Interest would continue to accrue until the date payment is made or excess payment is refunded for the part of the disputed Medicaid utilization information that the State and manufacturer agree is appropriate, as resolved through the dispute resolution procedures set forth in this section.

4. Interest Rate under Section 1903(d)(5) of the Act

The interest rate under section 1903(d)(5) of the Act is the average of the yield of the weekly 90-day Treasury bill auction rates during the period for which interest will be charged. For purposes of section 1903(d)(5) of the Act, the investment yield is considered the bond equivalent rate or the true discount rate. HCFA will supply the manufacturers and States with the rates to assure that both parties are using the same interest rates in the calculation.

Interest would be applied to disputed or unpaid amounts and late rebate payments but not to prior period adjustments of unit rebate amounts or State utilization adjustments.

Interest would begin accruing 38 calendar days from the date the State mails the State utilization data, as evidenced by the postmark by the United States Postal Service or other common mail carrier on the envelope (not a postage meter stamp). We would allow 7 additional days (from the 31st day after utilization data are sent from a State) to begin the interest clock which will allow time for receipt of the mailing by the manufacturer. For documentation purposes, we would require States to maintain a record of the date of mailing and manufacturers must maintain the envelope bearing the postmark from the State.

Interest accrues on the disputed portion of the rebate amount or on the total amount of the late rebate payment for all rebate periods beginning January 1, 1991 and only stops accruing on the date the check is disbursed. We would consider the date of disbursement to be the date the check is mailed by the manufacturer. Interest must be collected and may not be disregarded as part of the dispute resolution process by the State or manufacturer.

Interest calculation is based on a 365-day year with simple interest applied to the average of the yield of the weekly 90-day Treasury bill auction rates during the period for which interest will be charged. (For purposes of this calculation, include the rate for the entire week if the beginning and/or ending date fall within that week.)

The following formula and example illustrate how interest should be calculated:

Obtain yield rates (bond equivalent rates) for period involved:

Auction dates	Yield rates (Percent)
March 1, 1993	3.035
March 8, 1993	3.043
March 15, 1993	3.064
March 22, 1993	3.003
March 29, 1993	3.022

(a) Total the yield rates of each weekly auction of 90-day Treasury Bill. Total = 15.167%

(b) Divide the total from (a) by the number of rates to determine the average interest rate.

15.167% divided by 5 = 3.0334% = Average Interest Rate.

(c) Multiply average interest rate by amount of unpaid rebate.

$1,000 × 3.0334% = $30.33 Amount of Interest Due.

(d) Divide the amount of the interest due by 365 days to obtain the amount of interest due per day.

$30.33 divided by 365 days = $.08309 = Amount of Interest Due Per Day.

(e) Multiply daily amount of interest due per day by the number of days the unpaid rebate amount is outstanding.

$.08309 × 29 days (March 4, 1993–April 1, 1993) = $2.41 Total Interest Due.

5. Manufacturer's Right To Audit Data

The manufacturer retains the right provided under section 1927(b)(2)(B) of the Act to audit the Medicaid utilization information reported (or required to be reported) by the State. While not mandated by the statute or this regulation, but as specified in the national rebate agreement, we encourage the manufacturer and the State to develop mutually beneficial audit procedures that promote a cooperative relationship that saves time and money for both parties.

Adjustments to rebate payments will be made if information indicates either that Medicaid utilization were greater or less than the amount previously specified, or that other information is inaccurate (for example, a drug is not properly classified as a single source, innovator multiple source, or noninnovator multiple source drug that affects the amount of rebates).

6. Cost-Effectiveness of Dispute Resolution

In some cases, a State may consider that engaging in continued attempts to resolve a dispute with a manufacturer is not cost-effective in that the State resources required to settle the dispute exceed the amount in dispute, or that the accuracy of the utilization data can be established only to a certain degree. Many States have expressed concern that guidelines are needed to determine cost-effectiveness tolerance limits for the dispute resolution process. Thus, to effectuate the OBRA '90 drug rebate provisions in the most efficient manner, we would establish the following cost-effectiveness tolerance limits for States.

For any rebate period, a State need not proceed into further dispute resolution process steps beyond final negotiations (Step 4 of phase I) with a manufacturer if the disputed amount is (1) under $10,000 per manufacturer's labeler code, and (2) under $1,000 per product code. States must maintain supporting documentation of the determination that may be subject to review by the Department. Further, when a State decides to cease the dispute resolution process based on these cost-effectiveness criteria and adequately documents that the process is not cost-effective, as discussed above, FFP will generally be available for the drugs dispensed and the Federal portion of the rebate will generally not be required from the State.

States maintain the discretion to proceed with the dispute resolution process in cases that fall below the thresholds described in this section. We believe this policy provides States with the flexibility to determine the merits of pursuing disputed rebates in terms of cost-effectiveness.

VI. Formulas for Computation of Amount of Drug Rebates

Section 1927(c) of the Act specifies that each manufacturer must remit a basic rebate and an additional rebate to the State Medicaid agency for single source drugs and innovator multiple

source drugs, and a rebate for covered outpatient drugs other than single source and innovator multiple source drugs. We would require in regulations at § 447.546(a) and (b) that the manufacturer must make timely payment of the rebate, that is, within 30 days of receiving State Medicaid utilization information that includes, at a minimum, the number of units paid by NDC number during the rebate period under the approved State plan. We would also require in § 447.546(a)(3) that the manufacturer continue to make rebate payments for all of its covered outpatient drugs for as long as an agreement is in force and utilization information reports are made. Also, a rebate payment would be required for all drugs until the entire supply of the drug under an NDC number has expired; the drug has been taken off the market; or, for other reasons, there no longer exists the potential that the drug may be dispensed under the manufacturer's NDC number or paid for and a rebate requested by the State Medicaid agency.

Section 1927(c) of the Act specifies the formulas to be used to compute the rebates as follows:

A. Rebate for Noninnovator Multiple Source Drugs

The rebate for noninnovator multiple source drugs is—

For October 1, 1992—December 31, 1993: 10 percent of the AMP.

For January 1, 1994, and thereafter: 11 percent of the AMP.

B. Basic Rebate for Single Source Drugs and Innovator Multiple Source Drugs

In general, section 1927(c)(1)(B) of the Act, as established under OBRA '90, provided for the following basic rebate for single source drugs and innovator multiple source drugs:

For January 1, 1991–December 31, 1991: The greater of 12.5 percent of the AMP or the AMP minus best price. (The rebate is capped at 25 percent of AMP.)

For January 1, 1992–December 31, 1992: The greater of 12.5 percent of the AMP or the AMP minus best price. (The rebate is capped at 50 percent of AMP.)

For January 1, 1993 and thereafter: The greater of 15 percent of the AMP or the AMP minus best price. (The rebate is not capped.)

Section 601(c) of VHCA amended section 1927(c)(1)(B) of the Act to account for a budget neutrality adjustment to the basic rebate for single source drugs and innovator multiple source drugs. This budget neutrality adjustment was established to offset a reduction in rebates resulting from the additional exclusion of prices from the best price calculation required under section 601(a) of VHCA. On April 12, 1993, the Veterans Health Care Act of 1992—Technical Corrections (Public Law 103–18) was enacted. Section 2(a) of Public Law 103–18 amended section 1927(c)(1)(B)(ii)(II), as amended by section 601(c) of VHCA, to restore the 50 percent rebate cap for the rebate period October 1, 1992, through December 31, 1992. This amendment is effective as if it were included in the enactment of section 601(c) of VHCA. Thus, section 1927(c)(1)(B)(ii)(II) of the Act has been amended to provide that for the rebate period beginning after September 30, 1992, and before January 1, 1993, the amount of the rebate may not exceed 50 percent of the AMP.

In general, for period beginning with October 1, 1992, the following basic rebate for single source or innovator multiple source drugs are as follows:

For October 1, 1992–December 31, 1993: The greater of 15.7 percent of the AMP or the AMP minus best price. (The rebate is capped at 50 percent of AMP for the rebate period October 1, 1992–December 31, 1992.)

For January 1, 1994–December 31, 1994: The greater of 15.4 percent of the AMP or the AMP minus best price.

For January 1, 1995–December 31, 1995: The greater of 15.2 percent of the AMP or the AMP minus best price.

For January 1, 1996, and thereafter: The greater of 15.1 percent of the AMP or the AMP minus best price.

C. Additional Rebate for Single Source and Innovator Multiple Source Drugs

Section 1927(c)(2) of the Act requires that manufacturers pay an additional rebate amount for single source and innovator multiple source drugs if, for rebate periods beginning January 1, 1991, the AMP exceeds the ''base date'' AMP by a greater percentage than the percentage increase in the CPI–U for the rebate period from the ''base CPI–U.'' Section 13602(a)(1) of OBRA '93 made clarifying changes to section 1927(c)(2), deleted requirements that would have replaced the calculation with one based on a weighted average manufacturer price (WAMP), and changed the calculation method for drugs approved by the FDA after October 1, 1990. Under section 13602(d)(2) of OBRA '93, these amendments are effective without regard to whether or not regulations to carry out these amendments have been promulgated by that date. HCFA adopted an October 1, 1993 effective date with respect to the OBRA '93 amendments to section 1927(c). Using a retroactive effective date for these provisions would require HCFA, manufacturers, and States to recalculate additional rebates for 11 quarters. This would generate an enormous amount of prior period adjustments and changes to rebate amounts in the dispute resolution process. Such a volume of changes would place an undue administrative burden on States, manufacturers, and HCFA without a level of additional rebates to warrant the administrative costs involved in such a task. We believe our adoption of an October 1, 1993 effective date comports with HCFA's understanding of Congressional intent, as demonstrated in the legislative history. Since the amendments clarified but did not substantively change methods for calculating the additional rebate for drugs approved by the FDA before October 1, 1990, a single calculation method can be used for those drugs. Since OBRA '93 substantively changed the method for calculating the additional rebate for drugs approved by the FDA after October 1, 1990, different calculation methods must be used for the periods January 1, 1991 through September 30, 1993 and October 1, 1993 and thereafter. We discuss all of these methods in more detail below.

1. For Drugs Approved on or Before October 1, 1990

Section 1927(c)(2)(A) of the Act requires that manufacturers pay an additional rebate amount for single source and innovator multiple source drugs if, for rebate periods beginning January 1, 1991, the AMP exceeds the base date AMP by a greater percentage than the percentage increase in the CPI–U for the rebate period from the base CPI–U. The statute provides that the CPI–U used for calculating the additional rebate amounts be based on the CPI–U in effect for the month preceding the rebate period (or other period) involved. Therefore, to be consistent with the statute and the national rebate agreement, we have defined the following terms to be used in the formulas for calculating additional rebates:

Base Date AMP—The base date AMP means the AMP for the calendar quarter beginning July 1, 1990, i.e., that originally reported for the July–September 1990 rebate period. Section 1927(c)(2)(A)(ii)(II) of the Act, as amended by OBRA '93, provides that the base date AMP is the base date in effect at the time of the rebate period beginning July 1, 1990, without regard to whether or not the drug has been sold or transferred to an entity, including a division or subsidiary of the

manufacturer, after the first day of such rebate period.

Base CPI–U—The base CPI–U means the CPI–U in effect for September 1990; for example, the CPI–U in effect that month was 132.7.

2. For Drugs Approved After October 1, 1990

For drugs approved by the FDA after October 1, 1990, OBRA '93 defines base date AMP and base CPI–U different from how they are defined in OBRA '90. These changes affect how additional rebates are calculated for single source and innovator multiple source drugs approved after October 1, 1990. Generally, the base date AMP is the AMP in effect for the first full rebate period after the day the drug was first marketed. The base CPI–U is the CPI–U in effect for the month prior to the first full rebate period after the day the drug was first marketed.

HCFA adopted on October 1, 1993 effective date for these changes to section 1927(c). Therefore, these changes are effective with rebate periods beginning on or after October 1, 1993, and additional rebates will be calculated differently for these drugs for the period of January 1, 1991 through September 30 1993 and rebate periods beginning on or after October 1, 1993. Therefore, to be consistent with the statute, we have defined the following terms to be used in the formulas for calculating additional rebates. HCFA will issue specific instructions to manufacturers and States on how to calculate additional rebates for these different periods.

Base Date AMP for rebate periods beginning on or after January 1, 1991 through September 30 1993—The original policy in effect under OBRA '90 will continue to be used for base date AMP. That is, for this period, the base date AMP will continue to be that for the first day of the first full month in which the drug was first marketed.

Base CPI–U for rebate periods beginning January 1, 1991 through September 30, 1993—The original policy in effect under OBRA '90 will be used for the base CPI–U. That is, the base CPI–U continues to be the CPI–U in effect for the month before the month in which the drug was first marketed.

Base Date AMP for rebate periods beginning on or after October 1, 1993—In accordance with section 1927(c)(2)(B), the base date AMP is the AMP in effect for the first full rebate period after the day on which the drug was first marketed.

Base CPI–U for rebate periods beginning on or after October 1, 1993—The base CPI–U means the CPI–U in effect for the month prior to the month of the first full rebate period after the day on which the drug was first marketed.

VII. Payment Limitations for Covered Drugs

A. Applying Federal Reimbursement Upper Limits

OBRA '93 amended section 1927 of the Act regarding pharmacy reimbursement limits. Section 13602(a)(1) of OBRA '93 amended section 1927(f) by redesignating it as section 1927(e) and modifying the language in several subsections. OBRA '93 revised and redesignated section 1927(f)(1) of OBRA '90 as sections 1927(e)(1) and (e)(2), added section 1927(e)(3), and redesignated section 1927(f)(2) of OBRA '93 as section 1927(f)(4) of the Act.

Existing regulations at 42 CFR 447.331 through 447.334 establish methodologies for upper limits for payment of drugs covered under the Medicaid program, in accordance with section 1902(a)(30)(A) of the Act. Section 1927(e)(1) of the Act (redesignated from section 1927 (f)(1) under OBRA '90) imposed a moratorium period beginning January 1, 1991, and ending on December 31, 1994 with regard to pharmacy reimbursement limits. During this moratorium period, in accordance with section 1927(e)(1)(a), a State cannot reduce its reimbursement limits for covered outpatient drugs or the dispensing fees for these drugs in effect as of January 1, 1991 which were established in accordance with 42 CFR 447.331 through 447.334. In accordance with the statute, up to January 1, 1991, States retained the right to reduce payments to pharmacies.

Section 1927(e)(2) establishes a special rule for States that were not in compliance with these regulations. If a State is not in compliance with §§ 447.331 through 447.334, the provisions in section 1927(e)(1)(A) do not apply to the State until it is in compliance. That is, States which reduce reimbursement rates during January 1, 1991 through December 31, 1994 to comply with the regulations will not be violating the moratorium provision under section 1927(e)(1).

Since the statute refers specifically to States ''in compliance,'' States that were not in compliance with the regulations on January 1, 1991, are still required to come into compliance with the regulations and reduce reimbursement limits, as required by these regulations, after January 1, 1991. To be in compliance with the regulations, the State must demonstrate that the estimated acquisition cost (EAC) is set at the State Medicaid agency's ''best estimate'' of the prices that pharmacists in the State are generally and currently paying. (Section 447.301 contains the definition of EAC.)

Section 1927(e)(1)(B) of the Act provides that the Secretary may not modify by regulation the Federal upper limits formula used to determine reimbursement limits in §§ 447.331 through 447.334 to reduce the reimbursement limits for covered outpatient drugs. This provision applies to the Federal upper limits formula that was in effect on November 5, 1990 (the date of enactment of OBRA '90).

In accordance with section 1927(e)(3) of the Act (as added by OBRA '93), the moratorium provisions will not supersede or affect provisions in effect for State maximum allowable cost (MAC) limitations prior to January 1, 1991, or after December 31, 1994. MAC programs established by States prior to January 1, 1991, or after December 31, 1994 are allowable under the statute and are not considered a reduction in pharmacy reimbursement. States may continue to operate MAC programs in effect prior to January 1, 1991 in accordance with the terms of that program, e.g., States may adjust limits and add drugs within the requirements of the MAC programs in effect prior to January 1, 1991.

B. Multiple Source Drugs

1. Drugs Subject to Federal Upper Limits Under Section 447.332 (Upper Limits for Multiple Source Drugs)

Under existing § 447.332(a), an upper limit for a multiple source drug may be established if the following requirements are met:

- All of the formulations of the drug approved by the FDA have been evaluated as therapeutically equivalent in the current edition of the FDA publication, *Approved Drug Products with Therapeutic Equivalence Evaluations*; and
- At least three suppliers list the drug (which has been classified by the FDA as category ''A'') in the current editions (or updates) of published compendia of cost information for drugs available for sale nationally.

Under these existing provisions of § 447.332, a State agency's payment for multiple source drugs must not exceed in the aggregate the payment levels determined by applying for each drug a reasonable dispensing fee established by the agency plus an amount established by HCFA that is equal to 150 percent of the published price for the least costly therapeutic equivalent (using all

available national compendia) that can be purchased by pharmacists in quantities of 100 tablets (or capsules) or the commonly listed size. Upper limits do not apply to brand name drugs if a physician certifies in his or her own handwriting on the prescription that a specific brand is medically necessary for the recipient. HCFA identifies the multiple source drugs that are subject to upper limits and their prices on a periodic basis in the *State Medicaid Manual* under Part 6, Payment for Services.

2. Drugs Subject to Federal Upper Limits Under Section 1927(e)(4) of the Act

Section 1927(e)(4) of the Act (redesignated from section 1927(f)(2) under OBRA '93) contains a provision that establishes new conditions for determining which multiple source drugs are subject to upper limits and, thus, establishes a new group of drugs subject to upper limits. Section 1927(e)(4) requires HCFA to establish an upper reimbursement limit for each multiple source drug when there are at least three therapeutically and pharmaceutically equivalent (A-rated by the FDA) multiple source drugs. When this condition is met, an upper limit will be applied to the multiple source drug whether or not the FDA rating of the additional formulations of the drug are either A-rated or B-rated drugs. (§ 447.335.)

Given the moratorium provisions in section 1927(e)(1)(B) of the Act (discussed in section VII.A. of this preamble), we view section 1927(e)(4) of the Act as authority to establish upper payment limits for additional multiple source drugs, rather than a mandate to change the formula set forth in § 447.332. Any modification to existing § 447.332 during the moratorium period of January 1, 1991, to December 31, 1994, would conflict with section 1927(e)(1)(B) of the Act, which prohibits the Secretary from modifying by regulation the Federal upper limits formula in §§ 447.331 through 447.334. By prohibiting a change in the reimbursement methodology under section 1927(e)(1)(B), we believe that the Congress recognizes and approves of the current method of establishing upper limits under § 447.332.

In accordance with the moratorium provisions in section 1927(e)(1)(B) of the Act, we would not change the formula used to determine reimbursement limits that is presently set forth in §§ 447.331 through 447.334. However, we do not believe the moratorium provisions prevent HCFA from applying the existing upper payment limit formula to existing and additional drugs as required by section 1927(e)(4) of the Act.

To comply with the requirements of both 42 CFR 447.332 and section 1927(e)(4) of the Act, HCFA would establish an upper reimbursement limit for multiple source drugs using both sets of criteria found at the existing § 447.332 and the new § 447.335. We would specify in regulations at § 447.335 the conditions under which covered outpatient drugs will be subject to the Federal upper limits under section 1927(e)(4) of the Act. On a periodic basis, HCFA would consolidate both groups of drugs, including their prices, into one listing of drugs that are subject to the Federal upper limits. HCFA will issue this listing to the States in an electronic medium and in the *State Medicaid Manual* under Part 6, Payment for Services.

3. Inclusion of A- and B-Rated Drugs

The FDA publication, Approved Drug Products with Therapeutic Equivalence Evaluations, lists the application holders for the drugs and the accompanying A or B drug rating. This publication, however, does not list the current owner of the drug or distributors, that is, packagers or relabelers, and there is no Federal requirement that these repackagers or relabelers identify the source of their drug product. Therefore, the A and B rating is lost for all such drugs in the marketplace once they are repackaged or relabeled.

Because we are unable to identify an A or B rating for what we believe are the majority of drugs sold at the retail level of trade, we are including all drugs (A and B rated) in the rebate program. Otherwise, since there is no method to identify A-rated drugs, we would have to require all manufacturers that participate in the drug rebate program to sell only A-rated drugs to all its customers (as there is no method to determine which particular drug will be dispensed to a Medicaid recipient). This requirement would be the only feasible way to ensure that Medicaid recipients receive only A-rated drugs. However, such a requirement is not authorized under the provisions of section 1927 of the Act and would be contrary to FDA's current drug approval process which allows B-rated drugs to be marketed. Such a requirement would also not be consistent with our understanding of Congressional intent of the drug rebate program since it might reduce the number of manufacturers participating in the program that sell only B-rated products or a combination of A- and B-rated products, which could then decrease the availability of needed drugs to Medicaid recipients.

C. Denial of FFP When a Generic Substitution is Available

Section 1903(i)(10) of the Act provides that payment will not be made to a State for an innovator multiple source drug dispensed on or after July 1, 1991 if, under applicable State law, a less expensive noninnovator multiple source drug could have been dispensed but only to the extent that such amount exceeds the upper payment limit for such multiple source drugs. Consistent with our understanding of the statute and Congressional intent, we would interpret this provision in our regulations at § 447.550(b) to apply to drugs subject to the Federal upper limits under § 447.332(a). Therefore, we would include in regulations at § 447.335 that therapeutic equivalent drugs for upper limits under section 1903(i)(10) of the Act means drugs rated A or B by the FDA. We would apply this policy to only those drugs subject to the Federal upper limits to provide an established drug data base available to all States for determining if generic substitution is appropriate. The Federal upper limits program offers both pharmacists and the State Medicaid agencies a familiar, regularly updated guideline that can be easily used to compare the innovator and noninnovator drug prices.

We considered using national compendia prices or pharmacy charges in applying the generic substitution requirements; however, either alternative would be difficult to administer. Both alternatives would require the comparison of prices for the innovator and noninnovator multiple source drugs. These prices frequently change and, therefore, would require frequent update by the State Medicaid agency, possibly resulting in different lists in each State. Such alternatives could also disadvantage Medicaid recipients by substituting the regular medication they receive due to constant fluctuations in price which would determine whether the innovator multiple source drug could be dispensed at a given point in time.

Section 1903(i)(10) of the Act specifies that the substitution will be under applicable State law. FFP will be available for the dispensing of the innovator drug where the prescription has been hand annotated by the prescriber either as ''brand medically necessary'' or other such words to that effect as may be required under State law. Current regulations under § 447.331(c)(3) prohibit the use of a checkoff box on a form but allow the use

of a notation such as ''brand medically necessary.''

VIII. Compliance Action

A State's failure to comply with the reporting or drug access requirements of section 1927 of the Act is cause for compliance action against the State. Accordingly, we would specify in § 447.538 that a manufacturer may request HCFA to initiate compliance action against a State if the State fails to comply with the drug access requirements of section 1927 of the Act. A manufacturer may also request compliance action against a State if the manufacturer can show a pattern or history of inaccuracy in the drug utilization information provided by the State. It is incumbent upon the State to report accurate utilization data to ensure that rebates are paid in accordance with the statute.

Compliance actions taken by HCFA will not relieve the manufacturer from its obligation of making the rebate payment to States as set forth in section 1927 of the Act and will not bar the manufacturer from taking other actions against the State that are legally available to the manufacturer.

IX. Drug Rebate Agreement Provisions Not Addressed in This Document

On November 2, 1992, we published in the Federal Register (57 FR 49397) an interim final rule with comment period that addressed the following provisions of section 1927 of the Act:

- Drug Use Review—Section 1927(g) of the Act provides that a State must have, by January 1, 1993, a drug use review program for covered outpatient drugs that meet certain statutory requirements.
- Electronic Claims Management—Section 1927(h) of the Act provides that the Secretary shall encourage each State Medicaid agency to establish, as its principal means of processing claims for covered outpatient drugs under drug rebate agreements, a point-of-sale electronic claims management system, for the purpose of performing on-line, real time eligibility verifications, claims data capture, and adjudication of claims, and assisting pharmacists and other authorized persons in applying for and receiving payment.

A document that addresses public comments and finalizes rules is under development.

X. Summary of Public Comments on Notice and Departmental Responses

We received 20 timely pieces of correspondence from manufacturers, State agencies, a pharmaceutical manufacturer association, and other parties on the notice published in the Federal Register on February 21, 1991 (56 FR 7049) that reprinted the text of the national drug rebate agreement. A summary of these comments and the Department's responses follow:

A. Enforcement of Enhanced Access Provisions

1. Restrictive Formularies

Comment: The majority of the commenters stated that the rebate agreement, State instructions, and regulations implementing the drug rebate program should prohibit States from developing restrictive formularies.

Response: We agree that prior to OBRA '93, section 1902(a)(54) of the Act generally prohibited restrictive formularies (that is, formularies that impose access limitations for covered outpatient drugs covered under a rebate agreement). OBRA '93 revised section 1902(a)(54) to require that States comply with the applicable requirements of section 1927 and added section 1927(d)(4) which allows States to establish a drug formulary, effective October 1, 1993, which meets specific requirements. A State formulary must include covered outpatient drugs other than: (1) those drugs excluded under section 1927(d)(2); and (2) those drugs (with respect to the treatment of a specific disease or condition for an identified population) where the drug's labeling or compendia-based medically accepted indication does not have a significant, clinically meaningful therapeutic advantage, in terms of safety, effectiveness, or clinical outcome over other drugs included in the formulary.

We would require States to list in their State plans those drugs in section 1927(d) that they are excluding or restricting from coverage and also describe limitations or conditions of coverage (not including prior authorization programs). We would not require States to list in their State plans those drugs they are excluding or restricting from coverage with respect to the treatment of a specific disease or condition since States must have available to the public a written explanation of reasons for excluding the drugs. We believe requiring States to amend their State plans to include these drugs would be an unnecessary use of State resources.

2. Prior Authorization

Comment: The majority of commenters were adamant that States be required to implement what they characterized as statutorily acceptable prior authorization programs. They believed that medical factors should be the only criteria for approving or denying drugs subject to prior authorization and suggested that HCFA establish standards for State prior authorization programs to prevent abusive restrictions. One commenter was concerned that States would place on prior authorization: (1) All but the least expensive product in a therapeutic class; (2) the drugs of a manufacturer that does not provide an additional rebate above the amount required in the national agreement; and (3) the most expensive drug in a therapeutic class without regard for improved outcomes or reduction in total treatment costs associated with the more expensive drug therapy.

Response: Section 1927(d)(1)(A) of the Act provides that a State may subject any covered outpatient drug to prior authorization; that is, require approval of the drug before its dispensing for any medically accepted indication. In accordance with section 1927(d)(4)(E), a State's prior authorization formula is not considered a formulary subject to the requirements specified in section 1927(d)(4). The prior authorization system must meet two conditions specified under section 1927(d)(5) of the Act.

These proposed regulations would implement these provisions of section 1927 and allow States to maintain their prior authorization programs as they currently exist except that—

- A State must respond to a prior authorization request within 24 hours of the request; and
- A State must provide for the dispensing of at least a 72-hour supply of the drug in emergency situations.

In response to items numbered (1) and (3) in the comment, we believe that States should be able to consider both clinical and economic criteria in their prior authorization programs as long as medically necessary drugs are not denied. Prior to the drug rebate provisions, States could consider such criteria. We believe that OBRA '90 did not change that provision. We recognize, however, that the Congress, in passing the statutory provisions of the drug rebate program, was concerned with ensuring recipient access to medically necessary drugs. We would, therefore, require assurances from States that their prior authorization programs do not prevent access to medically necessary drugs.

In regard to item numbered (2) in this comment, States may, in accordance with sections 1927(a) (1) and (4) of the Act, negotiate separate agreements for additional rebates as long as they can establish that the requirements in section 1927 (as discussed in section II.

of this preamble) have been met. We will monitor the prior authorization programs to ensure that States are in compliance with these regulations.

We do not believe that, in light of the provisions of section 1927(d)(1)(A) of the Act, the Congress intended to set up any further requirements than those explicitly stated in the statute that would preclude States from requiring that prior authorization be obtained for any medically accepted indications, or requiring that the physician provide medical justification for using a particular drug within a therapeutic class, as long as access to medically necessary drugs is ensured. In accordance with the statute, we believe that a State continues to maintain the authority to prior authorize drugs provided the State approves the drug if medically necessary.

Additionally, section 4401(d)(3) of OBRA '90 requires that the Secretary, acting in consultation with the Comptroller General, study prior approval procedures utilized by State Medicaid programs conducted under title XIX of the Act. We will review the results of this study and, if necessary, consider additional changes to prior authorization programs at that time.

Comment: One commenter suggested that (1) a State should use a review board (similar to the drug utilization board) to establish criteria for selecting drugs subject to prior authorization; (2) the manufacturer should have input before a drug is placed on prior authorization or petition a State to remove a drug from prior authorization status; (3) the prior authorization process should be subject to the State Administrative Procedures Act; and (4) the prior authorization process should apply only for new prescriptions.

Response: We would require in § 447.526 that State staff who place drugs in a prior authorization system must be licensed to prescribe or dispense drugs, for example, physicians or pharmacists. We would provide, however, that State staff who respond to prior authorization requests need not be limited to persons licensed to prescribe or dispense drugs as long as all responses are made in consultation with these licensed professionals, or are made under guidelines promulgated by these licensed professionals and they are available for consultation in difficult or unusual cases. We believe that a State might benefit from a formulary committee for determining drugs that will be subjected to prior authorization but are not mandating this. However, we do not believe that we should limit the States' flexibility in operating their prior authorization programs to accommodate the commenter's other concerns since the statute supports the States' authority to maintain their prior authorization programs as they currently exist.

Comment: One commenter suggested that States should be required to disclose all information regarding the basis for selecting drugs and for denying drugs subject to prior authorization, and to generate a report for HCFA on all claims that were denied.

Response: In accordance with section 1927(d)(5) of the Act and our understanding of the legislative intent of OBRA '90, we expect States to operate their prior authorization programs in a manner that does not preclude access to medically necessary drugs. We believe States will be consistent in applying criteria as to how drugs are selected for prior authorization. We would also require annual assurances that a State's prior authorization program does not prevent access to medically necessary drugs. States may continue to disclose their records for prior authorization in the same manner that they did before the change in statute, as the statute made no changes in this area. We believe it would be overly burdensome to require States to generate specific reports on prior authorization claims and would be of nominal benefit to HCFA.

Comment: Several commenters believed that, if a State does not comply with the prior authorization requirements that the commenters believe are appropriate (as discussed above in other comments on prior authorization), the manufacturer should be able to withhold the rebate due the State.

Response: The statute requires a manufacturer to provide a rebate to the State for each rebate period based on utilization data submitted by the State. The rebate must be paid by the manufacturer to the State no later than 30 days after the date of receipt of the State's utilization data. There is no authority for the Secretary to permit a manufacturer to withhold a rebate (nor for a manufacturer to unilaterally withhold such a rebate) where a State does not comply with prior authorization requirements. We have a compliance process to ensure that States comply with all provisions of the Medicaid program and, as noted in the rebate agreement, manufacturers may notify the appropriate HCFA RO if they believe a State is not complying with a provision of the drug rebate program.

B. New Drug Coverage

Comment: Several commenters were concerned that States would not allow unrestricted access to new drugs. Some commenters believed that the new drug coverage protection afforded by section 1927(d)(6) prior to OBRA '93 should have provided that the 6 months of coverage for a new drug begin with the date when it is first marketed, and not from the date it is approved by the FDA. One commenter asserted that the Congress inadvertently reduced the time to less than 6 months because it may take several weeks, if not months, to bring a new drug on the market and suggested that HCFA support a technical amendment to the law. This commenter believed that prior to OBRA '93, section 1927(d)(6) of the Act encouraged manufacturers to bring new drugs to market prematurely since a manufacturer may need to educate and train physicians on a drug's use or administration once the drug is approved. Also, the commenter suggested that the FDA's approval of promotional materials and manufacturing specifications may not coincide with the drug approval date.

Response: OBRA '93 deleted section 1927(d)(6) and special coverage provisions for new drugs. Prior to OBRA '93, section 1927(d)(6) of the Act provided that a State may not exclude from coverage, subject to prior authorization or otherwise restrict any new drug or biological approved by the FDA for a 6-month period following the date of FDA approval. Effective October 1, 1993, these requirements no longer exist. New drugs approved by the FDA prior to October 1, 1993 will only receive the unrestricted coverage as specified in section 1927(d)(6) of the Act prior to OBRA '93 through September 30, 1993.

Based on our understanding of Congressional intent, we believe this 6-month period was specifically intended to be effective from the date of FDA approval to make prescribers familiar with a new drug and allow it to be introduced into the market place before it might require prior authorization by a State. Because this date was statutorily mandated, HCFA lacked authority to change this requirement to the date the drug was marketed.

Generally, with the exception of certain biological products, the approval of a new drug by the FDA under the NDA process does not include the approval of promotional materials. However, since the mid-1970s, the FDA has offered voluntary review and recommendations on proposed launch promotional materials to all sponsors. This review is utilized by well over 90 percent of the companies when marketing new products. With regard to manufacturing specifications, there are a few cases where compliance with the

manufacturing specifications was part of a post-NDA approval agreement that would be completed prior to marketing the product. However, since there are so few exceptions in this area and because we are bound to follow the statute, HCFA considered the 6-month period effective from the date the drug is approved by the FDA.

C. Confidentiality of Manufacturer Price Information

Comment: Many of the commenters believed that States should not have access to manufacturers' price information, including unit rebate amounts, since HCFA has access to this information. The commenters stated that the risk of disclosure and use of information for other purposes is too great.

Response: We have agreed not to disclose AMP and best price to States but maintain that the statute contemplates the disclosure of manufacturer pricing data to States. Section 1927(b)(3)(D) of the Act provides that information concerning drug prices must not be disclosed by ''the Secretary or a State agency (or contractor therewith).'' By including States within the confidentiality provisions, we believe that the Congress intended that States have the right to access of sufficient pricing information to calculate their rebates as required by the statute. The unit rebate amount, which provides the rebate due per tablet, etc., and which is the end result of the manufacturer's calculation, is, in our opinion, the minimum amount of information States need to accomplish this. At the same time, the statute protects the manufacturer's pricing data from disclosure. In accordance with section 1927(b)(3)(D) of the Act, information disclosed by manufacturers in connection with the rebate agreement is confidential and, notwithstanding other provisions of law (including the Freedom of Information Act, 5 U.S.C. 552) must not be disclosed by HCFA, the State agency, or its contractors in a form that reveals the manufacturer, except as necessary for the Secretary of HHS to carry out the provisions of section 1927 and for the Comptroller General or the Director of the Congressional Budget Office to review the information provided.

D. Unit Rebate Amounts

Comment: Several commenters believed that HCFA is not authorized by the statute to calculate the unit rebate amount since the law clearly states that the manufacturers will compute the information. They indicated that the penalties that may be imposed on manufacturers and HCFA's audit authority are sufficient to ensure that manufacturers make accurate and timely calculations.

Response: In accordance with sections 1902(a)(4), 1903, and 1927 of the Act, we believe that the Secretary has the authority and duty to implement and oversee various aspects of the drug rebate program. The Secretary has delegated this responsibility to HCFA. In accordance with this authority, HCFA is not precluded from calculating the unit rebate amount. We agree that manufacturers are responsible for calculating and paying rebates correctly. However, we believe that the administrative approach of HCFA supplying the States with unit rebate information to verify rebates is a practical and acceptable administrative oversight responsibility to ensure that States receive correct rebate payments and that the proper amount of FFP is made available to States.

E. Manufacturer's Requirements To List All Drugs

Comment: One commenter asserted that a manufacturer should not have to provide to HCFA a list of all of its covered outpatient drugs since some of its drugs may not be covered under Medicaid, that is, those drugs that a State may restrict or exclude from coverage under section 1927(d)(2) of the Act. The commenter believed that the requirement to list all of its drugs places an unnecessary administrative burden on the manufacturers and States. The commenter also believed that HCFA should review and evaluate each manufacturer's list of covered drugs after several rebate periods of experience in the drug rebate program and delete those drugs that are not covered under Medicaid or delete drugs that provide a minimal rebate.

Response: Under the terms of the national rebate agreement, a manufacturer is required to provide to HCFA rebates for all its covered outpatient drugs dispensed under the plan. Thus, in our opinion, there is no authority under the statute to delete drugs from the list of covered outpatient drugs where those drugs provide a minimal rebate from the drug rebate program.

F. Enforcement of State's Obligations

Comment: Several commenters asserted that HCFA's compliance action initiated against a State that fails to meet the various requirements under the drug rebate program, (for example, covering all drugs or new drugs from the date of FDA approval) is an ineffective and inadequate means of ensuring that States obey the requirements of sections 1902(a)(54) and 1927 of the Act.

The majority of commenters believed that manufacturers should be able to withhold rebate payments to a State until the State conforms its policies to the law. One commenter suggested that manufacturers should be allowed to withhold rebate payments in an amount equal to the sales lost during a rebate period, which would be estimated by the manufacturer, as a result of a State not properly covering drugs. Otherwise, the commenter was concerned that a State could ''reap a windfall'' since it would receive rebates and, at the same time, avoid paying for selected products that the State was required by statute to cover.

Response: Section 1904 of the Act and regulations at 42 CFR part 430, subpart C, provide that we may initiate a noncompliance action if States do not comply with all provisions of the Medicaid program. As noted in the rebate agreement, manufacturers may notify HCFA if they believe a State is not complying with a provision of the drug rebate program. The statute requires a manufacturer to provide a rebate to the State for each calendar rebate period based on utilization data submitted by the State. The rebate must be paid by the manufacturer to the State not later than 30 days after the date of receipt of the State's utilization data. Section 1927 of the Act does not contemplate that manufacturers can withhold rebates in those situations where a State does not comply with all of the provisions of the Medicaid program.

G. Adequacy of State Medicaid Utilization Data

Comment: One commenter asserted that section II. (b) of the national rebate agreement requires manufacturers to pay rebates to the States even if a State has failed to report all of the utilization data required by the statute and the agreement. The commenter believed this requirement is an attempt to relieve States of one of their primary responsibilities under the statute.

Response: Section 1927(b)(2)(A) of the Act requires that States use a standard reporting format established by the Secretary. In accordance with the statute, HCFA has defined the format for utilization data to include, in part, the use of NDC numbers. Given the provisions of the statute and our regulations at § 447.530, States would be required to report, at a minimum, the utilization data indicating the NDC number for the covered outpatient drugs and the total number of units of the drugs paid for during a rebate period. In

accordance with the statute, manufacturers must calculate and pay the rebate amounts within 30 days of the receipt of these two items of information. Furthermore, a manufacturer may audit these data that a State provides or is required to provide. If a manufacturer believes that a State has reported erroneous utilization data, the manufacturer is not required to pay a rebate on the portion of drugs for which the data are in question until the dispute is resolved.

Comment: Several commenters believed that Medicaid utilization data that States are required to supply to manufacturers are inadequate. They suggested that States should provide data at zip code level, and at a more detailed level if a manufacturer needs it, such as a claims history file that includes recipient, pharmacy, dispensing date and other claim information. They asserted that if States do not currently have this capability, we should require them to do so. These commenters also suggested that State utilization data should include monthly totals by NDC number and a rebate period summary, and that States should also be required to maintain the date that the drug was dispensed.

Several commenters stated that manufacturers should have the right to audit pharmacies and HCFA should ensure State cooperation with manufacturers in conducting these audits.

Response: We believe the data that the States provide under this regulation would be adequate for purposes of calculating the rebate. In addition, the manufacturer has the right, by law, to audit these data and adjustments to rebate amounts will be made to the extent that the data indicate that utilization was greater or less than the amount previously indicated. We would not require States to submit additional data, such as zip code-level information or a claims history, with their rebate period information. However, in the event of a dispute, we would require States to provide the manufacturer with this type of data if State confidentiality laws allow. (Section V.F. of the preamble contains further discussion on this issue.) Specific claim information that identifies a recipient is generally prohibited from being released to the public under the authority of section 1902(a)(7) of the Act and regulations at 42 CFR 431.300 through 431.307.

Manufacturers do not have the authority to audit pharmacies under section 1927 of the Act, but we expect States to audit pharmacy data in response to manufacturer requests when warranted.

H. Dispute Mechanism

Comment: One commenter believed that the timeframe of 30 days after receipt of a State's data is inadequate for a manufacturer to challenge errors made by the State. The commenter believed that the 30-day timeframe is unfair and may encourage premature challenges by manufacturers seeking to preserve their rights to use the dispute resolution process described in section V. of the rebate agreement.

Response: Section 1927(b)(1)(A) of the Act requires that manufacturers provide rebates within 30 days of receipt of State utilization data. In accordance with this requirement, we believe that the 30-day timeframe is reasonable for manufacturers to distinguish between legitimate disputed items and data inconsistencies and to attempt to resolve those disputes since data used to contest State data are similar to that needed to pay the rebate. If a manufacturer and State are unable to resolve discrepancies within the 30-day timeframe, the manufacturer must pay the rebate on the undisputed data and provide written notice of any discrepancies by submitting the RAR to the State agency. We would view it as a violation of these regulations and the rebate agreement if a manufacturer challenges the data simply as a method to extend the time period for reviewing data and avoid paying a rebate. The manufacturer also will be responsible for paying interest, as set forth in section 1903(d)(5) of the Act, on the disputed portion of the rebate if the State's data are not erroneous. (Section V.F. of the preamble contains a detailed discussion of the dispute resolution process.)

Comment: One commenter asserted that the dispute resolution process leaves States at financial risk when a dispute arises since HCFA will require its portion of the rebate payments from the States even though a manufacturer will withhold payments. The commenter believed that HCFA should assume some financial risk as well as play a more significant role in the dispute resolution.

Response: Manufacturers must pay States a rebate on the portion of the State utilization data that is not in dispute. We do not require the State to pay HCFA the Federal portion of the rate on the amount that is in dispute. Rather, we are requiring payment on those amounts that States receive in accordance with section 1927(b)(l)(B) of the Act. As a general rule, we believe we play a significant part as an overseer of the dispute resolution process between manufacturers and States. However, since both of these parties are directly responsible for the data they generate, we believe they must primarily work together to reconcile any differences.

I. Separate State Agreements

Comment: Several commenters believed that: (1) Modifications to existing State agreements are not permitted under the statute; (2) a State agreement may not legally provide for a different rebate amount than the amount in the national agreement; and (3) approval of an agreement under which a State exempts products from prior approval restrictions in exchange for rebates greater than those provided in the national agreement would be an abuse of HCFA's discretion even if the greater rebates were legal.

Response: We do not agree that modifications to existing agreements are prohibited under the statute. Section 1927(a)(4) of the Act specifies conditions that existing agreements must meet to be in compliance with the law. (Section II.A. of this preamble contains a discussion of the provisions of section 1927(a)(4).) Section 1927(a)(4) does not preclude modifications to existing agreements, such as allowing greater rebates.

We disagree that there is no legal authority to approve a separate agreement that provides for a different rebate amount than the amount in the national agreement. Section 1927(a)(1) of the Act recognizes the Secretary's authority to authorize individual State agreements and does not require that the individual State agreements incorporate the rebate amount requirements set forth in the national agreement. Thus, rebates under the individual State agreements need not match the rebates mandated under the national agreement. However, for the Secretary to accept them, as discussed in section II. of this preamble, they must be at least as large as the amount specified in the national agreement.

HCFA has the authority under the statute to approve individual State agreements and will review the agreements to ensure that the State is operating its prior authorization program in a manner consistent with the statute and regulations. However, given the provisions of section 1927(a) of the Act, we disagree that a State may not negotiate a separate rebate agreement that requires a higher rebate in exchange for removing drugs from the State's prior authorization program, provided that medically necessary drugs continue to be available to Medicaid recipients.

Comment: Several States contend that the 60-day timeframe allowed for the resolution of disputes is inadequate.

The States suggested that we expand the timeframe to approximately 120 days as a more realistic standard.

Response: We acknowledge that this timeframe is not adequate due to the complexity of resolving disputes. Therefore, we have revised the dispute resolution process, as discussed in section V.F. of the preamble, to reasonably accommodate all of the steps necessary to resolve a dispute. We are proposing to extend the entire timeframe to 240 days after the State receives the manufacturer's RAR for a State and manufacturer to settle the dispute. After this point, both parties may use arbitration, mediation, or the State hearing mechanism to settle the dispute. As discussed in section V.F. of the preamble, we established this timeframe after much discussion with States, manufacturers, and pharmacy groups. We believe the proposed dispute resolution process and the expanded timeframes meet the needs of both States and manufacturers.

J. Right of the Secretary to Audit AMP and Best Price Data

Comment: One commenter claimed that the statute does not give the Secretary an unqualified right to audit a manufacturer's data regarding AMP and best price calculations, as stated in the rebate agreement.

Response: Section 1927(b)(3)(B) of the Act clearly states that the Secretary has the right to survey wholesalers and manufacturers to verify manufacturer prices reported on AMP and best price. We believe this provision includes the right to audit pricing data, since an audit is often necessary to verify such pricing data.

K. Nonrenewal and Termination of Agreements

Comment: One commenter recommended that the national rebate agreement should be modified to specify that the effective date of manufacturer initiated termination/nonrenewal is the ''earlier'' of 60 days after a notice or the ending date of the term of contract if proper notice is given. The language of the published national agreement indicated that it is the ''later'' of these events.

Response: This was an error in the national agreement and will be corrected in the next revision of the national rebate agreement. We will honor nonrenewals up to 60 days before the end of the current period of the agreement and terminations up to 60 days before the end of the current rebate period (effective at the end of that rebate period). We have indicated the correct date in the regulations at § 447.514(c).

L. Administrative Procedure Act

Comment: Several commenters stated that they believed HCFA violated the Administrative Procedure Act (APA), 5 U.S.C. section 553, by using a model rebate agreement to implement the drug rebate program instead of developing formal regulations that allowed for public comment. They indicated that HCFA did not have adequate input from the States, manufacturers, pharmacy organizations, and the public while developing the policies that govern the rebate program. One commenter believed that failure to develop regulations or allow amendments to the national rebate agreement puts manufacturers in the untenable situation of having to sign an agreement without fully understanding the terms or risk losing their drug coverage under Medicaid.

Response: Section 4401 of OBRA '90 requires manufacturers to enter into and comply with the terms of the national rebate agreement by March 1, 1991, in order for payment to be made available under section 1903 of the Act for covered outpatient drugs. (As noted earlier, this date was extended to April 30, 1991, under the extenuating circumstances provision of section 1927(a)(3) of the Act.) Because of the short timeframe imposed by the Congress to implement the drug rebate provisions, it was impossible to issue regulations prior to the date that the national rebate agreement was required to be signed. In light of these short timeframes, and in the interest of receiving public comments, the contents of the rebate agreement were developed in direct consultation with representatives of drug manufacturers, States, and other interested parties. We considered this process an adequate means of providing actual notice and for obtaining public comments of affected parties within the time constraints. We believe that, given the circumstances, this approach was consistent with the provisions of the APA.

In addition, section 4207(j) of OBRA '90 authorizes the Secretary to issue regulations on an interim or other basis as may be necessary to implement the amendments made by the provisions of OBRA '90. In developing this proposed rule with comment period, we have taken into consideration, as appropriate, the public comments we received on the February 21, 1991, Federal Register notice, which included the contents of the national rebate agreement.

M. Timeframes for Signing Rebate Agreements

Comment: The majority of commenters indicated that manufacturers did not have adequate time to analyze and sign the national rebate agreement if they wanted their drugs covered retroactively to January 1, 1991. If they did not sign the agreement by the given deadline, their drugs would not be covered until July 1, 1991, thereby resulting in a large span of time within which drugs would not be covered.

Response: We realized that the timeframe that manufacturers had to analyze and sign the rebate agreement for their drugs to be covered retroactively to January 1, 1991 was very limited. The majority of manufacturers were able to sign the rebate agreement by the deadline. However, for those few that did not, we extended, under the extenuating circumstances clause in section 1927(a)(3)(B) of the Act, the original deadline of February 28, 1991, to April 30, 1991, for manufacturers to enter into a rebate agreement effective for drug coverage retroactive to January 1, 1991.

N. Amending the Language of the Rebate Agreement

Comment: One commenter recommended that HCFA include in regulations the process and timeframes that will be used to make changes to the national rebate agreement.

Response: We plan to periodically revise the rebate agreement language as needed. However, we believe that a scheduled timeframe for publication is not warranted since manufacturers have entered into the rebate agreement with coverage beginning in different rebate periods. We will further consider all comments from the February 21, 1991 notice and this proposed rule when we revise the national rebate agreement language.

O. Definition of Terms in the National Rebate Agreement

Comment: We received numerous comments on the definitions included in section I. of the national rebate agreement. Commenters claimed that our definitions were not in compliance with the statute.

Response: We considered comments on definitions when developing this proposed rule. Where we believed changes were necessary, we included them in the definitions contained in this proposed rule. After publication of the final rule, we intend to amend the national rebate agreement to reflect any new regulatory requirements and definitions.

P. National Drug Code

Comment: Several commenters recommended that States be required to maintain their records of NDC numbers by full 11-digit NDC numbers after a reasonable transition time period. The commenters also suggested that if a State does not comply with the 11-digit NDC number requirement by the specified deadline, manufacturers should have no responsibility to pay the rebate amounts until such a system is in place.

Response: OBRA '93 amended section 1927(b)(2)(A) of the Act to require that States report to manufacturers information on the total number of units of each dosage form and strength and package size of each covered outpatient drug, that is, States must use an 11-digit NDC number. This change is effective as if it was included in OBRA '90.

Prior to the enactment of OBRA '93, we agreed that States should maintain their records by the full 11-digit NDC number that indicates the manufacturer, product, and package size of a drug. In accordance with sections 1902(a)(54) and 1927(b)(2) of the Act, we began requiring States to report drug utilization data to HCFA and manufacturers using the 11-digit NDC numbers for claims paid on and after March 1, 1992. (During a transitional period of January 1, 1991 through February 29, l992, we allowed States that did not have the technical capability to report the 11-digit NDC number to use the 9-digit number (that is, the NDC number without the package size.)

We disagree, however, with the statement that a manufacturer should be able to withhold rebates. As stated earlier, the statute requires manufacturers to pay a rebate within 30 days of receiving State utilization data and does not authorize manufacturers to withhold a rebate when the State has submitted utilization data to the manufacturer. We will consider any State that does not maintain an 11-digit NDC number to be out of compliance.

Q. Definition of Nominal Price

Comment: One commenter contended that the definition of ''nominal price'' should not be predicated on a fixed percentage of 10 percent since this definition is not authorized by law and ignores the unique marketing and pricing practices of each drug manufacturer. This commenter believed that the company that claims a nominal price for a drug should have the burden of demonstrating to HCFA that the facts and circumstances concerning the drug render the price as nominal. The commenter stated that the standards and procedures to demonstrate a nominal price should be specified in the regulations. Another commenter agreed with the nominal price definition in the rebate agreement of ''any price less than 10 percent of the AMP.''

Response: We originally gave consideration to a definition that a nominal price be less than 1 percent of AMP. However, after discussions with manufacturers, States, and other parties, we believe the current definition of ''less than 10 percent of AMP'' to be sufficient to encompass the nominal prices offered by manufacturers. Prices greater than this appear to be for sales of the type meeting the definition for inclusion of AMP or best price.

We believe the administrative costs and burdens are too great to justify a policy that would require HCFA to review each manufacturer's case of why a nominal price for a drug is warranted and would offer no greater assurance of more accurately defining nominal price.

R. Additional Rebates Based on Rebate Period CPI–U Increases

Comment: One commenter recommended that the additional rebates (for increases in drug costs in excess of the increase in the CPI–U) should not be computed on a rebate period basis because manufacturers do not raise prices each rebate period and the effects of a rebate period CPI–U calculation would be uneven. However, the commenter believed that if the additional rebate is computed on a rebate period basis, it should be reconciled at the end of the year based on the increase of CPI–U compared to the increase in price. The commenter also suggested that we should consider comparing increases in prices to the projected annual increase in the CPI–U.

Response: The revision to the additional rebate calculation suggested by the commenter is contrary to section 1927 of the Act, which provides that the additional rebate is computed on the increase in CPI–U from a base date to the month before the beginning of the rebate period. OBRA '93 amended section 1927(c)(2) and removed the reference that an alternate period could be considered. We believe the intent of the law is to ensure that, for Medicaid purposes, drug price increases are equal to or less than the increase in the CPI–U on a rebate period basis.

Both of the commenter's proposals would allow drug prices to increase in excess of the rebate period CPI–U until the CPI–U ''caught up'', for example, a price increase of 10 percent in December 1990 would not cause an additional rebate for all of 1991 if the CPI–U increased 10 percent by December 1991.

Comment: One commenter suggested that the base CPI–U should be modified to use the June 1990 figure, the month before the rebate period used to determine the base AMP. The commenter believed this would make the time periods between the measurement of CPI–U and AMP the same.

Response: Section 1927(c)(2) of the Act provides that for drugs approved before October 1, 1990, we use the CPI–U from October 1, 1990. The CPI–U in effect on October 1, 1990, is the September 1990 CPI–U. For drugs approved after October 1, 1990, section VI. A. 2. of the preamble explains the criteria for determining the base CPI–U for the periods January 1, 1991—September 30, 1993, and October 1, 1993 and thereafter.

XI. Responses to Public Comments

Because of the large number of items of correspondence we normally receive on a rule, we are not able to acknowledge or respond to written public comments individually. However, we will consider all comments that we receive by the date specified in the ''Comment Date'' section of this preamble and respond to them in the preamble to any final rule that we issue.

XII. Paperwork Burden

Sections 447.508, 447.510, 447.514, 447.516(b), 447.524 (f) and (g), 447.526(c)(2)(i), 447.530, 447.534, 447.536, and 447.540(a)(2) of these proposed regulations contain requirements that are subject to review by the Office of Management and Budget under the Paperwork Reduction Act of 1980 (44 U.S.C. Chapter 35). These requirements have been approved by OMB under approval numbers 0938–0578 (for manufacturers) and 0938–0582 (for States).

Based on our experience with establishing new reporting systems, we estimate that the reporting requirements contained in these sections would be 39,289 burden hours per rebate period for manufacturers and 1,531 burden hours per rebate period for State Medicaid agencies.

XIII. Impact Analysis

A. Overall Impact

We generally prepare a regulatory flexibility analysis that is consistent with the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 through 612), unless the Secretary certifies that a regulation will not have a significant impact on a

substantial number of small entities. For purposes of the RFA, States and individuals are not small entities, but we consider some participating manufacturers as small entities.

In addition, section 1102(b) of the Act requires the Secretary to prepare a regulatory impact analysis for any proposed rule that may have a significant impact on the operations of a substantial number of small rural hospitals. Such an analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area and has fewer than 50 beds. We are not preparing a rural hospital impact statement because we have determined, and the Secretary certifies, that this proposed rule would not have a significant economic impact on the operations of a substantial number of small rural hospitals.

Although we view the anticipated results of these interim final regulations as beneficial to the Medicaid program as well as to Medicaid recipients and State governments, we recognize that some of the provisions could be controversial and may be responded to unfavorably by some affected entities. We also recognize that not all of the potential effects of these provisions can be definitely anticipated, especially in view of their interaction with other Federal, State and local activities regarding outpatient prescription drug costs. In particular, considering the effects of our simultaneous efforts to improve the delivery of Medicaid-covered outpatient prescription drugs, it is impossible to quantify meaningfully a projection of the future effect of all of these provisions on State and manufacturers' operating costs or on the frequency of substantial noncompliance and termination proceedings.

However, in a General Accounting Office report entitled ''Changes in Drug Prices Paid by Health Maintenance Organizations (HMOs) and Hospitals Since Enactment of Rebate Provisions'' (January, 1993, GAO/HRD–93–43), there was very little evidence of a significant effect on small rural hospitals. This report compares the year before and year after rebates went into effect. It concludes that there were only negligible effects on drug costs to hospitals (in fact, a slight decrease for inpatient drugs), but that HMOs' costs went up about 8 percent.

It is clear that a large number of small entities, such as manufacturers and pharmacies, will be affected by the implementation of these statutory provisions, and a substantial number of these entities may be required to make changes in their operations. For these reasons, we have prepared the following voluntary analysis. This analysis, in combination with the rest of the preamble, is consistent with the standards for analysis set forth by the RFA.

B. Anticipated Effects

1. Effects on the Medicaid Program

Primarily, the Medicaid drug rebate law was intended to reduce the amount State Medicaid programs pay for outpatient drugs by requiring manufacturers to offer States discounted prices for covered outpatient drugs. Below are estimates of Medicaid drug rebates. These estimates are based on data from actual rebates reported or paid for fiscal year 1992. These estimates also include the impact of section 601 of VHCA, which eliminated prices paid by the DVA and other entities from calculation of best price under the Medicaid drug rebate program. Projected Federal and State rebates have each been reduced by $10 million per year to account for the impact of the VHCA provisions.

[$ in millions]

	FY 94	FY 95	FY 96	FY 97
Federal	$870	$985	$1135	$1330
State	620	700	810	950

For fiscal year 1992, we estimated 12.76 percent rebate as a percentage of drug costs to the Medicaid program. Fiscal year 1993 data indicated an increase of the drug rebate of approximately 16 percent. Although we expect the percentage rebate to increase slightly over the estimable period reflected above, we are unable to do so with any degree of accuracy.

The estimates in the table represent savings generated from rebate payments from pharmaceutical manufacturers. They were the result of the following process:

- We developed a formula to estimate the manufacturer rebates as a percentage of Medicaid ingredient costs from a sample of drug claims drawn from the Medicaid Statistical Information System, otherwise known as MedStat.
- Average manufacturer prices were approximated by applying a discount to published average wholesale prices; the ''best price'' was developed from the DVA Federal supply schedule.
- The rebate formulas were modeled using a sample database from the data described above. The savings that resulted were expressed as a percentage of calculated Medicaid ingredient costs for the sample drugs.
- These saving percentages were applied to budget projections of Medicaid ingredient costs to obtain projected future savings. For this step the ingredient cost proportion of Medicaid drug spending and the distribution of brand name drugs versus generic drugs was derived from an analysis of data from the Pharmaceutical Data Service survey databases and MedStat data.
- The potential savings were reduced to account for rebate agreements that would have been negotiated between States and manufacturers in the absence of section 4401 of OBRA '90.

Further, section 13602 of OBRA '93 exhibited modifications to the Medicaid Drug Rebate law as previously indicated. We have made the following estimates of savings as a result of these changes.

[$ in millions]

	FY 94	FY 95	FY 96	FY 97	FY 98
Federal	$25	$55	$65	$70	$75
State	20	40	45	50	55

2. Effects on Pharmaceutical Manufacturers

Initially, it was anticipated that the outcome of these provisions would provide the Medicaid outpatient prescription drug program, representing 12 to 20 percent of all retail prescriptions in their respective States, with access to the best price for single source and innovator multiple source drugs. However, it was predicted in many circles that the pharmaceutical manufacturers would be unable to absorb these losses from 12 to 20 percent of retail sales and would respond by shifting the cost to other

non-Medicaid sectors of the prescription drug business. Various articles in newspapers and health journals have indicated that the pharmaceutical industry has elevated some prescription prices in non-Medicaid sectors. The overall impact of manufacturers raising drug prices for the non-Medicaid population cannot be accurately predicted.

Current data shows that approximately 515 manufacturers have signed agreements to participate in the Medicaid drug rebate program. Manufacturers appear to support the system and have minimal dissatisfaction. Recent studies done by the Office of Inspector General (OIG) show well over 90 percent of the drugs (and all major drugs) are covered compared to those covered prior to the program.

3. Effects on Non-Medicaid Sector

Reports indicate that some drug manufacturers are shifting higher drug costs to the DVA and the private sector. At one point, the DVA estimated that it would incur an additional $150 million in drug costs in 1991 and believed that these increased drug costs would be the result of manufacturers attempting to level out their pricing structure to avoid paying Medicaid significantly discounted best prices. In part, as a result of these estimates, the DVA Appropriations Act was enacted, which temporarily excluded until June 30, 1992, prices paid for drugs by the DVA from the best price. In addition, VHCA was enacted on November 4, 1992, which amended section 1927 in several areas and excluded prices paid by numerous entities from the best price component of the Medicaid drug rebate calculation. However, sufficient data do not exist to make a comprehensive evaluation of the overall impact on the non-Medicaid sectors.

If manufacturers attempt to maintain revenues as predicted by some sources, there could be several entities of the non-Medicaid sector affected other than government. If all discounts and contracts were rescinded and one price instituted for all, the economic impact on the hospital industry, for example, would be substantially negative since the industry receives large discounts for drug purchases, but for some other purchasers, it would be substantially positive.

C. Alternatives Considered

Section 1927 of the Act imposes strict legal and monetary savings requirements that the drug rebate program must meet. The only alternative to implementing the drug rebate program is to repeal section 4401 of OBRA '90 and section 13602 of OBRA '93. However, a repeal would impose additional costs on the Medicaid program since the drug rebate program is expected to generate substantial savings. Also, Federal and State administrative costs would be incurred to reverse the policy and operational procedures that were established to implement the drug rebate program.

A cost/benefit analysis of repealing the legislation was not conducted since the primary effect of this program simply includes what economists term an economic ''transfer''—reducing simultaneously and equally costs to the government and revenues of manufacturers through a change in purchasing procedures. The Congress passed this law to generate program savings from rebates to obtain price reduction that other sectors of the economy have received for years, and to provide the Medicaid population with equal access to the same prescription drugs that benefit the non-Medicaid population.

D. Interaction With Other Activities

The drug rebate program, in combination with the reimbursement moratorium, prospective and retrospective drug use review, electronic claims processing system, and demonstration projects, should ensure that the Medicaid prescription drug program will operate in the most economical manner possible. These provisions should result in decreased costs for both States and pharmacies once all aspects of section 1927 of the Act are fully implemented.

E. Conclusion

State and Federal Medicaid expenditures have grown at an extraordinary rate in recent years. Medicaid expenditures on prescription drugs, in particular, during the last half of the 1980s, grew at a rate greater than spending for many other Medicaid services. Therefore, we believe that the implementation of the above mentioned provisions in combination with measures that obtain an additional rebate based on the rate of growth of drug expenditures would help to reduce costs of the Medicaid program. We solicit public comments on the extent that any of the above mentioned entities are significantly economically affected by these provisions.

In accordance with the provisions of Executive Order 12866, this rule was reviewed by the Office of Management and Budget.

List of Subjects

42 CFR Part 441

Family planning, Grant programs—ealth, Infants and children, Medicaid, Penalties, Prescription drugs, Reporting and recordkeeping requirements, Safety.

42 CFR Part 447

Accounting, Administrative practice and procedure, Grant programs—health, Health facilities, Health professions, Medicaid, Reporting and recordkeeping requirements, Rural areas.

42 CFR chapter IV, subchapter C would be amended as follows:

A. Part 441 is amended as follows:

PART 441—SERVICES: REQUIREMENTS AND LIMITS APPLICABLE TO SPECIFIC SERVICES

1. The authority citation for part 441 continues to read as follows:

Authority: Sec. 1102 of the Social Security Act (42 U.S.C. 1302).

2. In § 441.10, the introductory text is republished, and a new paragraph (j) is added to read as follows:

§ 441.10 Basis.

This subpart is based on the following sections of the Act which state requirements and limits on the services specified or provide Secretarial authority to prescribe regulations relating to services:

* * * * *

(j) Sections 1903(a) and (i)(10) concerning FFP for State expenditures for drugs.

3. Section 441.25 is amended by adding a new paragraph (c) to read as follows:

§ 441.25 Prohibition on FFP for certain prescribed drugs.

* * * * *

(c) FFP is not available in State expenditures for covered outpatient drugs unless the requirements and conditions specified in subpart E of part 447 of this subchapter are met.

B. Part 447 is amended as follows:

PART 447—PAYMENTS FOR SERVICES

1. The authority citation for part 447 continues to read as follows:

Authority: Section 1102 of the Social Security Act (42 U.S.C. 1302).

2. Section 447.300 is revised to read as follows:

§ 447.300 Basis and purpose.

In this subpart—

(a) Sections 447.302 through 447.335 and 447.361 implement section

1902(a)(30) of the Act, which requires that payments be consistent with efficiency, economy, and quality of care; and section 1927(e)(4) of the Act, which specifies requirements for establishing upper limits on reimbursement for multiple source drugs dispensed under drug rebate agreements.

(b) Section 447.342 implements section 1902(a)(43) of the Act, which permits the State plan to provide for payment to a physician for laboratory services which the physician did not personally perform or supervise.

(c) Section 447.371 implements section 1902(a)(13)(F) of the Act, which requires that the State plan provide for payment for rural health clinic services in accordance with regulations prescribed by the Secretary.

3. Section 447.332 is revised to read as follows:

§ 447.332 Upper limits for multiple source drugs.

(a) *Establishment and issuance of listings.*

(1) HCFA will establish listings that identify and set upper limits for multiple source drugs that meet the following requirements:

(i) All of the formulations of the drug approved by the Food and Drug Administration (FDA) have been evaluated as therapeutically equivalent in the most current edition of its publication *Approved Drug Products with Therapeutic Equivalence Evaluations* (including supplements or in successor publications).

(ii) At least three suppliers list the drug (which has been classified by the FDA as category ''A'' in its publication, *Approved Drug Products with Therapeutic Equivalence Evaluations* (including supplements or in successor publications)) based on all listings contained in current editions (or updates) of published compendia of cost information for drugs available for sale nationally.

(2) HCFA will publish the lists of multiple source drugs for which upper limits have been established and revisions to the lists in Medicaid program instructions.

(3) HCFA will identify the sources used in compiling these lists.

(b) *Specific upper limits.*

(1) The agency's payment for multiple source drugs identified and listed in accordance with paragraph (a) of this section must not exceed, in the aggregate, payment levels determined by applying for each drug entity a reasonable dispensing fee established by the agency plus an amount established by HCFA that is equal to 150 percent of the published price for the least costly therapeutic equivalent drug (using all available national compendia) that can be purchased by pharmacists in quantities of 100 tablets or capsules (or, if the drug is not commonly available in quantities of 100, the package size commonly listed) or, in the case of liquids, the commonly listed size.

(2) For multiple source outpatient prescribed drugs identified in subpart E of this part, the formula specified in paragraph (b)(1) of this section is not subject to change by HCFA during the period January 1, 1991, through December 31, 1994.

(3) A State that is in compliance with the formula under paragraph (b)(1) of this section and § 447.331 may not reduce its reimbursement limits for covered outpatient drugs or dispensing fees for these drugs established under this formula during the period January 1, 1991, through December 31, 1994.

4. A new § 447.335 is added to read as follows:

§ 447.335 Additional upper limits for multiple source drugs.

(a) *Establishment and issuance of listings.*

(1) In addition to establishing listings specified in § 447.332, HCFA will establish listings that identify and set upper limits for multiple source drugs for which at least three of the formulations of the drug approved by the Food and Drug Administration (FDA) have been evaluated as therapeutically and pharmaceutically equivalent (category ''A'') in the most current edition of its publication *Approved Drug Products with Therapeutic Equivalence Evaluations* (including supplements or in successor publications), regardless of whether all additional formulations are rated as such.

(2) HCFA will publish the lists of multiple source drugs for which upper limits have been established and revisions to the lists in Medicaid program instructions.

(3) HCFA will identify the source(s) used in compiling these lists.

(b) *Specific upper limits.* The agency's payment for multiple source drugs identified and listed in accordance with paragraph (a) of this section must not exceed, in the aggregate, payment levels determined by applying for each drug entity a reasonable dispensing fee established by the agency plus an amount established by HCFA that is equal to 150 percent of the published price for the least costly therapeutic equivalent drug (using all available national compendia) that can be purchased by pharmacists in quantities of 100 tablets or capsules (or, if the drug is not commonly available in quantities of 100, the package size commonly listed) or, in the case of liquids, the commonly listed size. For purposes of this paragraph, therapeutic equivalent drugs mean drugs rated A or B by the FDA.

5. A new subpart I, consisting of §§ 447.500–447.550, is added to read as follows:

Subpart I—Payment for Outpatient Prescription Drugs Under Drug Rebate Agreements

Sec.
447.500 Basis and purpose.
447.502 Applicability.
447.504 Definitions.
447.506 Requirement for rebate agreements as a condition for payment for outpatient prescription drugs.
447.508 State plan requirements.
447.510 Rebate agreements: General requirements.
447.512 Terms of agreements.
447.514 Termination and nonrenewal of national rebate agreements.
447.516 Outpatient drugs subject to rebates.
447.518 Outpatient drugs of manufacturers without rebate agreements.
447.520 New drugs subject to rebates.
447.522 Drugs not subject to rebates.
447.524 Exclusions and restrictions on drugs subject to rebates.
447.526 Prior authorization programs.
447.530 State reporting requirements.
447.534 Manufacturer reporting requirements.
447.536 Resolution of disputes relating to information reported.
447.538 Resolution of disputes relating to drug access and State systems.
447.540 Confidentiality of reported information.
447.542 Penalties for failure to report or reporting false information.
447.546 Payment of rebates.
447.548 Computation of unit rebate amount.
447.550 Denial of FFP.

Subpart I—Payment for Outpatient Prescription Drugs Under Drug Rebate Agreements

§ 447.500 Basis and purpose.

(a) *Basis.* This subpart—

(1) Interprets section 1927 of the Act which provides in part that, in order for payment to be made under Medicaid for covered outpatient drugs of a manufacturer, the manufacturer must enter into and comply with a rebate agreement with the Secretary of HHS on behalf of States (or with States directly under specific authorization of the Secretary);

(2) Implements section 1902(a)(54) of the Act which includes a State plan requirement that provides that if a State elects to cover prescription drugs, the State must comply with the

requirements of section 1927 of the Act; and

(3) Implements section 1903(i)(10) of the Act which provides for denial of FFP in expenditures—

(i) For covered outpatient drugs of a manufacturer dispensed in any State if the manufacturer does not enter into and comply with a rebate agreement, except as prescribed in section 1927(a)(3) of the Act; and

(ii) For any amount expended which exceeds the upper payment limit for an innovator multiple source drug dispensed on or after July 1, 1991, if under applicable State law, a less expensive multiple source drug could have been dispensed.

(b) *Purpose.* This subpart specifies the requirements for State Medicaid agencies and the conditions under which FFP will be made for covered outpatient prescription drugs dispensed on or after January 1, 1991, under drug rebate agreements with manufacturers. This subpart also specifies the conditions for approval and renewal of rebate agreements with drug manufacturers and manufacturer reporting requirements.

§ 447.502 Applicability.

(a) The provisions of this subpart E apply to the 50 States (including any State that is furnishing medical assistance under a waiver granted under section 1115 of the Act) and the District of Columbia.

(b) The provisions of this subpart do not apply to covered outpatient drugs dispensed by:

(1) Health maintenance organizations (HMOs), including those organizations that contract with HCFA under section 1903(m) of the Act; and

(2) Hospitals that dispense covered outpatient drugs using drug formulary systems and bill Medicaid no more than the hospital's purchasing costs for these drugs as determined under the approved State plan.

§ 447.504 Definitions.

As used in this subpart E—

Covered outpatient prescription drugs or *covered outpatient drugs* means those drugs as defined in sections 1927(k) (2) through (4) of the Act and specified in § 447.516.

Depot means any Federal warehousing facility and distribution arrangement, including the Department of Defense's Electronic Commerce Initiative (ECI), whether:

(1) Government owned and operated;

(2) Government owned and privately operated; or

(3) Privately owned and operated.

Depot prices mean prices available to any depot of the Federal Government for purchase of drugs from a manufacturer through the depot system of procurement, irrespective of whether the drug products physically flow through the depot.

FDA refers to the Food and Drug Administration, Department of Health and Human Services.

Innovator multiple source drug means a multiple source drug from 1938 to present that was originally marketed under an original new drug application approved by the FDA.

Manufacturer. (1) A manufacturer means any entity that—

(i) Is engaged in the production, preparation, propagation, compounding, conversion, or processing of prescription drug products, either directly or indirectly by extraction from substances of natural origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis;

(ii) Is engaged in the packaging, repackaging, labeling, relabeling, or distribution of prescription drug products and is not a wholesale distributor of drugs or a retail pharmacy licensed under State law; and

(iii) Possesses legal title to the National Drug Code (NDC) number for a covered drug, or biological product.

(2) In the case of a corporation that meets the conditions of paragraphs (1)(i) and (1)(ii) of this definition, the entity includes—

(i) Any corporation that owns at least 80 percent of the total combined voting power of all classes of stocks or 80 percent of the total value of shares of all classes of stock in the entity (that is, a parent corporation);

(ii) Any other corporation in which the parent corporation of the entity owns at least 80 percent of the total combined voting power of all classes of stock or 80 percent of the total value of shares of all classes of stock in the other corporation (that is, a brother-sister corporation); and

(iii) Any other corporation in which the entity owns at least 80 percent of the total combined voting power of all classes of stock or 80 percent of the total value of shares of all classes of stock in the other corporation (that is, a subsidiary corporation).

Manufacturer-specific pricing data includes the average manufacturer price (AMP) (as defined in § 447.534(c)(1)), base date AMP, best price, or unit rebate amount in connection with a rebate agreement.

Marketed means that a drug was first sold by a manufacturer in the United States after FDA approval.

Medically accepted indication means any use for a covered outpatient drug approved under the Federal Food, Drug, and Cosmetic Act, or any use that is supported by one or more citations included or approved for inclusion in any of the following compendia: the American Hospital Formulary Service-Drug Information; the American Medical Association Drug Evaluations; and the United States Pharmacopeia-Drug Information.

Multiple source drug means a covered outpatient drug for which there are two or more drug products which—

(1) Are rated as therapeutically equivalent by the FDA in its current edition of its publication *Approved Drug Products with Therapeutic Equivalence Evaluations*;

(2) As determined by FDA, are pharmaceutically equivalent (the drug products contain identical amounts of the same active drug ingredient in the same dosage form and meet compendial or other applicable standards of strength, quality, purity, and identity) and are bioequivalent (the drugs do not present a known or potential bioequivalence problem, or if they do present such a problem, they are shown to meet an appropriate standard of bioequivalence). (This condition does not apply if FDA changes by regulation the requirement that in order for drug products to be rated as therapeutically equivalent, they must be pharmaceutically equivalent and bioequivalent);

(3) For purposes of coverage under the drug rebate program, are rated as ''A'' or ''B'' (therapeutic equivalence code) by the FDA in its current edition of its publication *Approved Drug Products with Therapeutic Equivalence Evaluations*; and

(4) Are sold or marketed in the State during a rebate period.

National rebate agreement means the rebate agreement developed by HCFA to implement section 1927 of the Act.

NDC refers to the National Drug Code number maintained by the FDA.

Nominal price refers to a price that is less than 10 percent of AMP.

Noninnovator multiple source drug means a multiple source drug that is not an innovator multiple source drug and that was marketed under an abbreviated new drug application approved by FDA, or any marketed, unapproved pre-1938 drug product for which the FDA has not made a final determination about its legal status. The term includes—

(1) All products approved under an abbreviated new drug application, paper new drug application under the FDA's former ''Paper NDA'' policy, or an application under section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act; and

(2) Any marketed, unapproved pre-1938 drug product that has not been evaluated under the new drug provisions of the Federal Food, Drug and Cosmetic Act.

Original New Drug Application (NDA) means an FDA-approved drug or biological application that received one or more forms of patent protection, patent extension under title II of Public Law 98–417, the Drug Price Competition and Patent Term Restoration Act, or marketing exclusivity rights granted by the FDA. This definition includes a new drug application (NDA), an amended NDA, an antibiotic drug application (ADA), an amended ADA, a product license application (PLA), and an amended PLA.

Single award contract prices means prices under a contract between the Federal Government and a manufacturer resulting in a single supplier for a covered outpatient drug within a class of drugs.

Single source drug means a covered outpatient drug which is produced or distributed under an original new drug application approved by the FDA, including a drug product marketed by any cross-licensed producers or distributors operating under the new drug application.

Wholesaler means any entity (including a pharmacy or chain of pharmacies) to which the manufacturer sells the covered outpatient drugs, but that does not relabel or repackage the covered outpatient drug.

§ 447.506 Requirement for rebate agreements as a condition for payment for outpatient prescription drugs.

In order for payments to be made under Medicaid for covered outpatient prescribed drugs described in §§ 440.120 and 447.516 of this subchapter, except as provided in § 447.518, the manufacturers of the drugs must have entered into and comply with:

(a) A rebate agreement with the Secretary on behalf of States, or with States directly, that meets the requirements of this subpart.

(b) A pharmaceutical pricing agreement with the Public Health Service, in accordance with section 340B of the Public Health Service Act, for all covered outpatient drugs purchased by a covered entity (as described in section 340B(a)(4) of the Public Health Service Act) on or after December 1, 1992.

(c) A pharmaceutical pricing agreement with the Department of Veterans Affairs (DVA), in accordance with 38 U.S.C. 8126, for all single source drugs, innovator multiple source drugs, biologicals, and insulin, effective January 1, 1993.

§ 447.508 State plan requirements.

A State Medicaid plan must provide that the Medicaid agency will comply with all of the applicable requirements of this subpart.

§ 447.510 Rebate agreements: General requirements.

(a) *Basic requirements.*

(1) Except as specified in paragraph (a)(2) of this section, a manufacturer of covered outpatient drugs that are dispensed under a State Medicaid program must have entered into and must comply with—

(i) A national rebate agreement authorized by HCFA; or

(ii) A State agreement that meets the conditions of paragraph (b) or (c) of this section and is authorized by HCFA.

(2) A manufacturer that has entered into a State agreement that meets the requirements of paragraph (b) or (c) of this section must also enter into the national rebate agreement.

(3) A manufacturer must include in its rebate agreement a list all of its drugs, by NDC numbers, that fall within the definition of covered outpatient drugs.

(4) A manufacturer may not specify that only a partial list of its covered outpatient drugs are subject to rebate under this subpart.

(b) *Existing State/manufacturer agreements.*

(1) HCFA will consider an individual drug rebate agreement between a manufacturer and a State Medicaid agency that is in effect on November 5, 1990, to be in compliance with the Federal requirements for drug rebates for the initial agreement period if—

(i) The initial term of the agreement provides for a minimum aggregate rebate of 10 percent of the average manufacturer price, as defined in § 447.534(c), for all of the manufacturer's drugs paid for by the State under Medicaid in a rebate period;

(ii) The State agency agrees to report to HCFA any rebates paid under the rebate agreement; and

(iii) The State agency submits to HCFA a written assurance from the manufacturer that the minimum 10-percent rebate was met under the agreement as of November 5, 1990.

(2) HCFA will consider an existing individual State rebate agreement to be in compliance with Federal requirements for drug rebates throughout the initial period of the agreement only if the manufacturer continues to provide rebates that meet the minimum 10-percent rebate requirement specified in paragraph (b)(1)(i) of this section throughout the initial period. If this requirement is not met, the manufacturer's drugs are subject to the terms of the national rebate agreement.

(3) A State and a manufacturer may amend the initial period of a rebate agreement that was in effect on November 5, 1990, that meets the requirements of paragraph (b)(1) of this section if the State and manufacturer are in agreement with all modifications and the terms of the agreement allow such modifications. Existing agreements may be amended to:

(i) Provide for a greater rebate; or

(ii) Add drugs if the minimum 10-percent aggregate rebate requirement is met.

(4) The manufacturer must have a rebate agreement that meets the requirements of section 1927(a) of the Act in every State and the District of Columbia for FFP to be available under Medicaid.

(c) *New State/manufacturer agreements.* If a State Medicaid agency did not have an existing agreement with its drug manufacturers in effect on November 5, 1990, it may enter into a new agreement under the conditions of this paragraph.

(1) The agreement must provide drug rebates as least as great as those required under the national rebate agreement.

(2) The State agency must agree to report to HCFA any rebates paid under the rebate agreement.

(3) The manufacturer must enter into the national rebate agreement.

(4) The State agency must provide to HCFA a written assurance from the manufacturer that the agreement provides rebates that equal or exceed the amounts in the national agreement.

(d) *Authorization by HCFA.* Existing and new agreements, and their renewals, must be specifically authorized by HCFA.

§ 447.512 Terms of agreements.

(a) *Initial period.*

(1) The initial period of an existing State/manufacturer agreement and a new State/manufacturer agreement is the period specified in the agreement. In the event no period is specified, the initial period is 1 year.

(2) The initial period of the national rebate agreement must be for at least 1 year.

(b) *Renewal of agreements.*

(1) An existing agreement may be renewed if—

(i) The agreement provides drug rebates as least as great as those required under the national rebate agreement;

(ii) The State agency agrees to report to HCFA any rebates paid under the rebate agreement;

(iii) The State agency provides to HCFA a written assurance from the manufacturer that the agreement provides rebates that equal or exceed the amounts in the national agreement; and

(iv) The manufacturer enters into the national rebate agreement.

(2) Each national agreement will be automatically renewed for successive periods of at least 1 year if the agreement continues to meet the conditions of the initial period of the agreement and requirements of these regulations, unless the manufacturer gives a written notice of intent not to renew the agreement or HCFA or the manufacturer terminates the agreement in accordance with § 447.514.

(c) *Effective dates of national rebate agreements.*

(1) A national rebate agreement that was entered into and authorized by HCFA between February 15, 1991, and April 30, 1991, is effective retroactive to January 1, 1991, unless the manufacturer requests a later effective date.

(2) A national rebate agreement that is entered into and authorized by HCFA on or after May 1, 1991, is effective the first day of the rebate period that begins more than 60 days after the date the agreement is entered into unless the manufacturer requests a later effective date.

§ 447.514 Termination and nonrenewal of national rebate agreements.

(a) *Who may terminate.* National rebate agreements may be terminated by HCFA or by the manufacturer as specified in paragraphs (b) and (c) of this section.

(b) *Termination by HCFA.*

(1) HCFA may terminate an agreement if the manufacturer violates the requirements of the rebate agreement or for ''other good cause'' shown. ''Other good cause'' includes, but is not limited to, any violations of the provisions of the national rebate agreement, section 1927 or the related regulations, or the persistent failure to provide timely information on pricing and other required information or to pay timely rebates.

(2) HCFA will send a written notice of the existence of a violation and the decision to terminate the agreement to the manufacturer and notify all State Medicaid agencies of the termination.

(3) The termination will be effective no earlier than 60 days after the date the notice of termination is sent to the manufacturer.

(4) If a manufacturer is dissatisfied with a termination decision made by HCFA, the manufacturer may request a hearing to appeal the termination under the procedures established in the national rebate agreement. However, a request for a hearing will not delay the effective date of the termination.

(c) *Termination by the manufacturer.* A manufacturer may terminate an agreement for any reason.

(1) *Reasons other than nonrenewal*—(i) *Written notice.* To terminate an agreement for reasons other than nonrenewal, a manufacturer must provide a written notice of termination to HCFA at least 60 days before the beginning of the calendar quarter in which the termination will occur.

(ii) *Effective dates.* Termination will be effective on the first day of the first rebate period beginning at least 60 days after the manufacturer gives written notice requesting termination, or a later date if so specified by the manufacturer.

(2) *Nonrenewals*—(i) *Written notice.* A manufacturer that wishes not to renew an agreement must provide a written notice of nonrenewal of the agreement to HCFA at least 60 days before the end of the current agreement period.

(ii) *Effective dates.*

(A) Termination resulting from nonrenewal will be effective on the ending date of the term of the agreement if the manufacturer has given the 60-day advance notice.

(B) If the manufacturer has not given the 60-day advance notice, the effective dates of termination specified in paragraph (c)(1)(ii) of this section will apply.

(3) *Date of notice.* The postmark date of the U.S. Postal Service or common mail carrier will be considered as the date a manufacturer gives written notice.

(d) *Reinstatement after termination.* If an agreement is terminated by either HCFA or the manufacturer, another agreement with the manufacturer (or a successor manufacturer) may not be entered into until a period of one calendar quarter has elapsed from the date of the termination, unless HCFA finds good cause for an earlier reinstatement.

(e) *Effect of termination or nonrenewal on rebates due.* Any nonrenewal or termination of a rebate agreement will not affect rebates due before the effective date of nonrenewal termination.

(f) *Notification of termination.* HCFA will notify States of any termination of a manufacturer from the drug rebate program at least 30 days prior to the effective date of the termination.

§ 447.516 Outpatient drugs subject to rebates.

(a) Except for the drugs or items listed in § 447.522, the following covered outpatient drugs are subject to rebates under this subpart:

(1) Drugs that are—

(i) Covered outpatient drugs of participating manufacturers under an approved State Medicaid plan; and

(ii) Dispensed by prescription (except certain over-the-counter drugs as specified in paragraph (a)(5) of this section);

(2) Drugs that meet the requirements of the Federal Food, Drug, and Cosmetic Act and the Drug Amendments of 1962 specified in section 1927(k)(2)(A) (i) through (iii) of the Act;

(3) A biological product other than a vaccine that may only be dispensed by prescription, is licensed under section 351 of the Public Health Service Act, and is produced at an establishment licensed under section 351 to produce such products;

(4) Insulin certified under section 506 of the Federal Food, Drug, and Cosmetic Act; and

(5) ''Over-the-counter'' drugs that are prescribed by a physician or other person authorized to prescribe drugs under State law, if the State provides for coverage of these drugs as prescribed drugs under its approved State Medicaid plan.

§ 447.518 Outpatient drugs of manufacturers without rebate agreements.

(a) *Definition.* For purposes of this section, *1–A rated drugs* means drugs classified as such by the FDA, prior to January 1, 1992, as new molecular or chemical entities that may provide effective therapy or diagnosis for a disease not adequately treated or diagnosed by any marketed drug, or provide improved treatment of a disease through improved effectiveness or safety (including decreased abuse potential) and identified in the FDA publication *Office of Drug Evaluation Statistical Report,* issued yearly. The term includes drugs rated as 1–A/AA.

(b) *Federal financial participation (FFP).* FFP is available for payments for single source and innovator multiple source 1–A rated drugs that are furnished by manufacturers without rebate agreements if—

(1) The State agency has determined that the availability of the drug is essential to the health of Medicaid recipients under the approved State plan;

(2) The prescribing physician has obtained approval for use of the drug before it is dispensed in accordance with a prior authorization program specified in § 447.526, or the Secretary has approved the State agency's determination regarding drug necessity under paragraph (b)(1) of this section.

§ 447.520 New drugs subject to rebates.

(a) Effective October 1, 1993, there is no special treatment for new drugs under the Medicaid drug rebate program.

(b) For the period January 1, 1991 through September 30, 1993—

(1) Subject only to the exclusions and restrictions specified in § 447.524 (a)(2) and (a)(3), a new drug of participating manufacturers must be covered for a period of 6 months after the date of approval of the drug by the FDA, regardless of when the manufacturer begins to market the drug.

(2) Except as specified in § 447.524(b), a State agency may not exclude, subject to the prior authorization conditions specified in § 447.526, or otherwise restrict the coverage of covered outpatient drugs under a drug rebate agreement any new drug or biological approved by the FDA for a period of 6 months after FDA approval.

(c) FFP is not available for coverage of new drugs furnished by manufacturers who do not have rebate agreements that were in effect for the 6-month period after FDA approval of the new drug, unless covered during the retroactive period of January 1, 1991, through March 31, 1991, or covered as a 1–A rated drug under § 447.518(b).

§ 447.522 Drugs not subject to rebates.

The following list indicates drugs or items that are not subject to rebates under this subpart:

(a) Any drug, biological product, or insulin provided as part of, or as incident to and in the same setting as any of the following (and for which Medicaid payment may be made as part of payment for the following and not as direct reimbursement for the drug):

(1) Inpatient hospital services;

(2) Hospice services;

(3) Dental services (except for drugs for which the approved State plan authorizes direct reimbursement to the dispensing dentist);

(4) Physician services;

(5) Outpatient hospital services;

(6) Nursing facility services and services provided by an intermediate care facility for the mentally retarded;

(7) Other laboratory and x-ray services; and

(8) Renal dialysis.

(b) Any drug, biological product, or insulin that is used for a medical indication that is not a medically accepted indication.

(c) Any drug, biological product, or insulin for which a NDC number is not required by the FDA.

(d) Medical supply items such as syringes (excluding insulin-filled syringes), urine and blood glucose testing strips and devices, lancets, and inhalers.

(e) Enteral nutrition products that are not approved by FDA as a drug under sections 505, 506, and 507 of the Federal Food, Drug, and Cosmetic Act.

(f) Parenteral nutrition products that are not approved by the FDA under section 505 of the Federal Food, Drug, and Cosmetic Act and given by the intravenous route of administration.

(g) Investigational new drugs (for example, Treatment IND drugs, Group C cancer drugs, and Parallel Track drugs).

§ 447.524 Exclusions and restrictions on drugs subject to rebates.

(a) A State agency may limit coverage of outpatient drugs that are subject to rebate by—

(1) Implementing a prior authorization program, as specified in § 447.526;

(2) Restricting or excluding certain drugs from coverage as specified in paragraphs (b) and (c) of this section; and

(3) Restricting the quantity of drugs per prescription and the number of refills, as specified in paragraph (e) of this section.

(b) A State may exclude or restrict from coverage, as an outpatient drug subject to rebate, any drug if—

(1) The prescribed use of the drug is not for a medically accepted indication;

(2) The drug, the class of drug, or its medical use is contained on the list as specified in paragraph (c) of this section;

(3) The drug is subject to restrictions in an existing or new manufacturer rebate agreement with the State agency that has been authorized by HCFA in accordance with § 447.510; or

(4) The State has excluded coverage of the drug from its formulary established in accordance with section 1927(d)(4) of the Act.

(c) A State may exclude or restrict from coverage, as outpatient drugs subject to rebate, any of the prescribed drugs it has elected to cover under its approved State Medicaid plan that fall within the following descriptions of drugs, classes of drugs, or their medical uses:

(1) Agents when used for anorexia, weight loss, or weight gain.

(2) Agents when used to promote fertility.

(3) Agents when used for cosmetic purposes or hair growth.

(4) Agents when used for the symptomatic relief of cough or colds.

(5) Agents when used to promote smoking cessation.

(6) Prescription vitamins and mineral products, except prenatal vitamins and fluoride preparation.

(7) Nonprescription drugs.

(8) Covered outpatient drugs for which the manufacturer seeks to require, as a condition of sale, that associated tests or monitoring services be purchased exclusively from the manufacturer or its designee.

(9) Barbiturates.

(10) Benzodiazepines.

(d) HCFA will periodically update, by regulation, the list of drugs subject to restriction as specified in paragraph (c) of this section by adding drugs, classes of drugs, or medical uses if it determines that there is evidence of clinical abuse or inappropriate use. HCFA will make this determination on the basis of data collected by the State Medicaid agency's surveillance and utilization review (SUR) program under part 456 of this subchapter.

(e) A State may restrict the minimum and maximum quantities of covered outpatient drugs per prescription and the number of refills within a therapeutic class of drugs. A State may also restrict one or more package sizes of a drug to be dispensed as long as the restriction does not result in a participating manufacturer's drugs not being covered at all under the Medicaid program.

(f) The agency must specify in its State Medicaid plan that, except for the restrictions and exclusions specified in this section, and drugs excluded from its formulary which meets the requirements of section 1927(d)(4) of the Social Security Act, the formulary will permit coverage of covered outpatient drugs of manufacturers which have met the requirements of § 447.506 that are prescribed for a medically accepted indication.

(g) The agency must include in its State Medicaid plan a list of covered outpatient drugs, classes of drugs, or medical uses under paragraph (c) of this section that it is excluding or restricting from coverage under this section and specify the limitations or conditions on coverage.

§ 447.526 Prior authorization programs.

(a) A State agency may establish a prior authorization program for any covered outpatient drug under which the drug must be approved before it is dispensed for any medically accepted indication.

(b) A State agency may determine which persons (for example, physician, pharmacist) are permitted to request prior authorization of a drug.

(c) Under a prior authorization program, the State agency must—

(1) Provide for a response by telephone or telecommunications device to a request for prior authorization

within 24 hours of receipt of a request; and

(2) In emergency situations, provide for dispensing of at least a 72-hour supply of drugs, except for those drugs that are excluded or restricted as outpatient prescribed drugs under § 447.524.

(i) The State agency must specify in its State plan the process that will be used to determine what constitutes an emergency situation.

(ii) The State agency must ensure that its response to a prior authorization request is given to the dispenser before the emergency supply is exhausted.

(iii) In emergency situations, the State must provide a mechanism so that a dispenser or physician can make a prior authorization request 24 hours before the supply is exhausted and a response returned by the State within that 24-hour period.

(d) State staff who place drugs in a prior authorization system must be licensed to prescribe or dispense drugs in the State, for example, physicians or pharmacists.

(e) State staff who respond to prior authorization requests are not limited to persons licensed to prescribe or dispense drugs as long as all decisions involving drugs subject to prior authorization are made—

(i) In consultation with these licensed professionals; or

(ii) Under guidelines promulgated by such individuals as long as States provide access to these licensed professionals in difficult or unusual cases.

(f) The State agency must establish a process to ensure that recipients have access to medically necessary covered outpatient drugs and must provide annual written assurances to HCFA that its prior authorization program does not prevent recipients from gaining access to medically needed drugs.

§ 447.530 State reporting requirements.

(a) *Basic requirement.* The State agency must provide to manufacturers with drug rebate agreements State drug utilization data specified in paragraph (b) of this section for which Medicaid payments have been made during a rebate period. For purposes of this section—

(1) The agency must use the 11-digit NDC number to report drug utilization data.

(2) *Unit* means the lowest commonly identifiable amount of a drug—for example, tablet or capsule for solid dosage forms, milliliter for liquid forms, and gram for ointments or creams, as described in the rebate agreement and accompanying appendices.

(b) *Type of data to be reported.* The State agency must submit to manufacturers the following information, based on claims paid by the agency during a rebate period:

(1) State identification;

(2) Rebate period and year for which data apply;

(3) The NDC number;

(4) Total units paid for during a rebate period by NDC.

(5) The product name (FDA registration name);

(6) Total amount of rebate that a State claims for each NDC;

(7) Total number of prescriptions paid for during the rebate period by NDC number; and

(8) The rebate amount per unit and the total amount paid for during the rebate period by NDC number to verify rebate payment.

(c) *Timeframe for reporting.*

(1) The State agency must report the utilization data no later than 60 days after the end of each rebate period.

(2) In the event that a due date falls on a weekend or Federal holiday, the report or other item will be due on the first business day following that weekend or Federal holiday.

(3) If a State does not submit its rebate period utilization data to the manufacturer within 1 year after the rebate period ends—

(i) A manufacturer is not required to pay a rebate on those drugs; and

(ii) A State may be considered out of compliance with section 1927 of the Act for failure to collect rebates.

(d) *Format of report.* The State agency must report the utilization data, using the NDC number, in a form prescribed by HCFA.

(e) *Administrative procedures for data collection.* The State agency must—

(1) Inform Medicaid participating drug dispensers that they are required to use accurate NDC numbers for the drugs dispensed in submitting their Medicaid claims and of potential payment denial, sanctions, including those for fraud and abuse, and possible termination of provider agreements, for incorrect coding of NDC numbers;

(2) Establish and implement an oversight and auditing plan to ensure proper pharmacy coding and reporting practices;

(3) Establish and implement procedures for investigating at the pharmacy level allegations of erroneous utilization data by manufacturers with rebate agreements; and

(4) Establish procedures for taking actions necessary to ensure accurate coding.

(f) *Use of data edits.* The State must verify the accuracy of utilization data through the use of data edits such as, but not limited to—

(1) Unit types are appropriate for NDCs;

(2) Units match amount paid by the State; and

(3) Amount paid by the State is appropriate for the drug.

(g) *Use of rounding indicators.* States must identify by NDC number those drugs for which the number of units has been rounded by showing a rounding indicator for the number of units dispensed.

§ 447.534 Manufacturer reporting requirements.

(a) *Basic requirements.* Under the terms of the drug rebate agreement, a manufacturer must—

(1) Supply HCFA with a list of all covered outpatient drugs (as specified in paragraph (c) of this section), the average manufacturer price, and, for single source and innovator multiple source drugs, the best price (as specified in paragraph (d) of this section) within 30 calendar days of entering into an agreement;

(2) Update the list of covered outpatient drugs as provided for in paragraph (b) of this section;

(3) Supply the information specified in paragraph (e) of this section for each rebate period in a format prescribed by HCFA in regulations or instructions; and

(4) Complete and submit to States the HCFA Form 302, the Remittance Advice Report (RAR), in a format prescribed by HCFA in regulations or instructions. The RAR must include the information specified in paragraph (f) of this section, along with any rebate period rebates due within 30 days of receiving from the State Medicaid drug utilization data.

(b) *Update to manufacturer's drug list.* A manufacturer must update its list of all covered outpatient drugs for each rebate period, including the average manufacturer price of each drug, and, for single source and innovator multiple source drugs, the manufacturer's best price.

(1) The updated list must be reported by the manufacturer to HCFA no later than 30 days after the last day of each rebate period.

(2) The updated list reported by the manufacturer must include the NDC number for each covered outpatient drug currently marketed by the manufacturer and for all drugs that the manufacturer no longer markets until the supply of the drug under an NDC has expired, the drug has been taken off the market, or for any other reason, there no longer exists the potential that the drug may be paid for under the manufacturer's NDC number.

(c) *''Average manufacturer price'' defined.*

(1) ''Average manufacturer price'' (AMP) means, with respect to a covered outpatient drug of the manufacturer for a rebate period, the average unit price paid to the manufacturer for the drug in the State by wholesalers for drugs distributed to the retail pharmacy class of trade (excluding sales to hospitals, health maintenance organizations and to wholesalers where the drug is relabeled under that distributor's NDC number), after deducting customary prompt pay discounts.

(2) Federal supply schedule prices are not included in the calculation of AMP.

(3) AMP includes cash discounts allowed and all other price reductions (other than rebates under this subpart), which reduce the actual price paid.

(4) AMP is calculated as a weighted average of prices for all the manufacturer's package sizes for each covered outpatient drug sold by the manufacturer during that rebate period. It is calculated as net sales divided by numbers of units sold, excluding goods or any other items given away, but not contingent on any purchase requirements. ''Net sales'' means quarterly gross sales revenues less cash discounts allowed and all other price reductions (other than rebates under section 1927 of the Act) which reduce the actual price paid. For bundled sales, the allocation of the discount is made proportionately to the dollar value of the units of each drug sold under the bundled arrangement. ''Bundled sales'' refers to the packaging of drugs of different types where the condition of rebate or discount is that more than one drug type is purchased, or where the resulting discount or rebate is greater than that which would have been received had the drug been purchased separately.

(5) The manufacturer must adjust the AMP for a rebate period if cumulative discounts or other arrangements subsequently adjust the prices actually realized.

(d) *''Best price'' defined.*

(1) ''Best price'' means, with respect to single source and innovator multiple source drugs, the lowest single price at which the manufacturer sells the covered outpatient drug to any purchaser in the United States in any package size in any pricing structure (including capitated payments), in the same quarter for which the AMP is computed.

(2) To determine best price, use the following prices in the best price calculation:

(i) *Prices included in best price.*

(A) Except for those prices specifically exempted by law, as specified in paragraphs (d)(2)(i)(B) and (d)(2)(ii) of this section, best price includes prices to wholesalers, retailers, providers, HMOs, nonprofit entities, or governmental entities within the States (excluding depot prices and single award contract prices of any agency of the Federal Government).

(B) For periods January 1, 1991, through October 27, 1991, and July 1, 1992, through September 30, 1992, best price includes any prices charged under the Federal Supply Schedule of the General Services Administration, including prices for drugs and biologicals paid by the DVA and drugs and biologicals in contracts administered by the DVA.

(ii) *Prices excluded from best price.*

(A) For periods beginning on or after October 1, 1992, best price excludes any prices charged to the Indian Health Service, the DVA, a State home receiving funds under 38 U.S.C. 1741, the Department of Defense, the Public Health Service, or a covered entity described in section 1927(a)(5)(B) of the Social Security Act; any prices charged for drugs and biologicals under the Federal Supply Schedule of the General Services Administration; or any prices used under a State pharmaceutical assistance program.

(B) For the period October 28, 1991, through June 30, 1992, best price excludes any prices charged under the Federal Supply Schedule of the General Services Administration for drugs and biologicals paid by the DVA and drugs and biologicals in contracts administered by the DVA.

(3) Calculations of best prices must include cash discounts, free goods that are contingent on any purchase requirements, volume discounts, and rebates, other than rebates under section 1927 of the Act.

(4) Best price must be determined on a unit basis without regard to special packaging, labeling, or identifiers on the dosage form or product or package, and must not take into account prices that are nominal in amount.

(5) For bundled sales, the allocation of the discount is made proportionately to the dollar value of the units of each drug sold under the bundled arrangement.

(6) The manufacturer must adjust the best price for a rebate period if cumulative discounts, rebates, or other arrangements subsequently adjust the prices actually realized.

(7) For purpose of this section, *provider* means a physician, hospital and other health maintenance organizations or entities that treat individuals for illnesses or injuries or provides services or items in the provisions of health care.

(e) *Contents of quarterly report.* The manufacturer's quarterly reports to HCFA must include—

(1) NDC number with labeler code, product code, and package size code;

(2) Period covered for rebates (rebate period and year);

(3) Product FDA registration name;

(4) Drug category of single source, innovator multiple source, or noninnovator multiple source;

(5) Indicator for drug reviewed under the Drug Efficacy Study Implementation (DESI) program;

(6) FDA therapeutic equivalence explanation code;

(7) Unit type;

(8) Units per package size;

(9) AMP;

(10) Basedate AMP;

(11) Best price;

(12) FDA approval date;

(13) Date drug entered market;

(14) Drug termination date;

(15) Drug type; and

(16) Correction record flag which signals that the record contains corrected information from a previous submission.

(f) *Contents of Remittance Advice Report (RAR) (HCFA Form 304).* The manufacturer's RARs to States must include—

(1) Manufacturer name, labeler code, address, and name, telephone number, and facsimile number of contact person;

(2) State;

(3) Rebate period and year for which the information applies;

(4) Invoice number, if State provided one;

(5) NDC number and product name;

(6) Rebate amount per unit;

(7) Units invoiced;

(8) Rebate amount invoiced;

(9) Rebate amount paid;

(10) Adjusted rebate per unit, if applicable;

(11) Adjustment code, if applicable;

(12) Credit/debit indicator, if applicable;

(13) Adjusted invoice amount, if applicable;

(14) Units disputed, if applicable;

(15) Dispute code, if applicable;

(16) Withheld invoice amount, if applicable;

(17) Total rebate amount invoiced;

(18) Total rebate amount paid;

(19) Total adjusted invoice amount, if applicable; and

(20) Total withheld invoice amount, if applicable.

(g) *Recordkeeping requirements.*

(1)(i) Except as set forth in paragraph (e) of this section, a manufacturer must retain records (written or electronic) for

3 years from the date the manufacturer reports that rebate period's data. The records must include the data and any other materials from which the calculations of the AMP and best price are derived, including a record of any assumptions made in the calculations.

(ii) A manufacturer must retain records beyond the 3-year period if audit findings have not been resolved.

(2) Both the State and manufacturer must retain supporting documentation (written or electronic) related to the dispute resolution process and the RAR for 3 years from the date a dispute is resolved between the manufacturer and State.

(h) *Timeframe for reporting revised AMP or best price.* A manufacturer must report changes to AMP or best price for 3 years after the quarter to which the data pertains.

§ 447.536 Resolution of disputes relating to information reported.

(a) *Resolving data inconsistencies.*

(1) The manufacturer must attempt to identify and resolve data inconsistencies in State Medicaid drug utilization data prior to initiating the dispute resolution process described in paragraphs (b) and (c) of this section.

(2) The manufacturer must attempt to resolve any data inconsistencies under paragraph (a)(1) of this section with the State by no later than 30 days after receipt of State Medicaid drug utilization data. The manufacturer may initiate this process through telephone contact with the State.

(3) If data inconsistencies are resolved by the manufacturer and State, the manufacturer must record this fact on the RAR and the State must maintain supporting documentation to substantiate the resolution of the data inconsistencies.

(b) *Reporting disputes.*

(1) If, in any rebate period, a manufacturer and the State are unable to resolve data inconsistencies under paragraph (a) of this section or other disputed items within 30 days after the manufacturer receives State Medicaid drug utilization data, the manufacturer must complete and submit the RAR to the State in accordance with § 447.534(a)(4) or the State's utilization data are considered final and binding and the entire rebate payment is due.

(2) The RAR must include the information specified in § 447.534(f) and identify by each NDC the reason(s) why the manufacturer is disputing the data.

(3) The manufacturer must submit to the State supporting documentation for certain types of disputes as indicated on the RAR. The manufacturer must submit supporting documentation for certain types of disputes as indicated on the RAR if a State requests the documentation to verify information.

(4) The RAR must be postmarked by the United States Postal Service or common mail carrier on or prior to the due date for the rebate period payment of the rebates to the State agency.

(c) *Resolving disputes.*

(1) Within 90 days after the State receives the RAR, the State must contact the manufacturer in writing or by telephone to discuss the dispute and to present the State's preliminary response on the disputed items to the manufacturer. If the dispute is resolved, the manufacturer and the State must both maintain supporting documentation of the resolution for 3 years from the date the dispute is resolved.

(2) If the dispute is not resolved in accordance with paragraph (c)(1) of this section, the State must, within 150 days after the State receives the RAR and in accordance with State confidentiality laws—

(i) Provide the manufacturer with drug utilization data, such as zip code-level data, pharmacy-level data, sampling of pharmacy claims, or historical trends on those items in dispute; and

(ii) Submit to the manufacturer the same type of drug utilization data used by the manufacturer to identify disputed items.

(3) If State confidentiality laws prohibit the State from releasing the types of information in paragraph (c)(2) of this section, the State may require the manufacturer to provide the data upon which the manufacturer based the dispute to the State. Upon such request, the manufacturer must furnish such data to the State within 150 days after the State receives the RAR.

(4) Within 240 days after the State receives the RAR, the State and manufacturer must complete negotiations. One of the following actions must occur:

(i) The State ceases the dispute resolution process based on a cost-effectiveness determination in accordance with paragraph (k) of this section;

(ii) The State and the manufacturer settle on the State Medicaid drug utilization data and agree to make appropriate adjustments to any rebate amounts;

(iii) The State and the manufacturer agree to a resolution based on mutually acceptable data which is more representative of actual Medicaid utilization;

(iv) If no resolution is reached, the State must schedule a hearing in accordance with paragraph (d) of this section or the State may be subject to a compliance action by HCFA; or

(v) In lieu of a State hearing, the State and manufacturer may agree to arbitration or mediation to settle the dispute.

(5) The State must maintain documentation which clearly describes its decision to—

(i) Cease the dispute resolution based on cost-effectiveness as specified in paragraph (k) of this section; or

(ii) Agree with the manufacturer on a settlement as specified in paragraphs (c)(4)(ii) or (c)(4)(iii) of this section.

(d) *State hearing.*

(1) If no settlement has been reached between the State and the manufacturer within 240 days after the State receives the RAR, the State, must within 30 days, schedule a hearing. The hearing must be conducted within 1 year from the 240th day after the State receives the manufacturer's RAR.

(2) The manufacturer may require a State to schedule a hearing at any stage of the process if the State does not take the required actions of the dispute process within the specified timeframes. The State must, within 30 days, schedule a hearing.

(3) If the manufacturer does not comply with its timeframes specified in the agreement, the State may—

(i) At any stage of the process schedule a hearing which must be conducted within 1 year from the 240th day after the State received the manufacturer's RAR;

(ii) Follow the administrative law or judicial process for collecting rebate payments; and/or

(iii) Request HCFA, through the Regional Office, to terminate the manufacturer's national rebate agreement.

(e) *Use of arbitration or mediation.*

(1) In lieu of a State hearing, the State and the manufacturer may agree to arbitration or mediation to resolve the dispute.

(2) The State must maintain documentation which clearly describes the agreement with the manufacturer to resolve the dispute through arbitration or mediation rather than a State hearing.

(3) The State must maintain documentation for a period of 3 years from the date the dispute is resolved through arbitration or mediation.

(f) *Payment of rebate pending resolution of disputes.*

(1) The manufacturer must pay the State agency that portion of the rebate claimed which is not in dispute by the due date of the required rebate period rebate payment.

(2) The manufacturer may, at its option, make payment on the disputed portion of the data.

(g) *Interest on disputed amounts.*

(1) The manufacturer or the State agency must pay or credit the balance due, if any, plus a rate of interest as specified in section 1903(d)(5) of the Act by the due date of the first rebate period payment after resolution of the dispute.

(2) For disputed amounts withheld by the manufacturer and due the State, the interest is computed from the 38th day after the State mails its Medicaid drug utilization data and stops accruing on the later of the date the dispute is resolved, and the date the disputed amount is paid or credited to the proper party.

(3) For amounts paid by the manufacturer on the disputed the amount, interest must be paid by the State when resolution results in payment to the manufacturer. Interest must be paid for the period from the date of receipt of payment for the disputed data to the date the dispute is resolved and the disputed amount is paid or credited to the manufacturer.

(h) *Adjustment of rebate payment.* The State agency must adjust rebate payments if information indicates that Medicaid utilization data was greater or less than previously specified on the State's invoice for rebate payments.

(i) *Availability of FFP for rebates lost in a dispute.* FFP is available for otherwise properly dispensed drugs that involve disputed drug utilization data, and the Federal portion of the rebate is not required from the State, when—

(1) A dispute was terminated because the State determined and adequately documented that the dispute resolution process was not cost-effective as specified in paragraph (k) of this section; or

(2) Less than the full rebate resulted from a dispute resolution between a State and a manufacturer as specified in paragraph (c)(4)(ii) or (c)(4)(iii) of this section.

(j) *Rebate tolerances*—(1) *Administrative cost tolerance.* Generally, the State is not required to invoice manufacturers for rebates per labeler code which are less than the administrative cost tolerance of $50 associated with the preparation of the invoice.

(2) *Updates to administrative cost tolerance.* HCFA will update the administrative cost tolerance through Medicaid program instructions.

(k) *Cost-effectiveness tolerance for disputed amounts*—(1) *Cost-effectiveness tolerance.* Under paragraph (c)(4)(i) of this section, a State may cease the dispute resolution process based on the following cost-effectiveness tolerances:

(i) The disputed amount is less than $10,000 per labeler code; and

(ii) The disputed amount is less than $1,000 per product code.

(2) *Updates to cost-effectiveness tolerance.* HCFA will update the cost-effectiveness tolerances through Medicaid program instructions.

§ 447.538 Resolution of disputes relating to drug access and State systems.

(a) A manufacturer may request HCFA to initiate compliance action against a State if the State fails to comply with section 1927 of the Act. The manufacturer may also request HCFA to initiate compliance action when the State agency shows a pattern or history of inaccuracy in reporting Medicaid drug utilization data.

(b) Any compliance action initiated by HCFA will not relieve the manufacturer from its obligation of making the rebate payment as provided in § 447.546.

§ 447.540 Confidentiality of reported information.

(a) *State agency requirements.*

(1) Except as specified in paragraph (a)(2) of this section and notwithstanding other laws, including, but not limited to, the Freedom of Information Act (5 U.S.C. 552), the State agency and its contractors must not disclose any manufacturer-specific pricing data collected or reported in connection with a rebate agreement in any form that reveals the manufacturer or wholesaler of a drug or prices for the drugs that are charged by the manufacturer or wholesaler.

(2) The State agency and its contractors must provide to HCFA information that is necessary to carry out the provisions of section 1927 of the Act and to permit review under section 1927 of the Act by the Comptroller General and the Director of the Congressional Budget Office.

(3) A State agency may release its utilization data, excluding manufacturer-specific pricing data, to the extent such release of information is allowed under a State's confidentiality laws.

(b) *Manufacturer requirements.*

(1) A manufacturer or its contractors must not disclose information contained in the State's drug utilization reports.

(2) A manufacturer must observe State confidentiality laws and regulations.

§ 447.542 Penalties for failure to report or reporting false information.

(a) *Surveys and audits.*

(1) HHS surveys wholesalers, manufacturers, and direct sellers that distribute covered outpatient drugs, when necessary, to verify manufacturer prices reported to HCFA.

(2) HHS may audit a manufacturer's calculations of AMP and best price of covered outpatient drugs, as necessary, to verify reported data.

(b) *Imposition of penalties.*

(1) The Secretary may impose on any wholesaler, manufacturer, or direct seller of a covered outpatient drug that refuses a request for information about charges or prices in connection with a survey or knowingly provides false information a civil monetary penalty in an amount not to exceed $100,000 for each item.

(2) The Secretary may impose on a manufacturer who fails to provide the required information on AMP and best price or the list of covered outpatient drugs on a timely basis a civil money penalty of $10,000 for each day beyond the due date that the information is not provided.

(i) If the information is not reported within 90 days of the due date, HCFA may suspend the drug rebate agreement after the end of the 90-day period.

(ii) The suspension is for a period of at least 30 days and continues until the information is provided.

(3) The Secretary may impose on a manufacturer that knowingly provides false information an additional penalty not to exceed $100,000 for each item of false information. These civil money penalties are in addition to other penalties as may be prescribed by law.

(c) *Procedures for imposing penalties.* The imposition of a civil money penalty will be made in accordance with the provisions of sections 1128A and 1927(b)(3) of the Act.

§ 447.546 Payment of rebates.

(a) *Basic requirements.* In order for FFP to be available to a State for expenditures for covered outpatient drugs of a manufacturer, the manufacturer must agree to—

(1) Calculate a rebate payment using the formulas specified in paragraph (b) of this section and make a rebate payment to each State Medicaid agency for the manufacturer's covered outpatient drugs paid for by the State Medicaid agency during the rebate period;

(2) Make the rebate payments for each rebate period within 30 days after receiving from the State Medicaid drug utilization data on the total number of units of covered outpatient drugs, by NDC number, paid by the State under the plan during the rebate period, as

reported in accordance with § 447.530; and

(3) Continue to make rebate payments for all of its covered outpatient drugs for as long as an agreement is in force and drug utilization data reports are made and until—

(i) The entire supply of the drug under an NDC number has expired;

(ii) The drug has been taken off the market; or

(iii) For another reason, there no longer exists the potential that the drug may be paid for under the manufacturer's NDC number.

(b) *Formulas for rebates.*

(1) The basic rebate for single source drugs and innovator multiple source drugs is—

(i) For January 1, 1991, through December 31, 1991: The greater of 12.5 percent of the AMP or the AMP minus best price. (The rebate is capped at 25 percent of AMP.)

(ii) For January 1, 1992, through September 30, 1992: The greater of 12.5 percent of the AMP or the AMP minus best price. (The rebate is capped at 50 percent of AMP.)

(iii) For October 1, 1992, through December 31, 1993: The greater of 15.7 percent of the AMP or the AMP minus best price. (The rebate is capped at 50 percent of the AMP for the rebate period of October 1, 1992, through December 31, 1992.)

(iv) For January 1, 1994, through December 31, 1994: The greater of 15.4 percent of the AMP or the AMP minus best price.

(v) For January 1, 1995, through December 31, 1995: The greater of 15.2 percent of the AMP or the AMP minus best price.

(vi) For January 1, 1996, and thereafter: The greater of 15.1 percent of the AMP or the AMP minus best price.

(2) The additional rebate for single source and innovator multiple source drugs is for calendar years 1991 through 1993: On a drug-by-drug basis, the amount by which the increase in the AMP exceeds the increase in the Consumer Price Index-Urban (CPI-U) from October 1, 1990, to the month before the rebate period of the rebate.

(3) The rebate for noninnovator multiple source and other drugs is—

(i) For calendar years 1991 through 1993: 10 percent of the AMP.

(ii) For calendar years 1994 and thereafter: 11 percent of the AMP.

(c) *Late submittal of data.* The manufacturer is not required to pay a rebate if the State does not submit its rebate period utilization data to the manufacturer within 1 year after the rebate period ended.

§ 447.548 Computation of unit rebate amount.

(a) HCFA computes a per drug unit rebate amount on the basis of the formulas specified in § 447.546(b). The rebate amount will be based on unit pricing information supplied by the manufacturer in accordance with § 447.534.

(b) HCFA supplies the per drug unit rebate amount to each State on a rebate period basis. The State must compute the total rebate anticipated, based on its own utilization records, and send an invoice to the manufacturers for a total rebate amount due. However, the manufacturer remains responsible for correctly calculating the rebate amount based on State reported utilization data and its correct determination of AMP and, where applicable, base date AMP and best price, as defined in § 447.534.

§ 447.550 Denial of FFP.

(a) Except for those drugs described in § 447.518, FFP will be denied for payment of any dispensed covered outpatient drug of a manufacturer that does not have in effect and comply with:

(1) A drug rebate agreement, as specified in this subpart;

(2) A pharmaceutical pricing agreement with the Public Health Service, in accordance with section 340B of the Public Health Service Act, for all covered outpatient drugs purchased by a covered entity (as described in section 340B(a)(4) of the Public Health Service Act) on or after December 1, 1992; and

(3) A pharmaceutical pricing agreement with the DVA, in accordance with 38 U.S.C. 8126, for all single source drugs, innovator multiple source drugs, biologicals, and insulin, effective January 1, 1993.

(b) FFP is not available for payment for expenditures that exceed the upper payment limit for an innovator multiple source drug that is subject to the Federal upper limits in §§ 447.332(a) and 447.335 dispensed on or after July 1, 1991, if, under applicable State law, a less expensive noninnovator multiple source drug could have been dispensed.

(Catalog of Federal Domestic Assistance Program No. 93.778, Medical Assistance Programs)

Dated: April 12, 1995.

Bruce C. Vladeck,

Administrator, Health Care Financing Administration.

Dated: August 31, 1995.

Donna E. Shalala,

Secretary.

[FR Doc. 95–22860 Filed 9–18–95; 8:45 am]

BILLING CODE 4120–01–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 90

[PR Docket No. 92–235, DA 95–1967]

Examination of Exclusivity and Frequency Assignment Policies

AGENCY: Federal Communications Commission.

ACTION: Proposed rule; extension of comment period.

SUMMARY: On June 15, 1995, the Commission adopted a *Further Notice of Proposed Rule Making* which seeks to introduce market forces into the Private Land Mobile Radio (PLMR) bands. The *Further Notice of Proposed Rule Making* proposed three options to introduce market forces into these bands: exclusivity, user fees, and competitive bidding. The Commission sought comment on each of these options in order to assist in the development and implementation of an overall strategy on how to promote greater efficiency in these bands. This proposed rule extends the period of time in which commenters have to file comments and reply comments.

DATES: Comments are to be filed on or before October 16, 1995, and reply comments are to be filed on or before November 20, 1995.

FOR FURTHER INFORMATION CONTACT: Mark Rubin of the Wireless Telecommunications Bureau at (202) 418–0680.

SUPPLEMENTARY INFORMATION:

Order Extending Comment and Reply Comment Period

Adopted: September 12, 1995
Released: September 13, 1995

By the Chief, Private Wireless Division:

1. On September 1, 1995, the American Public Transit Association (APTA) requested that the time for filing comments in response to the *Further Notice of Proposed Rule Making* in the above-captioned proceeding released by the Commission on June 23, 1995,[1] be extended from September 15, 1995, to October 16, 1995. Likewise, on September 5, 1995, the Land Mobile Communications Council (LMCC) filed a Motion For Extension Of Time until November 20, 1995, to file comments. LMCC also requested that the time for filing reply comments be extended from October 16, 1995, to January 5, 1996.

2. APTA, which represents approximately 400 American public and private mass transit systems, states that

[1] FCC 95–255, 60 Fed. Reg. 37148 (1995).

it needs additional time to submit comments in order to afford its membership a chance to respond to the Commission's June 15, 1995, action. LMCC states that a deadline for filing comments on November 20th is warranted as that date is coterminous with the due date for the industry's report on its service consolidation efforts. LMCC emphasizes that service consolidation decisions must be made in tandem with those relating to channel exclusivity in order to respond adequately to the Commission's proposals.

3. The Commission does not routinely grant extensions of time. In this instance, however, it is desirable that the record be as complete as possible and that it include the views of as large a cross section of the private land mobile radio (PLMR) user community as possible. We believe an extension of thirty (30) days to be adequate to give the PLMR community sufficient time to respond to the above-captioned proceeding. We therefore extend the period of time for filing comments to and including October 16, 1995, and we extend the period for filing reply comments to and including November 20, 1995. The new reply comment date coincides with the due date for the industry's report on radio service consolidation.

4. Accordingly, it is hereby ordered that AMTA's request to extend the deadline for filing comments in this proceeding is granted and LMCC's Motion For Extension of Time is granted to the extent indicated herein and otherwise denied.

5. This action is taken pursuant to the authority provided in Section 1.46 of the Commission's Rules, 47 C.F.R. 1.46.

Federal Communications Commission.

Robert H. McNamara,

Chief, Private Wireless Division.

[FR Doc. 95–23170 Filed 9–18–95; 8:45 am]

BILLING CODE 6712–01–M

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 85

RIN 1018–AC67

Clean Vessel Act Pumpout Symbol, Slogan and Program Crediting

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Proposed rule.

SUMMARY: This proposed rule provides definitions for facilities open to the public and public versus private facilities, clarification on submitting proposals and points for education, and the requirements for a pumpout symbol, slogan and program crediting for the Clean Vessel Act of 1992 as authorized in 50 CFR Part 85. This rule provides a uniform symbol, slogan and crediting logo for the Clean Vessel Act Pumpout Grant Program.

DATES: Comments must be received November 20, 1995.

ADDRESSES: Comments may be mailed to the Division of Federal Aid, Fish and Wildlife Service, U.S. Department of the Interior, 1849 C Street, NW., (MS 140 ARLSZ), Washington, DC 20240, or delivered to Room 140, 4401 North Fairfax Drive, Arlington, Virginia 22203.

FOR FURTHER INFORMATION CONTACT: Robert D. Pacific, (703) 358–1845.

SUPPLEMENTARY INFORMATION:

Background

Section 5604 of the Clean Vessel Act (Pub. L. 102–587, Title V, Subtitle F) authorizes the Director of the U.S. Fish and Wildlife Service to make grants to coastal States for constructing/renovating pumpout and portable toilet dump stations and for implementing associated education programs.

In response to a request from a State and the marine community, the definitions of facilities open to the public, and public versus private facilities have been added. The definition of public/private follows definitions developed earlier by the marine community for surveying marinas for pumpout and other information.

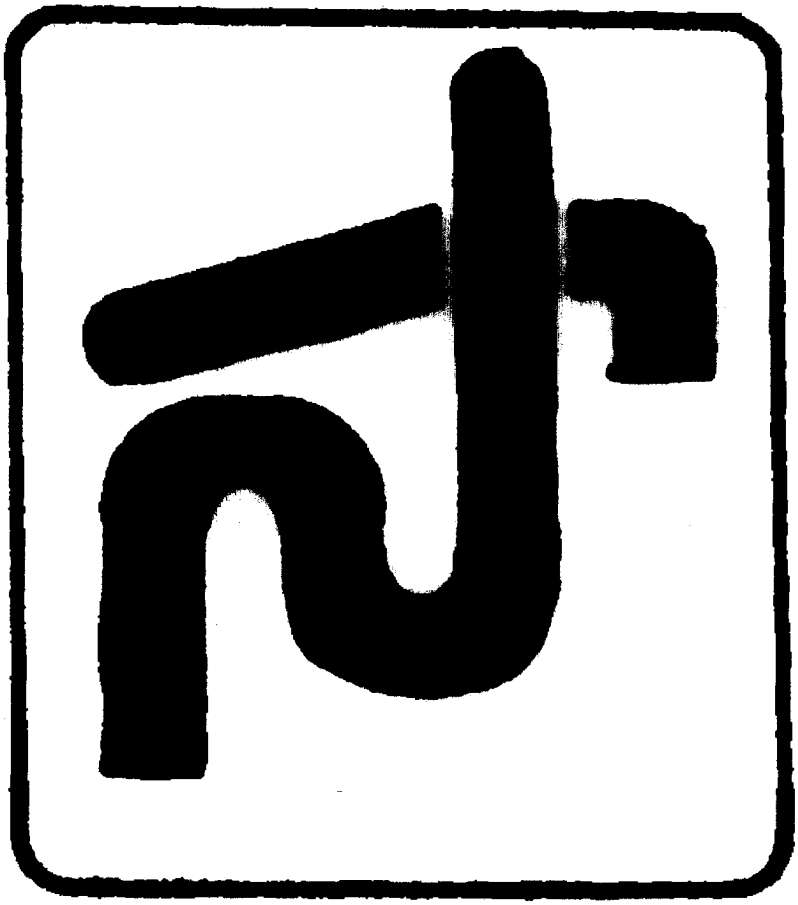
Two proposals are required by coastal States when submitting projects in coastal and inland portions of the State. Without this differentiation, adequate evaluation of proposals is not possible since points are different for the two zones.

Clarification on points for education was added so that States could receive points for education if they had an active, ongoing education program and did not need additional funds in a particular year. Otherwise, States would be forced to request funds to get points even if they did not need the funds.

In order to increase public awareness of the program, the marine community has recommended developing a pumpout symbol, slogan, and program crediting logo. This rule provides the requirements for that pumpout symbol, slogan, and crediting logo.

There has been an International Standards Organization international symbol since 1972. This symbol is depicted below.

BILLING CODE 4310–55–M



BILLING CODE 4310–55–C

There is also a symbol which appears on National Oceanic and Atmospheric Administration's National Ocean Service nautical charts. The letter ''P'' and the circle around the ''P'' are magenta-colored. This symbol is depicted below.

BILLING CODE 4310–55–M

Pump-out facilities

BILLING CODE 4310–55–C

The international symbol has been described by the marine community as not conveying a distinct meaning and is not understood by boaters. That symbol, therefore, has not been accepted by boaters and is not in general use in the United States. Likewise, the NOAA magenta ''P'' and circle on charts was not accepted as having a distinct message when presented to the marine community and has been deemed by Federal Highway Administration and marine community groups as possibly being in conflict with the symbol for ''parking''. Therefore, there is no nationally recognized pumpout symbol in general use to indicate to boaters traveling in different parts of the country where pumpout and portable toilet dump stations are located.

Likewise, there is no nationally recognized slogan. There are several State and private pumpout and portable toilet dump station symbols and slogans in use. Each one is different, so that the image and words are different from State to State. In order to have a successful campaign nationwide to get boaters to use pumpouts, a single, coordinated message and symbol is needed.

Therefore, a pumpout symbol and slogan have been developed to provide boaters with a single nationwide symbol of pumpout and portable toilet dump station locations, and to provide a consistent message about the program nationally in education materials produced by each State. Advertising the program with one widely-accepted symbol and slogan will decrease confusion, better advertise the program, result in greater use of pumpout and portable toilet dump stations, improve the aquatic environment, and thus contribute to improve economic and health conditions. The symbol and slogan contributes to environmental improvement goals of other Federal, State and local governmental agencies and has the support of boaters, the boating industry and the marine community.

Currently, § 80.26 of 50 CFR Part 80 contains a crediting logo, and § 85.47 of 50 CFR Part 85 contains suggested

language to acknowledge that facilities were constructed with Clean Vessel Act funds. These sections were also reviewed and suggestions made for changes.

Developing a Pumpout Symbol

The Fish and Wildlife Service consulted with Federal and State agencies, and with organizations and individuals within the marine industry and boating community, in developing a pumpout symbol. A scoping meeting was held April 8, 1993 to obtain input on a pumpout symbol. States that presently have pumpout symbols were invited to attend, as well as others. Maryland and Virginia attended, as well as the following Federal agency representatives: National Oceanic and Atmospheric Administration, Environmental Protection Agency, U.S. Coast Guard, and Federal Highway Administration. Representatives from States Organization of Boating Access, National Marine Manufacturers Association, American League of Anglers and Boaters, and the International Association of Fish and Wildlife Agencies also attended. Oregon and the National Association of State Boating Law Administrators did not attend, but provided comments, examples of their current symbols and/or suggested symbols.

A draft scoping document, encompassing the information in this notice, was sent to nearly 250 individuals and organizations for review and comment on July 8, 1994. Comments were received from three Fish and Wildlife Service Regions, Environmental Protection Agency Chesapeake Bay Program, Federal Highway Administration, U.S. Coast Guard (3 letters), Massachusetts Department of Fisheries, Wildlife and Environmental Law Enforcement, Oregon State Marine Board, Maryland Department of Natural Resources Boating Administration, Florida Department of Environmental Protection, National Marine Manufacturers Association, Sealand Technology, Inc., Keco, Inc., and Neil Ross Consultants. A summary of their comments follow.

General: Letters were received from the U.S. Coast Guard, Massachusetts and Oregon, and Keco, Inc., supporting the development of a symbol. Florida expressed concern with publishing a final rule without publishing a draft. Response: The symbol is being developed, and will be published in draft.

Symbol criteria: Oregon agreed with the criteria. Florida and Neil Ross Consultants does not believe that Criterion 7, use of symbol on deck fitting caps, is necessary or important. Response: Criterion 7 was dropped.

Pumpout symbol: The suggested symbol had a white arrow with a blue background, similar to the arrow proposed in this rule, except without the holding tank or boat. Maryland and Neil Ross Consultants supported the symbol, while the Federal Highway Administration, EPA Chesapeake Bay Program, Florida, Oregon, Massachusetts, National Marine Manufacturers Association, Keco, Inc., and Sealand Technology felt it was too abstract, non-communicative, and could be confused with a directional arrow. Fourteen alternative symbols were suggested, ten of which included boats. EPA included a marine toilet, and Massachusetts suggested words only, such as ''Pumpout''. Response: The overwhelming comments were in favor of a symbol. Therefore, the use of words only was not selected. A boat and holding tank have been added to the symbol.

Sign color and shape: Coast Guard and Florida provided copies of Code of Federal Regulations with sign color and shape requirements on waterways which follow the U.S. Aids to Navigation System. Depending on purpose the sign could have a white background with orange border and orange or black symbol. Oregon and NMMA agreed with the blue and white colors as providing consistency with FHWA standards. Massachusetts stated the FHWA blue and white color scheme would not be visible on the water, and suggested a black symbol on an orange background. Maryland suggested using a red symbol with an orange background, which would not conflict with Coast Guard regulations. Florida suggested an orange border, white background, and black symbol and letters. FWS Atlanta Region, FHWA, Florida and NMMA suggested using reflectorized paint or illuminating the sign. Response: An international orange border with white background and black symbol and letters was selected. These colors follow the Coast Guard colors because of boater recognition and because they are easily visible on the water. Coast Guard colors were selected over FHWA colors because signs will be located on the water rather than on highways. Reflectorized paint or film, or sign illumination is suggested.

Qualifying signs: FHWA, Massachusetts, and NMMA recommended educational plaques to explain the symbol until boaters learn its meaning. Oregon and Keco, Inc. do not support additional signs due to cost and over-signage. Response: The rule provides for both options.

Slogan: Maryland suggested its slogan ''Pump Don't Dump'', and Oregon and NMMA supports that slogan. Massachusetts and Neil Ross Consultants believe the Maryland slogan is not adequate. Keco, Inc. has indicated the slogan ''PUMP IT DON'T DUMP IT'' is trademarked by them and no similar slogan should be used. Fifty-two alternative slogans were suggested. Response: The 52 alternatives were reduced to 17, and boaters at four focus group meetings identified the most acceptible slogans. The top four were then reviewed by the FWS, USCG, EPA, and NOAA and one of the four, ''KEEP OUR WATER CLEAN—USE PUMPOUTS'', was selected.

Crediting logo: FHWA suggested placing the crediting logo away from the symbol so it would not interfere with the pumpout message. Florida suggested the symbol and crediting logo should be strongly correlated. Florida and Oregon suggested crediting language. NMMA supports a crediting logo. Response: A crediting logo is identified in the rule along with crediting language, with instructions on when and where to use the logo and language.

Numerous consultations and scoping meetings were held with Federal, State and marine community staffs, groups and individuals throughout this period. Focus group meetings were held in Miami, FL, Minneapolis, MN, Seattle, WA, and Annapolis, MD, between June 14 and 28, to obtain inputs on a symbol, slogan, and boater attitudes toward pumping out their sewage. Each group was shown the suggested symbol and results show that ''the symbol, as tested, is appropriate and easily understood. Boaters volunteered that this symbol can become the 'universal' visual for pumpout stations.''

Consultation occurred with the International Standards Organization, American National Standards Institute, American Boat and Yacht Council, Society of Automotive Engineers, American Institute of Graphic Arts, British Standards Institution, and Permanent International Association of Navigation Congresses. Input was obtained on several pumpout symbol designs at the following meetings: seven EPA-sponsored Regional Workshops in 1994, through a grant with The International Marina Institute; at the University of Wisconsin-Madison Docks and Marina National Conference; and, at several marine community conferences, workshops and meetings.

The following current symbols were reviewed: ISO international pumpout symbol, NOAA National Ocean Service

Nautical Chart magenta ''P'' and circle. Maryland, North Carolina and Keco, Inc. (Pumpout symbols), and Virginia (Pumpout and portable toilet dump station symbols).

The following documents were reviewed: (1) Symbol Signs, The System of Passenger/Pedestrian Oriented Symbols, Developed for the U.S. Dept. of Transportation (DOT), The American Institute of Graphic Arts, 1981; (2) Surface Vehicle Recommended Practice, SAE International, Graphic Symbols for Boats, SAE J1449, Society of Automotive Engineers, Inc., February 1987; (3) British Standard Marine Series: Specification for Shipbuilding—Yachts—Waste water fittings, BS MA 84:1978, ISO 4567–1978, UDC [629.125.12 + 629.125.22] : 628.2, British Standards Institution, London, England; (4) American National Standard Graphic Symbols for Plumbing Fixtures, American National Standards Institute Y32.4–1977; (5) Manual on Uniform Traffic Control Devices for Streets and Highways (MUTCD), U.S. DOT, FHWA, 1988; (6) Standard Highway Signs as Specified in the MUTCD, DOT, FHWA; (7) Standard Alphabets for Highway Signs, DOT, FHWA, Reprinted 4/84.

Over 50 alternative symbols were reviewed by the Service. These symbols were developed by and were reviewed by members of the marine community, and State and Federal agencies. These symbols ranged from very complex, with depictions of water, boats, toilets, docks, pumpout stations, arrows and messages, to very simple, with an arrow and messages.

In addition to a pumpout symbol, three different portable toilet dump station symbols, and three combination pumpout/portable toilet dump station symbols were suggested. Some were completely separate portable toilet dump station or combination symbols, and some were pumpout symbols adapted to portable toilet dump station or combination symbols.

Criteria Used To Develop the Symbol

The following criteria were developed to select the pumpout symbol after discussions with individuals involved in the marine community and State and Federal agencies, and review of the documents identified in this rule: (1) How well the symbol represents the message (It should be kept in mind that many symbols must be learned before there is adequate recognition of the symbol. Constant repetition of the symbol is more important than the style of drawing or appropriateness of concept). (2) The ease with which people learn the symbol (The simpler the symbol, the easier to learn). (3) How well the symbol relates to national standards. (4) How well the symbol is reproducible on letters, etc. (5) How visible the sign is to viewers (The simpler the symbol, the easier to recognize it at greater distances and under all light and background conditions). (6) How easy to reproduce, reduce and enlarge the symbol (The symbol must be legible when reduced significantly).

The Proposed Pumpout Symbol

The current international symbol was rejected by nearly all who commented as not being understood by boaters and not communicating a distinct meaning. The NOAA NOS nautical magenta ''P'' and circle, although it may be suitable on the NOAA nautical charts, also does not convey the pumpout message adequately on signs and may be in conflict with other symbols such as parking signs, according to comments made by people in the marine community. The current symbols used by States, and the suggested complex symbols, did not fully comply with the criteria. A suggestion was made to develop separate symbols for pumpout and portable toilet dump stations. Comments on this suggestion favored one single symbol which would encompass both pumpout and portable toilet dump stations to decrease confusion and costs.

The proposed symbol encompasses the one feature that invariably appeared in the 50 symbols: the ''arrow'', as well as the ''holding tank'' and ''boat''. The proposed symbol, therefore, represents the core of current and suggested symbols. The symbol is simple and should be easy to learn. The symbol follows U.S. Coast Guard format and color standards for signs on waterways (Symbol is black, border is international orange, and background is white). The symbol is easily reproducible on charts, etc., and should be easily recognizable to viewers at a great distance. The symbol is easily reduced or enlarged without losing legibility.

Developing a Pumpout Slogan

In addition to the pumpout symbol, the Service is proposing a slogan. Some States currently have a slogan, however, no slogan exists which would provide a national level focus for the program. The July 8, 1994, scoping document resulted in 52 suggested slogans. This number was reduced to 17 and presented to boaters at the focus group meetings held June 14 through 28, 1995, around the country. The proposed slogan, ''KEEP OUR WATER CLEAN—USE PUMPOUTS'', was then selected by the cooperating Federal agencies (FWS, NOAA, EPA and USCG), based on the top four slogans recommended by the boaters. ''Boaters prefer a short, straight-forward slogan'' as identified during the focus group meetings.

Developing a Program Crediting Logo

In addition to the crediting logo for the Federal Aid in Sport Fish Restoration Act in § 80.26 of 50 CFR Part 80. § 85.47 of 50 CFR Part 85 contains examples of suggested language for crediting the Clean Vessel Act. Inputs were received from the July 8, 1994, scoping document request, and subsequently from States and Fish and Wildlife Service Regions. Suggested language was selected based on these comments.

Public Comment

The policy of the Department of the Interior is, whenever practicable, to afford the public an opportunity to participate in the rulemaking process. Accordingly, interested persons may submit written comments, suggestions or objections regarding the proposed rule to the location identified in the Address section. Comments must be received on or before November 20, 1995.

Environmental Effects

Because this rule is an administrative action, the effects on the physical biological and sociological environment are too broad, speculative, and conjectural to be analyzed meaningfully. Therefore, the action is categorically excluded from any National Environmental Policy Act documentation pursuant to 516 DM 2.3 A (2). However, installation of symbol signs will be reviewed as part of the construction or renovation of pumpout and portable toilet dump stations which will require separate environmental consideration.

Information Collection Requirements

This proposed rule does not contain information collection requirements that require approval by the Office of Management and Budget under the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*).

Statement of Effects

This rule was not subject to Office of Management and Budget review under Executive Order 12866. The program does not have significant ''taking'' implications, as described in Executive Order 12630. The rule allows eligible States to make decisions regarding the use of the pumpout symbol, slogan and crediting logo. This rule does not

contain any federalism impacts as described in Executive Order 12612 on Federalism. This rule will not have a significant economic effect on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. *et seq.*) The effects of these rules occur to agencies in the States, Puerto Rico, Guam, the Virgin Islands, American Samoa, the District of Columbia and the Northern Mariana Islands. These are not small entities under the Regulatory Flexibility Act.

Intergovernmental Review of Federal Programs

This Clean Vessel Act Grant Program is covered under Executive Order 12372 ''Intergovernmental Review of Federal Programs'' and 43 CFR Part 9 ''Intergovernmental Review of Department of the Interior Programs and Activities.'' Under the Order, States may design their own processes for reviewing and commenting on proposed Federal assistance under covered programs.

Author

The primary author of this rule is Robert D. Pacific, U.S. Fish and Wildlife Service.

List of Subjects in 50 CFR Part 85

Coastal zone, Grant programs—Natural resources, Reporting and recordkeeping requirements, Sewage disposal, and Vessels.

Regulation Promulgation

For the reasons set out in the preamble, Subchapter F of Chapter I, Title 50, Part 85 of the Code of Federal Regulations is proposed to be amended as set forth below.

PART 85—CLEAN VESSEL ACT GRANT PROGRAM

1. The authority citation continues to read as follows:

Authority: Public Law 102–587, Title V, Subtitle F.

Subpart A—General

2. Section 85.11 is amended by removing the paragraph designations and adding the following definitions, in alphabetical order, to read as follows:

§ 85.11 Definitions.

* * * * *

Equitable fees. Fees should be equal for all pumpout users at a marina, for that facility to be open and available to the public. However, members and customers may prepay for pumpouts within a fee structure, so that a separate fee for pumpouts would not be needed for those members and customers.

Facility open to the public. A Clean Vessel Act facility that is open and available to the public is one in which the public has full and reasonable access to the pumpout/dump station at that public or private facility for pumping out, including provisions of signage visible from the water to direct boaters to pumpout/dump stations, location of pumpouts to facilitate ease of use by all boats typical to that particular marina, equitable fees, and reasonable open periods.

Private Facilities. Private facilities include those operated by the following:

(1) For profit or non-profit private marinas, docks etc.,

(2) For profit or non-profit concessionaires, whether they are leased or private facilities, on public lands, and

(3) Yacht or boating clubs, whether they are open to the public or members-only facilities.

Public facilities. Public facilities include municipal, port authority, State and Federal marinas, docks, etc., operated by those agencies.

Reasonable open periods. While no specific hours, days and seasons are specified, some suggested examples, provided no other factors are involved, are presented:

(1) Pumpout/dump stations may be open during the same period the fuel docks are normally open.

(2) Pumpout stations may be open when the marina is open and staff is present to pump out boats.

(3) Pumpout/dump stations may be open during the hours considered to be normal marina business hours as adjusted by seasonal differences, and may be closed entirely during cold winter months.

* * * * *

Subpart B—Application for Grants

3. Section 85.21 is amended by adding a second sentence to the introductory text of paragraph (a) to read as follows:

§ 85.21 Application procedures.

(a) * * * If coastal States submit proposals for both the coastal zone and the inland portion of their States, two separate proposals must be submitted.

* * * * *

Subpart C—Grant Selection

4. Section 85.30(f) is revised to read as follows:

§ 85.30 Grant selection criteria.

* * * * *

(f) Proposals that include an education/information component, or the State has an active, ongoing education program;

* * * * *

Subpart D—Conditions on Use/Acceptance of Funds

5. Section 85.43 is revised to read as follows:

§ 85.43 Signs and symbols.

(a) *Signs.* Appropriate information signs should be installed at pumpout and portable toilet dump stations. Such information should indicate fees, restrictions, hours of operation, operating instructions, and a contact name and telephone number if the facility is inoperable.

(b) *Pumpout symbol.* (1) A pumpout symbol should be used according to Service specifications at the appropriate times to increase public awareness of the Clean Vessel Act Pumpout Grant Program. The symbol is meant to be used

(i) As a sign at the entrance to a marina advertising the presence of a pumpout and/or portable toilet dump station.

(ii) As a directional sign within a marina.

(iii) As a sign at a pumpout and/or portable toilet dump station.

(iv) As a symbol on education and informational material, and

(v) For other uses as appropriate to advance the purposes of the Clean Vessel Act

(2) To avoid confusion with having two symbols, the selected symbol is to be used both for pumpout stations and portable dump stations. This pumpout symbol is not copyrighted, and its appropriate use is encouraged. The NOAA NOS magenta ''P'' within a magenta circle will continue to be used on nautical charts to identify the location of pumpout and portable toilet dump stations. NOAA will include information about the selected pumpout symbol in the U.S. Coast Pilots, a supplement to the charts, to relate this symbol to the NOAA Nautical Chart magenta ''P'' and circle.

(3) All recipients identified in § 85.11 should display the appropriate pumpout symbol on facilities, such as pumpout and portable toilet dump stations, or on printed material or other visual representations relating to project accomplishments or education/information, and should encourage others to do so. Subrecipients should also display the symbol and should encourage use by others for purposes as stated in this paragraph.

(4) Other persons or organizations are encouraged to use the symbol to

advance the purposes of the Clean Vessel Act program, such as marinas with pumpout stations not constructed with Clean Vessels Act funds.

(5) The following specifications shall apply: The symbol is black, the background is white, and the border is international orange. There is no standard for the black and white, but use black and white colors, not shades. The standards for the international orange color is as follows: For day boards (signs), use retroflective international orange film. For paint, use international orange conforming to FED–STD 595B, chip number 12197 in daylight conditions. For inks us Pantone Matching System color chart 179C. The symbol sign should use reflectorized film or paint, or should be illuminated so it is viewable at night. Currently, the symbol shown is a rough mockup. When the symbol is finalized, the symbol will be developed on a grid and technical specifications will be completed for constructing signs and for other purposes.

(6) The following rules govern the graphic reproduction of the symbols:

(i) The symbol should not be used smaller than is legible.

(ii) The size and position relationship of the symbol should not be changed in any way.

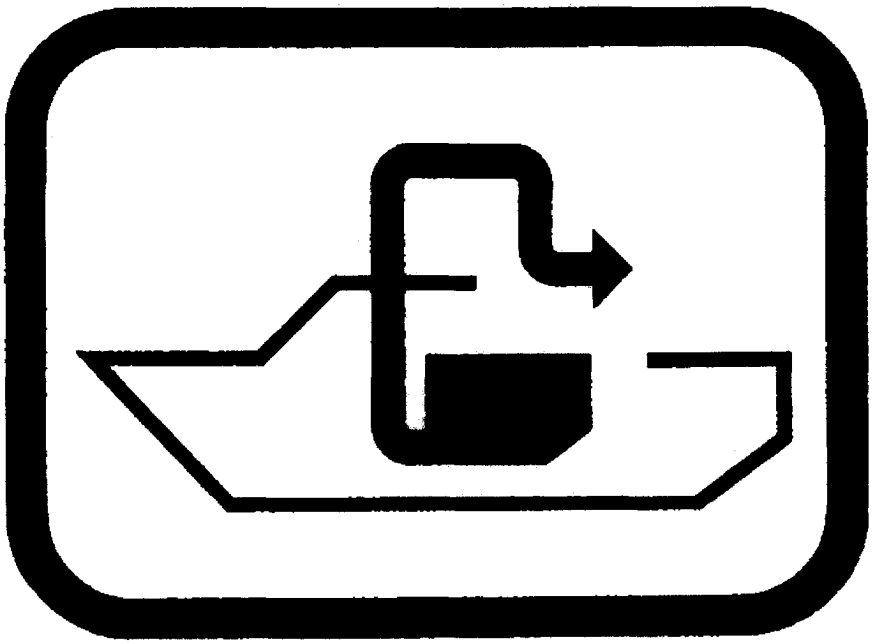
(iii) No portion of the symbol should be obscured by overprinting.

(iv) The symbol should not be placed where it will be split by unlike backgrounds.

(v) The symbol should not be placed on a background that is highly textured or patterned.

(7) The pumpout symbol is depicted as follows:

BILLING CODE 4310–55–M



BILLING CODE 4310–55–C

(c) *Qualifying signs.* (1) In conjunction with the symbol, other qualifying signs may be used below the symbol, either on the same sign or on a separate sign.

(i) The message ''(P) PUMP OUT'', ''(P) PUMPOUT STATION'', ''(P) PORTABLE'' appropriate qualifier, may be placed beneath the symbol. The magenta-colored ''P'' and circle should be placed in front of the message to relate the pumpout symbol to the NOAA NOS nautical charts. Messages may be appropriate for several years until the symbol is understood without the message.

(ii) Directional arrows may be placed beneath the symbol to indicate the direction of pumpout or portable toilet dump station facilities.

(2) The following specifications shall apply: Symbols, such as directional arrows, and letters, are black, and the background is white. For using inks to create the magenta color, use PMS color chart 259U. Letters and black and white colors shall follow the Federal Highway Administration's Manual on Uniform Traffic Control Devices for Streets and Highways (MUTCD). FHWA, 1988. The 1988 MUTCD, including Revision No. 3 dated September 3, 1993, may be purchased from the Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402 and has Stock No. 050–001–00308–2.

(3) The same rules governing the graphic reproduction of the pumpout symbol shall apply to qualifying signs.

(d) *Pumpout slogan.* (1) A pumpout slogan should be used according to Service specifications to help increase awareness of the Clean Vessel Act Pumpout Grant Program. The slogan is meant to be used in conjunction with the pumpout symbol, on educational/informational material, and for other uses as appropriate to advance the purposes of the Clean Vessel Act. The slogan is not copyrighted, and its appropriate use is encouraged.

(2) All recipients identified in § 85.11 should display the pumpout slogan on facilities, such as pumpout and portable toilet dump stations as appropriate, and on printed material or other visual representations relating to project accomplishments or education/information, and should encourage others to do so. Subrecipients should display the slogan for purposes as stated in this paragraph and should encourage others to do so.

(3) Other persons or organizations are encouraged to use the slogan to advance the purposes of the Clean Vessel Act program, such as marinas with pumpout stations not constructed with Clean Vessel Act funds.

(4) The following specifications shall apply for signs: Letters are black and background is white. The same reference for paragraph (c)(2) of this section shall apply.

(5) The same rules governing the graphic reproduction of the pumpout symbol shall apply to the pumpout slogan.

(6) The pumpout slogan is depicted as follows:

KEEP OUR WATER CLEAN—USE PUMPOUTS

6. Section 85.47 is revised to read as follows:

§ 85.47 Program crediting.

(a) *Crediting logo.* Signs should acknowledge that the facility was constructed or improved with funds from the Sport Fish Restoration Account. The crediting logo identified in § 80.26 of this chapter is prescribed to identify projects funded by the Clean Vessel Act and to identify items on which taxes and duties have been collected to support the Act. That logo is depicted as follows:

BILLING CODE 4310–55–M

BILLING CODE 4310–55–C

(b) *Recipient logo display.* All recipients identified in § 85.11 are authorized, according to § 80.26 of this chapter, to display the appropriate logo on facilities, such as pumpout and portable toilet dump stations, acquired, developed, operated or maintained by these grants, or on printed material or other visual representations relating to project accomplishments or education/information. Recipients may require sub-recipients to display the logo.

(c) *Other display of logo.* Other persons or organizations may use the logo for purposes related to the Federal Aid Clean Vessel Act program as authorized in § 80.26 of this chapter.

(d) *Crediting language.* Following are suggested examples of language to use when crediting the Clean Vessel Act:

(1) Example 1: This pumpout facility was funded under the Sport Fish Restoration Program by your purchase of fishing equipment and motorboat fuels.

(2) This facility is being constructed under the Sport Fish Restoration Program by your purchase of fishing equipment and motorboat fuels.

(3) This pamphlet was funded under the Sport Fish Restoration Program by your purchase of fishing equipment and motorboat fuels.

Dated: August 3, 1995.

George T. Frampton, Jr.,

Assistant Secretary for Fish and Wildlife and Parks.

[FR Doc. 95–23144 Filed 9–18–95; 8:45 am]

BILLING CODE 4310–55–M

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 658

[I.D. 091295B]

Shrimp Fishery of the Gulf of Mexico; Amendment 8

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

ACTION: Notice of availability of an amendment to a fishery management plan; request for comments.

SUMMARY: NMFS announces that the Gulf of Mexico Fishery Management Council (Council) has submitted Amendment 8 to the Fishery Management Plan for the Shrimp Fishery of the Gulf of Mexico (FMP) for review by NMFS. Written comments are requested from the public.

DATES: Written comments must be received on or before November 13, 1995.

ADDRESSES: Comments must be mailed to the Southeast Regional Office, NMFS, 9721 Executive Center Drive N., St. Petersburg, FL 33702.

Requests for copies of Amendment 8, which includes an environmental assessment and a regulatory impact review, should be sent to the Gulf of Mexico Fishery Management Council, 5401 W. Kennedy Boulevard, Suite 331, Tampa, FL 33609-2486, FAX: 813-225-7015.

FOR FURTHER INFORMATION CONTACT: Michael E. Justen, 813-570-5305.

SUPPLEMENTARY INFORMATION: The Magnuson Fishery Conservation and Management Act (Magnuson Act), requires that a council-prepared amendment to a fishery management

plan be submitted to NMFS for review and approval, disapproval, or partial disapproval. The Magnuson Act also requires that NMFS, upon receiving an amendment, immediately publish a notice that the amendment is available for public review and comment.

Amendment 8 proposes to establish a framework rulemaking procedure for establishing or modifying the maximum sustainable yield (MSY), optimum yield (OY), and total allowable catch (TAC) for royal red shrimp harvested from the exclusive economic zone of the Gulf of Mexico. That procedure would authorize the Council to recommend, and NMFS to approve and implement, TAC for royal red shrimp no higher than MSY plus 30 percent for a test period of up to 2 consecutive years. This action will allow for testing the response of the resource to a controlled increase in fishing effort and to obtain additional management data on the royal red shrimp resource for refining estimates of MSY and OY.

Proposed regulations to implement Amendment 8 are scheduled for publication within 15 days.

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

Dated: September 13, 1995.

Richard W. Surdi,

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

[FR Doc. 95–23149 Filed 9–14–95; 12:25 pm]

BILLING CODE 3510–22–F

Notices

Federal Register
Vol. 60, No. 181
Tuesday, September 19, 1995

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.

ADVISORY COUNCIL ON HISTORIC PRESERVATION

Historical Reservation Advisory Council Meeting

AGENCY: Advisory Council on Historic Preservation.

ACTION: Notice of meeting.

SUMMARY: Notice is hereby given that the Advisory Council on Historic Preservation will meet on Wednesday, September 27, 1995. The meeting will be held in Room M09 at the Old Post Office, 1100 Pennsylvania Avenue, NW., Washington, D.C., beginning at 8:30 a.m.

The Council was established by the National Historic Preservation Act of 1966 (16 U.S.C. Section 470) to advise the President and the Congress on matters relating to historic preservation and to comment upon Federal, federally assisted, and federally licensed undertakings having an effect upon properties listed in or eligible for inclusion in the National Register of Historic Places. The Council's members are the Architect of the Capitol; the Secretaries of the Interior, Agriculture, Housing and Urban Development, and Transportation; the Administrators of the Environmental Protection Agency and General Services Administration; the Chairman of the National Trust for Historic Preservation; the President of the National Conference of State Historic Preservation Officers; a Governor; a Mayor; a Native American; and eight non-Federal members appointed by the President.

The agenda for the meeting includes the following:

I. Chairman's Welcome/Opening
II. Task Force Report on Council's Future
III. Status Report on Appropriations for FY 1996
IV. Report on Council's Regulations
V. Section 106 Cases
VI. Executive Director's Report
VII. New Business
VIII. Adjourn

Note: The meetings of the Council are open to the public. If you need special accommodations due to a disability, please contact the Advisory Council on Historic Preservation, 1100 Pennsylvania Ave., NW., Room 809, Washington, DC., 202–606–8503, at least seven (7) days prior to the meeting.

FOR FURTHER INFORMATION CONTACT: Additional information concerning the meeting is available from the Executive Director, Advisory Council on Historic Preservation, 1100 Pennsylvania Ave., NW., #809, Washington, DC 20004.

Dated: September 14, 1995.

Robert D. Bush,

Executive Director.

[FR Doc. 95–23200 Filed 9–18–95; 8:45 am]

BILLING CODE 4310–10–M

DEPARTMENT OF AGRICULTURE

Forest Service

Willamette Provincial Interagency Executive Committee (PIEC), Advisory Committee

AGENCY: Forest Service, USDA.

ACTION: Notice of meeting.

SUMMARY: The Willamette PIEC Advisory Committee will meet on Thursday, October 19, 1995. The meeting will be at the Monarch Hotel and Conference Center, 12566 SE 93rd Avenue; Clackamas, Oregon; phone (503) 652–1515; located in the Clackamas Town Center. The meeting is scheduled to begin at 9:00 a.m. and conclude at approximately 4:00 p.m. Topics scheduled on the agenda include: (1) FY 1995 Status Report of Northwest Forest Plan Implementation in the Willamette Province, (2) NW Forest Plan Standards and Guidelines—Riparian Reserves Practices and Adjustments. (3) Recession Bill Timber Provisions and Linkages to the NW Forest Plan, (4) Watershed Restoration—Examples of Private/Public Initiatives and PAC Role.

The meeting is open to the public and opportunity will be available to address the Advisory Committee during a public forum. The public forum will follow the agenda topics mentioned above and will occur in the afternoon. Time allotted for individual presentations to the committee will be limited to 3–5 minutes each. Written comments are encouraged and can be submitted prior to the meeting.

FOR FURTHER INFORMATION CONTACT: For more information regarding this meeting, such as a detailed agenda, contact Neal Forrester, Designated Federal Official; Willamette National Forest, 211 East Seventh Avenue; Eugene, Oregon; 503–465–6924.

Dated: September 12, 1995.

Darrel L. Kenops,

Forest Supervisor.

[FR Doc. 95–23196 Filed 9–18–95; 8:45 am]

BILLING CODE 3410–11–M

DEPARTMENT OF COMMERCE

Agency Form Under Review by the Office of Management and Budget

DOC has submitted to the Office of Management and Budget (OMB) for clearance the following proposal for collection of information under the provisions of the Paperwork Reduction Act (44 U.S.C. chapter 35).

Agency: Bureau of the Census.

Title: Shipper's Export Declaration Form.

Form Number(s): Form 7525–V–Alternate (Intermodal).

Agency Approval Number: 0607–0152.

Type of Request: Extension of a currently approved collection.

Burden: 473,445 hours.

Number of Respondents: 2,544,037.

Avg Hours Per Response: 11 minutes.

Needs and Uses: Shipper's Export Declarations (SED's) are required from exporters for all shipments valued over $2500 from the United States, Puerto Rico, and the U.S. Virgin Islands to all foreign countries except Canada; between the United States and Puerto Rico; and from the United States or Puerto Rico to the U.S. Virgin Islands. Information on the cargo, its origin and destination, and method and date of export are requested. Customs officials gather the SED forms from export carriers and transmit them to the Census Bureau. The Census Bureau designed Form 7525–V–Alternate primarily for waterborne shipments to simplify documentation. SED's are the basic source of the official U.S. export statistics compiled by the Census Bureau. These statistics provide data for the merchandise trade balance, a major economic indicator and component of the gross domestic product.

Affected Public: Business or other for-profit, Individuals or households, Not-

for-profit institutions, Farms, Federal Government, State, local or tribal government.

Frequency: On occasion.

Respondent's Obligation: Mandatory.

OMB Desk Officer: Maria Gonzalez, (202) 395–7313.

Copies of the above information collection proposal can be obtained by calling or writing Gerald TacheAE1, DOC Forms Clearance Officer, (202) 482–3271, Department of Commerce, room 5312, 14th and Constitution Avenue, NW, Washington, DC 20230.

Written comments and recommendations for the proposed information collection should be sent to Maria Gonzalez, OMB Desk Officer, room 10201, New Executive Office Building, Washington, DC 20503.

Dated: September 12, 1995.

Gerald Taché,

Departmental Forms Clearance Officer, Office of Management and Organization.

[FR Doc. 95-23228 Filed 9-18-95; 8:45 am]

BILLING CODE 3510-07-F

Agency Form Under Review by the Office of Management and Budget

DOC has submitted to the Office of Management and Budget (OMB) for clearance the following proposal for collection of information under the provisions of the Paperwork Reduction Act (44 U.S.C. chapter 35).

Agency: Bureau of the Census.

Title: Shipper's Export Declaration.

Form Number(s): Form 7525–V.

Agency Approval Number: 0607–0018.

Type of Request: Extension of a currently approved collection.

Burden: 627,590 hours.

Number of Respondents: 3,372,394.

Avg Hours Per Response: 11 minutes.

Needs and Uses: Shipper's Export Declarations (SED's) are required from exporters for all shipments valued over $2500 from the United States, Puerto Rico, and the U.S. Virgin Islands to all foreign countries except Canada; between the United States and Puerto Rico; and from the United States or Puerto Rico to the U.S. Virgin Islands. Information on the cargo, its origin and destination, and method and date of export are requested. Customs officials gather the SED forms from export carriers and transmit them to the Census Bureau. The vertical SED, Form 7525–V is the standard form used to collect these data. SED's are the basic source of the official U.S. export statistics compiled by the Census Bureau. These statistics provide data for the merchandise trade balance, a major economic indicator and component of the gross domestic product.

Affected Public: Business or other for–profit, Individuals or households, Not–for–profit institutions, Farms, Federal Government, State, local or tribal government.

Frequency: On occasion.

Respondent's Obligation: Mandatory.

OMB Desk Officer: Maria Gonzalez, (202) 395–7313.

Copies of the above information collection proposal can be obtained by calling or writing Gerald Taché, DOC Forms Clearance Officer, (202) 482–3271, Department of Commerce, room 5312, 14th and Constitution Avenue, NW, Washington, DC 20230.

Written comments and recommendations for the proposed information collection should be sent to Maria Gonzalez, OMB Desk Officer, room 10201, New Executive Office Building, Washington, DC 20503.

Dated: September 12, 1995.

Gerald Taché,

Departmental Forms Clearance Officer, Office of Management and Organization.

[FR Doc. 95–23227 Filed 9–18–95; 8:45 am]

BILLING CODE 3510–07–F

Agency Form Under Review by the Office of Management and Budget

DOC has submitted to the Office of Management and Budget (OMB) for clearance the following proposal for collection of information under the provisions of the Paperwork Reduction Act (44 U.S.C. chapter 35).

Agency: Bureau of the Census.

Title: Shipper's Export Declaration.

Form Number(s): Form 7513.

Agency Approval Number: 0607–0001.

Type of Request: Extension of a currently approved collection.

Burden: 26,165 hours.

Number of Respondents: 140,626.

Avg Hours Per Response: 11 minutes.

Needs and Uses: Shipper's Export Declarations (SED's) are required from exporters for all shipments valued over $2500 from the United States, Puerto Rico, and the U.S. Virgin Islands to all foreign countries except Canada; between the United States and Puerto Rico; and from the United States or Puerto Rico to the U.S. Virgin Islands. Information on the cargo, its origin and destination, and method and date of export are requested. Customs officials gather the SED forms from export carriers and transmit them to the Census Bureau. Carriers must file Form 7513 for merchandise shipped in bond by vessel through the United States enroute from one foreign country to another without having been entered as an import (in–transit goods). SED's are the basic source of the official U.S. export statistics compiled by the Census Bureau. These statistics provide data for the merchandise trade balance, a major economic indicator and component of the gross domestic product.

Affected Public: Business or other for–profit, Individuals or households, Not–for–profit institutions, Farms, Federal Government, State, local or tribal government.

Frequency: On occasion.

Respondent's Obligation: Mandatory.

OMB Desk Officer: Maria Gonzalez, (202) 395–7313.

Copies of the above information collection proposal can be obtained by calling or writing Gerald Taché, DOC Forms Clearance Officer, (202) 482–3271, Department of Commerce, room 5312, 14th and Constitution Avenue NW., Washington, DC 20230.

Written comments and recommendations for the proposed information collection should be sent to Maria Gonzalez, OMB Desk Officer, room 10201, New Executive Office Building, Washington, DC 20503.

Dated: September 12, 1995.

Gerald Taché,

Departmental Forms Clearance Officer, Office of Management and Organization.

[FR Doc. 95–23226 Filed 9–18–95; 8:45 am]

BILLING CODE 3510–07–F

Agency Forms Under Review by the Office of Management and Budget

DOC has submitted to the Office of Management and Budget (OMB) for clearance the following proposals for collection of information under the provisions of the Paperwork Reduction Act (44 U.S.C. Chapter 35).

Agency: Bureau of Export Administration (BXA).

Title: Export of Parcels Through the Postal Service.

Agency Form Numbers: None.

OMB Approval Number: None.

Type of Request: Existing collection in use without an OMB control number.

Burden: 11,110 hours.

Number of Respondents: 8,000,000.

Avg Hours Per Response: A few seconds.

Needs and Uses: The Export Administration Regulations require that persons exporting through the U.S. Postal Service place on the parcel the authorization for the export –– i.e., the validated license number or the general license symbol. This information is the declaration to the government that the shipment is allowed.

Affected Public: Businesses or other for–profit organizations.

Frequency: On occasion.
Respondent's Obligation: Required to obtain or retain benefits.
OMB Desk Officer: Don Arbuckle, (202) 395–7340.
Agency: Bureau of Export Administration.
Title: Destination Control Statement.
Agency Form Number: None.
OMB Approval Number: None.
Type of Request: Existing collection in use without an OMB control number.
Burden: 1,700 hours.
Number of Respondents: 612,000.
Avg Hours Per Response: 5 seconds.
Needs and Uses: The Destination Control Statement serves as notice to all foreign parties in an export transaction that further shipment to any country not authorized is prohibited. In any Office of Export Enforcement proceeding, evidence of the sending of the commercial invoice, bill of lading or other form of notice of the prohibition against diversion will serve as proof of the person's receipt of the notice.
Affected Public: Businesses or other for–profit organizations.
Frequency: On occasion.
Respondent's Obligation: Mandatory.
OMB Desk Officer: Don Arbuckle, (202) 395–7340.
Agency: Bureau of Export Administration.
Title: Export License Information on Bill of Lading.
Agency Form Number: None.
OMB Approval Number: None.
Type of Request: Existing collection in use without an OMB control number.
Burden: 4,600 hours.
Number of Respondents: 3,500,000.
Avg Hours Per Response: Several seconds.
Needs and Uses: The Export Administration Regulations requires that all forwarders or brokers who are exempt from filing an individual Shipper's Export Declaration to include on shipping documentation the general license symbol or validated license number. This information furnishes official representation to customs officials that the export is permitted.
Affected Public: Businesses or other for–profit organizations.
Frequency: On occasion.
Respondent's Obligation: Mandatory.
OMB Desk Officer: Don Arbuckle, (202) 395–7340.
Agency: Bureau of Export Administration (BXA).
Title: Five Year Record Retention Period.
Agency Form Number: None.
OMB Approval Number: None.
Type of Request: New Recordkeeping Requirement.
Burden: 259 hours.
Number of Respondents: 154,816.
Avg Hours Per Response: 10 seconds per record.
Needs and Uses: BXA is proposing that its record retention requirements for records pertaining to exports and foreign boycotts be increased to five years. This change when implemented will correspond with the five year statute of limitations for criminal actions brought under the Export Administration Act. Most firms now have electronic systems for recordkeeping and thus the burden per response is minimal. This request will supplement documents already approved for a five year retention period –– namely supporting documentation that was previously submitted to BXA at the time of making application for a license.
Affected Public: Businesses or other for–profit organizations.
Frequency: On occasion.
Respondent's Obligation: Mandatory.
OMB Desk Officer: Don Arbuckle, (202) 395–7340.
Agency: Bureau of Export Administration (BXA).
Title: Delivery Verification Procedure.
Agency Form Number: BXA–647P.
OMB Approval Number: 0694–0016.
Type of Request: Extension of a currently approved collection.
Burden: 57 hours.
Number of Respondents: 200.
Avg Hours Per Responses: Approximately 15 minutes and recordkeeping.
Needs and Uses: In order to increase the effectiveness of export controls on international trade in strategic commodities, certain countries participate in the import certificate – delivery verification procedure. Its purpose is to make sure that strategic items are not diverted. When a U.S. importer is requested to furnish their foreign supplier with a certificate, the importer must supply certain information to BXA so that the documentation can be issued.
Affected Public: Businesses or other for–profit organizations.
Frequency: On occasion.
Respondent's Obligation: Required to obtain or retain benefits.
OMB Desk Officer: Don Arbuckle, (202) 395–7340.
Agency: Bureau of Export Administration (BXA).
Title: Short Supply Regulations – Petroleum Products.
Agency Form Number: None.
OMB Approval Number: 0694–0026.
Type of Request: Revision of a currently approved collection.
Burden: 43 hours.
Number of Respondents: 165.
Avg Hours Per Response: 15 minutes required for general license shipments and 30 minutes for documentation supporting an export license.
Needs and Uses: The Naval Petroleum Reserves Production Act of 1976 restricts the export of any petroleum product produced from crude oil derived from National Petroleum Reserves. Under very limited circumstances, petroleum products can be exported if a validated license is obtained. For other shipments under a general license, support documentation is required to prove that the petroleum being exported in not from the Naval Reserves.
Affected Public: Businesses or other for–profit organizations.
Frequency: On occasion.
Respondent's Obligation: Required to obtain or retain benefits.
OMB Desk Officer: Don Arbuckle, (202) 395–7340.
Agency: Bureau of Export Administration (BXA).
Title: Statement by Foreign Consignee in Support of Special License Application.
Agency Form Number: BXA–6052P (BXA–752 under new regulations).
OMB Approval Number: 0694–0050.
Type of Request: Extension of a currently approved collection.
Burden: 173 hours.
Number of Respondents: 323.
Avg Hours Per Response: 30 minutes.
Needs and Uses: This form is used as supporting document for three of BXA's special licenses: Project, Distribution and Service Supply Licenses. The completed form provides BXA with end–use and reexport information to aid in controlling commodities shipped under special license procedures.
Affected Public: Businesses or other for–profit organizations.
Frequency: On occasion.
Respondent's Obligation: Required to obtain or retain benefits.
OMB Desk Officer: Don Arbuckle, (202) 395–7340.
Agency: Bureau of Export Administration (BXA).
Title: Procedures for Supporting Documentation.
Agency Form Number: None.
OMB Approval Number: 0694–0064.
Type of Request: Extension of the expiration date of a currently approved collection.
Burden: 313 hours.
Number of Respondents: 3,558.
Avg Hours Per Response: Varies between 1 and 30 minutes depending on the requirement.
Needs and Uses: The Export Administration Act requires exporters to maintain certain supporting

documentation in their files in support of license applications. This clearance also covers the procedures for returning an unused or partially used import certification, as well as what must be done when a change in representation occurs.

Affected Public: Businesses or other for–profit organizations.

Frequency: On occasion.

Respondent's Obligation: Required to obtain or retain benefits.

OMB Desk Officer: Don Arbuckle, (202) 395–7340.

Agency: Bureau of Export Administration (BXA).

Title: Multi–Purpose Application.

Agency Form Number: BXA–622P, BXA–685P, BXA–699P, BXA–748P.

OMB Approval Number: 0694–0088.

Burden: 13,631 hours.

Number of Respondents: 14,910.

Avg Hours Per Response: Varies between 2 and 45 minutes depending on the requirement.

Needs and Uses: This collection is required in compliance with U.S. export regulations. The information furnished by U.S. exporters provides the basis for decisions to grant licenses for export, reexport, and classifications of commodities, goods and technologies that are controlled for reasons of national security and foreign policy. This revision is necessary to comply with the Paperwork Reduction Act of 1995, which now recognizes and includes the burden associated with third party disclosures, certifications and notification requirements imposed on the public.

Affected Public: Businesses and other for–profit organizations.

Frequency: On occasion.

Respondent's Obligation: Required to obtain or retain benefits.

OMB Desk Officer: Don Arbuckle, (202) 395–7340.

Copies of the above information collection proposals can be obtained by calling or writing Gerald Tache, DOC Forms Clearance Officer, (202) 482–3271, Department of Commerce, Room 5327, 14th and Constitution Avenue NW., Washington, DC 20230.

Written comments and recommendations for the proposed information collections should be sent to Don Arbuckle, OMB Desk Officer, Room 10202, New Executive Office Building, Washington, DC 20503.

Dated: September 12, 1995.

Gerald Taché,

Departmental Forms Clearance Officer, Office of Management and Organization.

[FR Doc. 95–23225 Filed 9–18–95; 8:45 am]

BILLING CODE 3510–CW–F

Foreign-Trade Zones Board

[Docket 52–95]

Foreign-Trade Zone 12—McAllen, Texas, Area Application for Expansion

An application has been submitted to the Foreign-Trade Zones Board (the Board) by the McAllen Economic Development Corporation, grantee of Foreign-Trade Zone 12, McAllen, Texas, requesting authority to expand its zone to include an additional site in the McAllen, Texas, area, within the Hidalgo Customs port of entry. The application was submitted pursuant to the provisions of the Foreign-Trade Zones Act, as amended (19 U.S.C. 81a-81u), and the regulations of the Board (15 CFR Part 400). It was formally filed on September 11, 1995.

FTZ 12 was approved on October 23, 1970 (Board Order 84, 35 FR 16962, 11/3/70) and expanded on May 2, 1984 (Board Order 254, 49 FR 22842, 6/1/84) and June 19, 1990 (Board Order 469, 55 FR 26225, 6/27/90). The zone currently consists of: Site 1 (80 acres)—within the McAllen Southwest Industrial Area, FM 1016 and Ware Road, Hidalgo County, and, Site 2 (8.5 acres)—at the Air Cargo Facility within McAllen Miller International Airport complex, McAllen, Texas.

The applicant is now requesting authority to expand Site 1 to include an adjacent 695-acre industrial park area located on FM 1016 between Bentsen Road and Shary Road, Hidalgo County, 5 miles south of the McAllen Miller International Airport.

No specific manufacturing requests are being made at this time. Such requests would be made to the Board on a case-by-case basis.

In accordance with the Board's regulations (as revised, 56 FR 50790–50808, 10–8–91), a member of the FTZ Staff has been designated examiner to investigate the application and report to the Board.

Public comment on the application is invited from interested parties. Submissions (original and 3 copies) shall be addressed to the Board's Executive Secretary at the address below. The closing period for their receipt is November 20, 1995. Rebuttal comments in response to material submitted during the foregoing period may be submitted during the subsequent 15-day period (to December 4, 1995).

A copy of the application and accompanying exhibits will be available for public inspection at each of the following locations:

Office of the Port Director, U.S. Customs Service, Administration Building, International Bridge, Hidalgo, Texas 78557

Office of the Executive Secretary, Foreign-Trade Zones Board, Room 3716, U.S. Department of Commerce, 14th and Pennsylvania Avenue, NW., Washington, DC 20230

Dated: September 13, 1995.

John J. Da Ponte, Jr.,

Executive Secretary.

[FR Doc. 95–23221 Filed 9–18–95; 8:45 am]

BILLING CODE 3510–DS–P

International Trade Administration

[A–401–805]

Certain Cut-to-Length Carbon Steel Plate From Sweden: Preliminary Results of Antidumping Duty Administrative Review

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

ACTION: Notice of Preliminary Results of Antidumping Duty Administrative Review.

SUMMARY: In response to a request by a respondent, the Department of Commerce (the Department) is conducting an administrative review of the antidumping duty order on *Certain Cut-to Length Carbon Steel Plate from Sweden* (A–401–805). This review covers one manufacturer/exporter of the subject merchandise to the United States during the period of review (POR) February 4, 1993, through July 31, 1994.

We have preliminarily determined that sales to the United States have been made below the foreign market value (FMV). If these preliminary results are adopted in our final results of administrative review, we will instruct U.S. Customs to assess antidumping duties equal to the difference between the United States price (USP) and the FMV. Interested parties are invited to comment on these preliminary results. Parties who submit argument in this proceeding are requested to submit with the argument (1) a statement of the issue and (2) a brief summary of the argument.

EFFECTIVE DATE: September 19, 1995.

FOR FURTHER INFORMATION CONTACT: Elizabeth Patience or Jean Kemp, Office of Agreements Compliance, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, N.W., Washington, D.C. 20230, telephone: (202) 482–3793.

SUPPLEMENTARY INFORMATION:

Applicable Statute and Regulations

Unless otherwise indicated, all citations to the statute and to the Department's regulations are references to the provisions as they existed on December 31, 1994.

Background

On July 9, 1993, the Department published in the Federal Register (58 FR 37213) the final affirmative antidumping duty determination on Certain Cut-to-Length Carbon Steel Plate from Sweden, and published an antidumping duty order on August 19, 1993 (58 FR 44168). On August 3, 1994, the Department published the notice of ''Opportunity to Request an Administrative Review'' of this order for the period February 4, 1993, through July 31, 1994 (59 FR 39543). The Department received a request for an administrative review from Svenskt Stal AB (SSAB). On September 8, 1994 (59 FR 46391), we initiated the administrative review of SSAB.

The Department is now conducting this review in accordance with section 751 of the Tariff Act of 1930, as amended (the Tariff Act). This review covers sales of certain cut-to-length carbon steel plate from Sweden. The POR is February 4, 1993 through July 31, 1994.

Scope of the Review

The products covered by this administrative review constitute one ''class or kind'' of merchandise: certain cut-to-length carbon steel plate. These products include hot-rolled carbon steel universal mill plates (*i.e.*, flat-rolled products rolled on four faces or in closed box pass, of a width exceeding 150 millimeters but not exceeding 1,250 millimeters and of a thickness of not less than 4 millimeters, not in coils and without patterns in relief), of rectangular shape, neither clad, plated nor coated with metal, whether or not painted, varnished or coated with plastics or other nonmetallic substances; and certain hot-rolled carbon steel flat-rolled products in straight lengths, of rectangular shape, hot rolled, neither clad, plated, nor coated with metal, whether or not painted, varnished, or coated with metal, whether or not painted, varnished, or coated with plastics or other nonmetallic substances, 4.75 millimeters or more in thickness and of a width which exceeds 150 millimeters and measures at least twice the thickness, as currently classifiable in the Harmonized Tariff Schedule (HTS) under item numbers 7208.31.0000, 7208.32.0000, 7208.33.1000, 7208.33.5000, 7208.41.0000, 7208.42.0000, 7208.43.0000, 7208.90.0000, 7210.70.3000, 7210.90.9000, 7211.11.0000, 7211.12.0000, 7211.21.0000, 7211.22.0045, 7211.90.0000,7212.40.1000, 7212.40.5000, and 7212.50.0000. Included are flat-rolled products of nonrectangular cross-section where such cross-section is achieved subsequent to the rolling process (*i.e.*, products which have been ''worked after rolling'')—for example, products which have been bevelled or rounded at the edges. Excluded is grade X–70 plate. These HTS item numbers are provided for convenience and Customs purposes. The written description remains dispositive.

Verification

As provided in section 776(b) of the Tariff Act, we verified information provided by the respondent by using standard verification procedures, including onsite inspection of the manufacturer's facilities, the examination of relevant sales and financial records, and selection of original documentation containing relevant information. Our verification results are outlined in the public versions of the verification reports.

United States Price

All of SSAB's U.S. sales were based on the packed price to the first unrelated purchaser in the United States. Because the sales were made prior to importation to the United States, the Department determined that purchase price, as defined in section 772(b) of the Tariff Act, was the appropriate basis for calculating USP. For terms of sale, please see Analysis Memorandum to the File, August 31, 1995. We made deductions from purchase price, where appropriate, for foreign inland freight and insurance, ocean freight, marine insurance, brokerage and handling, port charges, U.S. customs duties and fees, wharfage, and U.S. inland freight.

We used as date of sale the date of contract (if the contract set quantity and value) or, if either price or quantity was not set, the date of order confirmation (the date on which price and quantity are fixed).

We adjusted USP for Swedish value-added taxes (VAT) in accordance with our practice as outlined in recent determinations, including Silicomanganese from Venezuela, Final Determination of Sales at Less Than Fair Value, 59 FR 55435, 55439 (November 7, 1994).

Foreign Market Value

Based on a comparison of the volume of home market and third country sales, we determined that the home market was viable because the amount of similar merchandise sold in the home market is more than five percent of the amount sold to third countries. See 19 CFR 353.48(a). Further, SSAB had sales both to related and unrelated parties in the home market during the POR. In order to determine whether sales to related parties might be appropriate to use as the basis of FMV, the Department compared prices of those sales to prices to unrelated parties, on a model-by-model basis. When possible, the Department used unrelated party sales at the same level of trade as the related party sales for this comparison. When the price ratio of related to unrelated purchases was less than 99.5 percent, we determined that those sales were not arm's length sales and disregarded those sales. See Final Determination of Sales at Less Than Fair Value: Certain Cold-Rolled Carbon Steel Flat Products from Argentina, (58 FR 37062, July 9, 1993).

We used prices to related purchasers only if such sales were made at arm's length as defined above. In addition, we determined that sales made by SSAB through its related distributor, Tibnor AB (TAB), were a significant portion of the home market sales listing. We asked SSAB to report the portion of home market sales made through TAB to the first unrelated customer. SSAB claimed TAB could not identify the supplying producer for sales to unrelated customers. We verified this claim. We also verified that TAB's reported price is set without regard to the supplying producer. We asked SSAB to develop an allocation methodology to account for SSAB sales through TAB to unrelated customers. However, TAB's proposed allocation methodology for reporting the downstream sales is inconsistent with standard accounting principles because it does not consider the impact of purchases from non-SSAB suppliers, it assumes that TAB's beginning inventory was zero, and it assumes that the first plate sold is always SSAB plate. It is also inconsistent with TAB's normal methodology for valuing its inventory. Additionally, at verification, we found that the percentage of TAB purchases of SSAB merchandise is significantly less than respondent's methodology assumes. Therefore, the impact of merchandise sourced from producers other than SSAB is greater than indicated by respondent's methodology. After evaluating the larger percentage of non-SSAB merchandise purchased by TAB, the lack of information regarding

non-SSAB purchases, and the inconsistencies with standard accounting practices, we decided not to use respondent's methodology. However, we determined that as the final price to the customer was set regardless of producer and that TAB accurately reported most of its expenses and adjustments, it was reasonable to use TAB's sales listing. Therefore, we rejected TAB's allocation methodology, revised TAB's reported sales to neutralize the effect of non-SSAB suppliers and used the revised sales listing in our calculations. For more information on our use of SSAB's downstream sales, see Analysis Memorandum to the File, August 31, 1995.

In accordance with 19 CFR 353.58 and 353.55, we compared U.S. sales to home market sales made at the same level of trade, and in comparable commercial quantities, where possible. SSAB reported a number of sales in its home market database in currencies other than the Swedish currency. Company officials explained these are typically sales where the merchandise was shipped to an address in Sweden, as indicated by the destination code of the sale, but customer's invoicing address was not in Sweden. We verified that SSAB properly included these home market sales in its reporting to the Department. Therefore, we included these sales in our calculations.

SSAB had sales of secondary merchandise (non-prime) in the home market; however, there were no sales of secondary merchandise in the U.S. market during the POR. Therefore, as per our established model match criteria, the Department only compared prime merchandise sold in the United States to prime merchandise sold in the home market.

Based on the Department's previous determination of sales made at below the cost of production (COP) in the original LTFV investigation in accordance with section 773(b) of the Tariff Act, we determined that there were reasonable grounds to believe or suspect that, for this review period, SSAB had made sales of subject merchandise in the home market at prices less than the COP. As a result, we investigated whether SSAB sold such or similar merchandise in the home market at prices below the COP over an extended period of time, and whether such sales were made at prices which permitted recovery of all costs within a reasonable period of time in the normal course of trade. In accordance with 19 CFR 353.51(c), we calculated COP for SSAB as the sum of reported materials, labor, factory overhead, and general expenses. We compared COP to home market prices, net of price adjustments, discounts, and movement expenses.

Based upon data collected during verification of SSAB, we recalculated SSAB's general and administrative expenses, after adjusting cost of goods sold for one subsidiary for the effect of inter-company transfers. We also recalculated finance expense using SSAB's consolidated financial statements.

Pursuant to the Department's practice, for each model for which less than 10 percent, by quantity, of the home market sales during the POR were made at prices below COP, we included all sales of that model in the computation of FMV. For each model for which 10 percent or more, but less than 90 percent, of the home market sales during the POR were priced below COP, we excluded from the calculation of FMV those home market sales which were priced below COP, provided that they were made over an extended period of time. For each model for which 90 percent or more of the home market sales during the POR were priced below COP and were made over an extended period of time, we disregarded all sales of that model in our calculation. See Final Determination of Sales at Less Than Fair Value: Certain Carbon Steel Butt-Weld Pipe Fittings from the United Kingdom, (60 FR 10558, February 27, 1995).

In accordance with section 773(b)(1) of the Tariff Act, to determine whether sales below cost had been made over an extended period of time, we compared the number of months in which sales below cost occurred for a particular model to the number of months in which that model was sold. If the model was sold in fewer than three months, we did not disregard below-cost sales unless there were below-cost sales of that model in each month sold. If a model was sold in three or more months, we did not disregard below-cost sales unless there were sales below cost in at least three of the months in which the model was sold. See Tapered Roller Bearings and Parts Thereof, Finished and Unfinished, From Japan and Tapered Roller Bearings, Four Inches or Less in Outside Diameter, and Components Thereof, From Japan; Final Results of Antidumping Duty Administrative Reviews, 58 FR 64720, 64729 (December 8, 1993).

Because SSAB provided no indication that its below-cost sales of models within the ''greater than 90 percent'' and the ''between 10 and 90 percent'' categories were at prices that would permit recovery of all costs within a reasonable period of time and in the normal course of trade, we disregarded those sales of models within the ''10 to 90 percent'' category which were made below cost over an extended period of time.

SSAB did not report COP information for all product models. This affected both the home market and downstream sales listings. For certain of these models, respondent provided a methodology for assigning average costs for similar products. We used their methodology to the extent possible. However, this methodology did not cover all product models with missing COP. We have assigned the highest costs for similar products to the sales of models missing COP information as partial BIA. For more information, see our Analysis Memorandum of August 31, 1995.

In accordance with section 773(b) of the Tariff Act, the Department normally uses the constructed value (CV) of those models for which home market price has been disregarded as below COP. See, e.g., Mechanical Transfer Presses from Japan, Final Results of Antidumping Duty Administrative Review, 59 FR 9958 (March 2, 1994). We did not use CV as FMV for those U.S. models for which we were unable to find a home market match because we found during verification that SSAB had not reported certain home market sales of subject merchandise. We therefore assume that all unmatched sales were the result of this reporting failure. We used a margin based upon BIA only for those unmatched U.S. sales. As BIA, we applied to those sales SSAB's final margin determined in the less-than-fair value (LTFV) investigation. We have determined that resorting to total BIA is not warranted because SSAB's U.S. database is not sufficiently flawed such that the response as a whole is unreliable. *See National Steel Corporation* v. *United States,* 870 F. Supp. 1130, 1135 (CIT 1994).

In accordance with section 773 (a)(1)(A) of the Tariff Act, for those U.S. models for which we were able to find a home market such or similar match, we calculated FMV based on the packed home market sales price to unrelated and related purchasers in the home market. For terms of sale, please see Analysis Memorandum to the File, August 31, 1995.

Pursuant to section 773(a)(4)(B) of the Tariff Act and 19 CFR 353.56(a)(2), we made circumstance of sale adjustments to FMV, where applicable, for credit expenses, handling expense, inland freight, discounts and rebates. Where appropriate, we deducted from FMV home market packing costs and added to FMV packing expenses incurred in

Sweden for U.S. sales. We also adjusted FMV, where appropriate, for physical differences in the merchandise, in accordance with 19 CFR 353.57. Due to discrepancies found at verification, reporting errors, and unsupported adjustments, we disallowed and/or recalculated certain expenses and adjustments. See Analysis Memorandum to the File, August 31, 1995 for more information on these disallowed and/or recalculated adjustments.

Preliminary Results of Review

As a result of our comparison of USP to FMV, we preliminarily determine that the following margin exists for the period February 4, 1993, through July 31, 1994:

Manufacturer	Margin (percent)
SSAB	10.96

Interested parties may request disclosure within 5 days of the date of publication of this notice and may request a hearing within 10 days of publication. Any hearing, if requested, will be held 44 days after the date of publication or the first business day thereafter. Case briefs and/or written comments from interested parties may be submitted no later than 30 days after the date of publication. Rebuttal briefs and rebuttals to written comments, limited to issues raised in those comments, may be filed not later than 37 days after the date of publication of this notice. The Department will publish the final results of this administrative review including the results of its analysis of issues raised in any such written comments or at a hearing.

The Department shall determine, and the Customs Service shall assess, antidumping duties on all appropriate entries. Individual differences between the USP and FMV may vary from the percentages stated above.

Furthermore, the following deposit requirements will be effective for all shipments of the subject merchandise entered, or withdrawn from warehouse, for consumption on or after the publication date of the final results of this administrative review, as provided for by section 751(a)(1) of the Tariff Act. A cash deposit of estimated antidumping duties shall be required on shipments of Certain Cut-to-Length Carbon Steel Plate from Sweden as follows: (1) the cash deposit rate for the reviewed company will be the rate established in the final results of this review; (2) for previously reviewed or investigated companies not listed above, the cash deposit rate will continue to be the company-specific rate published for the most recent period; (3) if the exporter is not a firm covered in this review, or the original LTFV investigation, but the manufacturer is, the cash deposit rate will be the rate established for the most recent period for the manufacturer of the merchandise; and (4) if neither the exporter nor the manufacturer is a firm covered in this review, the cash deposit rate will be 24.23 percent, which is the ''all others'' rate from the LTFV investigation. See Final Determination of Sales at Less Than Fair Value: Certain Cut-to-Length Carbon Steel Plate from Sweden, (58 FR 37213, July 9, 1993).

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

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

Dated: September 13, 1995.

Susan G. Esserman,

Assistant Secretary for Import Administration.

[FR Doc. 95–23220 Filed 9–18–95; 8:45 am]

BILLING CODE 3510–DS–P

Applications for Duty-Free Entry of Scientific Instruments

Pursuant to Section 6(c) of the Educational, Scientific and Cultural Materials Importation Act of 1966 (Pub. L. 89–651; 80 Stat. 897; 15 CFR part 301), we invite comments on the question of whether instruments of equivalent scientific value, for the purposes for which the instruments shown below are intended to be used, are being manufactured in the United States.

Comments must comply with 15 CFR 301.5(a)(3) and (4) of the regulations and be filed within 20 days with the Statutory Import Programs Staff, U.S. Department of Commerce, Washington, D.C. 20230. Applications may be examined between 8:30 A.M. and 5:00 P.M. in Room 4211, U.S. Department of Commerce, 14th Street and Constitution Avenue, N.W., Washington, D.C.

Docket Number: 95-067. *Applicant:* The Salk Institute for Biological Studies, 10010 North Torrey Pines Road, La Jolla, CA 92037. *Instrument:* DIP-2000 Imaging Plate X-ray Diffraction Image Processor with Kappa-goniometer and SRA M18XHF Rotating Anode X-ray Generator. *Manufacturer:* MAC Science Co., Ltd., Japan. *Intended Use:* The instrument will be used to collect X-ray diffraction data from crystals made with biological macromolecules such as signal transduction, ion conductance, and protein-DNA recognition during the study of proteins such as transducin from bovine eye and potassium channels from rat kidney. *Application Accepted by Commissioner of Customs:* August 1, 1995.

Docket Number: 95–068. *Applicant:* University of California, Department of Nutritional Sciences, 119 Morgan Hall, Berkeley, CA 94720-3104. *Instrument:* Mass Spectrometer, Model JMS-AX505WA. *Manufacturer:* JEOL, Japan. *Intended Use:* The instrument will be used to measure isotope incorporation levels in different metabolites during studies of glucose, fat and protein metabolism in animals and humans. *Application Accepted by Commissioner of Customs:* August 1, 1995.

Docket Number: 95–069. *Applicant:* Saint Barnabas Medical Center, 94 Old Short Hills Road, Livingston, NJ 07039. *Instrument:* Electron Microscope, Model JEM-1210. *Manufacturer:* JEOL, Japan. *Intended Use:* The instrument will be used in several research projects to study ultrastructural features of biomedical research specimens from experimental animals, cultured cells and various tissues from patients with pathological disorders. In addition, the instrument will be used to train pathology residents in the application of the electron microscope. *Application Accepted by Commissioner of Customs:* August 1, 1995.

Docket Number: 95–070. *Applicant:* Rutgers, The State University, Waksman Institute, P.O. Box 6999, Piscataway, NJ 08855-6999. *Instrument:* Cryogenic Cooling System. *Manufacturer:* Oxford Cryosystems, United Kingdom. *Intended Use:* The instrument will be used for X-ray crystallographic studies of proteins with the objective of solving the atomic structure of a subject protein. The instrument will also be used to teach undergraduate courses in crystallography in which students will be trained in the skills necessary to the analysis of protein crystal by means of X-ray Diffraction. *Application Accepted by Commissioner of Customs:* August 4, 1995.

Docket Number: 95–071. *Applicant:* Colorado State University, Natural

Resource Ecology Lab, NESB Building, Fort Collins, CO 80523. *Instrument:* Mass Spectrometer, Model OPTIMA. *Manufacturer:* VG - Fisons, United Kingdom. *Intended Use:* The instrument will be used to measure the isotopic abundance of carbon, nitrogen, hydrogen, and oxygen in plant, soil and air samples in experiments ranging from field studies to laboratory analysis. In addition, the instrument will be used in the course Physiological Plant Ecology and Isotope Biogeochemistry to examine plant and soil processes that modify isotope fractionation. *Application Accepted by Commissioner of Customs:* August 4, 1995.

Frank W. Creel

Director, Statutory Import Programs Staff

[FR Doc. 95-23223 Filed 9-18-95; 8:45 am]

BILLING CODE 3510-DS-F

Applications for Duty-Free Entry of Scientific Instruments

Pursuant to Section 6(c) of the Educational, Scientific and Cultural Materials Importation Act of 1966 (Pub. L. 89–651; 80 Stat. 897; 15 CFR part 301), we invite comments on the question of whether instruments of equivalent scientific value, for the purposes for which the instruments shown below are intended to be used, are being manufactured in the United States.

Comments must comply with 15 CFR 301.5(a)(3) and (4) of the regulations and be filed within 20 days with the Statutory Import Programs Staff, U.S. Department of Commerce, Washington, D.C. 20230. Applications may be examined between 8:30 A.M. and 5:00 P.M. in Room 4211, U.S. Department of Commerce, 14th Street and Constitution Avenue, N.W., Washington, D.C.

Docket Number: 95–072. *Applicant:* University of Michigan, Department of Geological Sciences, 425 E. University, Ann Arbor, MI 48109-1063. *Instrument:* ICP Multicollector Mass Spectrometer, Model Plasma 54. *Manufacturer:* Fisons Elemental, United Kingdom. *Intended Use:* The instrument will be used in experiments that consist of extracting and purifying elements of interest and measuring their isotopic compositions, with or without enriched spikes to measure concentrations. In addition, the instrument will be used for training purposes in relevant geochemistry courses. *Application Accepted by Commissioner of Customs:* August 11, 1995.

Docket Number: 95–073. *Applicant:* Texas A&M University, College Station, TX 77843. *Instrument:* Automatic Carbonate Preparation Device, Model Kiel II. *Manufacturer:* Finnigan MAT, Germany. *Intended Use:* The instrument is an accessory to an existing mass spectrometer that will be used to provide the means for measuring the stable oxygen and carbon isotopic ratios of very small, individually reacted carbonate mineral samples under study. The instrument will also be used to collect data for classroom teaching and M.S. and Ph.D. thesis. *Application Accepted by Commissioner of Customs:* August 11, 1995.

Docket Number: 95–074. *Applicant:* University of South Florida, Marine Science Department, MSL 119, 830 1st Street South, St. Petersburg, FL 33701. *Instrument:* Fluorimeter, Model Aquatraka MKIII. *Manufacturer:* Chelsea Instruments Ltd., United Kingdom. *Intended Use:* The instrument will be used to measure chlorophyll *a* fluorescence in aquatic environments in a study of the plant plankton in the Caribbean Sea, part of a larger effort to identify and analyze the biological/chemical constituents of marine waters in the Caribbean Sea. In addition, the instrument will be used for educational purposes in the course Remote Sensing in Oceanography. *Application Accepted by Commissioner of Customs:* August 16, 1995.

Docket Number: 95–075. *Applicant:* Georgetown University, 37th and ''O'' Streets, NW, Washington, DC 20057. *Instrument:* Time-Correlated Single Photon Counting Spectrometer, Model FL900. *Manufacturer:* Edinburgh Instruments, Ltd., United Kingdom. *Intended Use:* The instrument will be used to monitor the excited state lifetime of organic and polymeric molecules by their emissive properties during the study of basic and exotic polymers, gels, liquid crystals, crystals and other materials. The objective of the studies is to characterize the environment in which molecules in the above phases are located. In addition, the instrument will be used for training graduate and undergraduate students to characterize materials of significance. *Application Accepted by Commissioner of Customs:* August 25, 1995.

Docket Number: 95–076. *Applicant:* University of Michigan, 1028 College of Pharmacy, 428 Church Street, Ann Arbor, MI 48109-1065. *Instrument:* Stopped-flow Spectrometer System, Model SF-61AFX. *Manufacturer:* Hi-Tech Scientific, United Kingdom. *Intended Use:* The instrument will be used to study rapid reaction kinetics over the millisecond time scale in experiments involving purification of the enzymes from either bovine lung (guanylate cyclase) or a macrophage cell line (nitric oxide synthase). *Application Accepted by Commissioner of Customs:* August 25, 1995.

Docket Number: 95–077. *Applicant:* Shriners Hospital - Spokane Unit, 911 West Fifth Avenue, Spokane, WA 99204-2472. *Instrument:* 3-Dimensional Motion Analyser System, Model VICON 370. *Manufacturer:* Oxford Metrics, Ltd., United Kingdom. *Intended Use:* The instrument will be used to study the gait cycle/walking patterns, muscle activity and various motions of human subjects. The analysis of this data will then be used in aiding the physicians and therapists in determining the needs of the patient (i.e. continuing therapy, a change in therapy, surgery, etc.). *Application Accepted by Commissioner of Customs:* August 29, 1995.

Docket Number: 95–079. *Applicant:* University of California, Department of Pharmaceutical Chemistry, San Francisco, CA 94143-0446. *Instrument:* Tandem Mass Spectrometer, Model AUTOSPEC - 5000. *Manufacturer:* Fisons Instruments, United Kingdom. *Intended Use:* The instrument will be used for studies of the macromolecular components of normal human and tumor cells and bacterial and viral human pathogens in the context of correlations between cell phenotype and genotype. Overall research purposes will emphasize interdisciplinary studies addressing key unsolved structural issues revolving around the delineation of protein sequence and covalent modification, protein glycosylation, peptide antigens, glycolipid antigens and xenobiotic protein and DNA covalent adducts. In addition, the instrument will be used for educational purposes in the course Pharmaceutical Chemistry 235: Mass Spectrometry in the Health and Life Sciences. *Application Accepted by Commissioner of Customs:* August 29, 1995.

Docket Number: 95–080. *Applicant:* Santa Rosa Outpatient Rehab, 4319 Medical Drive, San Antonio, TX 78229-4899. *Instrument:* 3-Dimensional Motion Analyser System, Model VICON 370. *Manufacturer:* Oxford Metrics, Ltd., United Kingdom. *Intended Use:* The instrument will be used for the study of the walking patterns (i.e. gait) of human subjects, to provide precise information on muscle activity, joint motion, and the forces acting at the joint at different points of human gait or various motions. *Application Accepted by Commissioner of Customs:* August 29, 1995.

Frank W. Creel,

Director, Statutory Import Programs Staff.

[FR Doc. 95-23222 Filed 9-18-95; 8:45 am]

BILLING CODE 3510-DS-F

University of Pennsylvania, Notice of Decision on Application for Duty-Free Entry of Scientific Instrument

This decision is made pursuant to Section 6(c) of the Educational, Scientific, and Cultural Materials Importation Act of 1966 (Pub. L. 89–651, 80 Stat. 897; 15 CFR part 301). Related records can be viewed between 8:30 A.M. and 5:00 P.M. in Room 4211, U.S. Department of Commerce, 14th and Constitution Avenue NW., Washington, DC.

Docket Number: 95–030. *Applicant:* University of Pennsylvania, Philadelphia, PA 19104. *Instrument:* Olfactometer, Transformation Unit and Compressor-Vacuum-Unit, Model OM/4. *Manufacturer:* Heinrich Burghart, Germany. *Intended Use:* See notice at 60 FR 29826, June 6, 1995.

Comments: None received. *Decision:* Approved. No instrument of equivalent scientific value to the foreign instrument, for such purposes as it is intended to be used, is being manufactured in the United States. *Reasons:* The foreign instrument provides: (1) filtered and humidified pulsed odor/air stimuli, (2) controlled stimulus duration between 50ms and infinity, and (3) thermostabilized odorant flow with manual or external triggering. The National Institutes of Health advises in its memorandum dated July 11, 1995 that (1) these capabilities are pertinent to the applicant's intended purpose and (2) it knows of no domestic instrument or apparatus of equivalent scientific value to the foreign instrument for the applicant's intended use.

We know of no other instrument or apparatus of equivalent scientific value to the foreign instrument which is being manufactured in the United States.

Frank W. Creel,

Director, Statutory Import Programs Staff.

[FR Doc. 95–23224 Filed 9–18–95; 8:45 am]

BILLING CODE 3510–DS–F

National Oceanic and Atmospheric Administration

Monterey Bay National Marine Sanctuary Advisory Council; Meeting

AGENCY: Sanctuaries and Reserves Division (SRD), Office of Ocean and Coastal Resource Management (OCRM), National Ocean Service (NOS), National Oceanic and Atmospheric Administration (NOAA), Department of Commerce.

ACTION: Monterey Bay National Marine Sanctuary Advisory Council Open Meeting.

SUMMARY: The Advisory Council was established in December 1993 to advise NOAA's Sanctuaries and Reserve Division regarding the management of the Monterey Bay National Marine Sanctuary. The Advisory Council was convened under the National Marine Sanctuaries Act.

TIME AND PLACE: Friday, September 29, 1995, from 8:30 until 4:30. The meeting will be held at the Moss Landing Chamber of Commerce, Moss Landing, California.

AGENDA: General issues related to the Monterey Bay National Marine Sanctuary are expected to be discussed, including an update from the Sanctuary Manager, reports from the working groups, an update on the Sanctuary license plate marketing program, and discussions about the establishment of a Sanctuary Foundation and proposed central valley water reclamation projects.

PUBLIC PARTICIPATION: The meeting will be open to the public. Seats will be available on a first-come, first-served basis.

FOR FURTHER INFORMATION CONTACT: Jane Delay at (408) 647–4246 or Elizabeth Moore at (301) 713–3141.

Federal Domestic Assistance Catalog Number 11.429

Marine Sanctuary Program

Dated: September 12, 1995.

David L. Evans,

Acting Deputy Assistant Administrator for Ocean Services and Coastal Zone Management.

[FR Doc. 95–23157 Filed 9–18–95; 8:45 am]

BILLING CODE 3510–08–M

DEPARTMENT OF DEFENSE

Office of the Secretary

Ballistic Missile Defense Advisory Committee; Meeting

ACTION: Notice of Advisory Committee Meeting.

SUMMARY: The Ballistic Missile Defense (BMD) Advisory Committee will meet in closed session in Washington, D.C., on October 5–6, 1995.

The mission of the BMD Advisory Committee is to advise the Secretary of Defense and Deputy Secretary of Defense, through the Under Secretary of Defense (Acquisition and Technology), on all matters relating to BMD acquisition, system development, and technology.

In accordance with Section 10(d) of the Federal Advisory Committee Act, Public Law No. 92–463, as amended by 5 U.S.C., Appendix II, it is hereby determined that this BMD Advisory-Committee meeting concerns matters listed in 5 U.S.C., 552b(c)(1), and that accordingly this meeting will be closed to the public.

Dated: September 14, 1995.

Linda M. Bynum,

OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 95–23190 Filed 9–18–95; 8:45 am]

BILLING CODE 5000–04–M

Department of the Army

Meeting of the Industry/Government Working Group for Performance Criteria of Military Clothing and Equipment

AGENCY: U.S. Army Soldier Systems Command, DoD.

ACTION: Meeting announcement.

SUMMARY: The Industry/Government Working Group for Performance Criteria of Military Clothing and Equipment will meet on Wednesday, 25 October 1995 in the Conference Center at the Soldier Systems Command, Natick Research, Development and Engineering Center, Natick, MA. The meeting will be devoted to Comfort, Durability, and Protection Performance Criteria subgroup activities.

The purpose of the Industry/Government Working Group is to identify performance criteria and test methodology that will be used to measure comfort, durability, and protection performance of military clothing and individual equipment. The U.S. Army is interested in consumer and market research data in the areas of comfort, durability, and flame resistance of fabrics, clothing and equipment, as well as related test methods, standards, specifications, or handbooks.

FOR FURTHER INFORMATION CONTACT: Carole A. Faria, Textile Technologist, at (508) 651–5460.

Dated: September 18, 1995.

Carole A. Faria,

Textile Technologist.

[FR Doc. 95–23140 Filed 9–18–95; 8:45 am]

BILLING CODE 3710–08–M

Defense Information Systems Agency

Membership of the Defense Information Systems Agency Senior Executive Service (SES) Performance Review Board (PRB)

AGENCY: Defense Information System Agency.

ACTION: Notice of Membership of the Defense Information Systems Agency Performance Review Board.

SUMMARY: This notice announces the appointment of the members of the Performance Review Board of the Defense Information Systems Agency. The publication of membership is required by 5 U.S.C. 4314(c)(4).

The Performance Review Board provides fair and impartial review of Senior Executive Service performance appraisals and makes recommendations regarding performance ratings and performance awards to the Director, DISA.

EFFECTIVE DATE: August 14, 1995.

FOR FURTHER INFORMATION CONTACT: Ms. Carrie K. Bazemore, SES Program Manager, Civilian Personnel Division, Personnel and Administration Directorate, Defense Information Systems Agency (703) 607–4411.

SUPPLEMENTARY INFORMATION: In accordance with 5 U.S.C. 4314(c)(4), the following are names and titles of the executives who have been appointed to serve as members of the SES Performance Review Board. They will serve a one-year renewable term, effective 14 August 1995.

Slawson, Michael F., Deputy Director, Personnel and Administration
Neill, Louise T., Deputy Director for Procurement and Logistics
Fountaine, D. Diane, Deputy Manager, National Communication Systems
Gauss, John, RADM, USN, Deputy Director for Engineering and Interoperability
Mestrovich, Michael, Dr., Deputy Director for Enterprise Integration

William McAlpin,

Lieutenant Colonel, USA, Acting Chief, Civilian Personnel.

[FR Doc. 95–23189 Filed 9–18–95; 8:45 am]

BILLING CODE 3610–05–M

DEPARTMENT OF EDUCATION

Notice of Proposed Information Collection Requests

AGENCY: Department of Education.

ACTION: Notice of proposed information collection requests.

SUMMARY: The Director, Information Resources Group, invites comments on the proposed information collection requests as required by the Paperwork Reduction Act of 1995.

DATES: Interested persons are invited to submit comments on or before November 20, 1995.

ADDRESSES: Written comments and requests for copies of the proposed information collection requests should be addressed to Patrick J. Sherrill, Department of Education, 600 Independence Avenue SW., Room 5624, Regional Office Building 3, Washington, DC 20202–4651, or should be electronic mailed to the internet address #FIRB@ed.gov, or should be faxed to 202–708–9346.

FOR FURTHER INFORMATION CONTACT: Patick J. Sherrill (202) 708–8196. 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 3506 of the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35) requires that the Department of Education (ED) provide interested Federal agencies and the public an early opportunity to comment on information collection requests. The Office of Management and Budget (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 Director of the Information Resources Group, publishes this notice containing proposed information collection requests at the beginning of the Departmental review of the information collection. 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) Summary of the collection; (4) Description of the need for, and proposed use of, the information; (5) Respondents and frequency of collection; and (6) Reporting and/or Recordkeeping burden. ED invites public comment at the address specified above. Copies of the requests are available from Patrick J. Sherrill at the address specified above.

The Department of Education is especially interested in public comment addressing the following issues: (1) Is this collection necessary to the proper functions of the Department, (2) will this information be processed and used in a timely manner, (3) is the estimate of burden accurate, (4) how might the Department enhance the quality, utility, and clarity of the information to be collected, and (5) how might the Department minimize the burden of this collection on the respondents, including through the use of information technology.

Dated: September 13, 1995.

Gloria Parker,

Director, Information Resources Group.

Office of Postsecondary Education

Type of Review: Revision
Title: Reporting and Recordkeeping requirements for the William D. Ford Federal Direct Loan Program
Frequency: Varies by Section
Affected Public: Individuals or households
Reporting Burden:
Responses: 6,394,992
Burden Hours: 1,990, 713
Recordkeeping Burden:
Recordkeepers: 0
Burden Hours: 0
Abstract: The proposed rules require collection activities that enable the Secretary to determine borrower eligibility and repayment schedules for Direct Loans.

[FR Doc. 95–23124 Filed 9–18–95; 8:45 am]

BILLING CODE 4000–01–M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. EG95–79–000, et al.]

Brooklyn Navy Yard Cogeneration Partners, L.P., et al.; Electric Rate and Corporate Regulation Filings

September 12, 1995.

Take notice that the following filings have been made with the Commission:

1. Brooklyn Navy Yard Cogeneration Partners, L.P.

[Docket No. EG95–79–000]

On August 16, 1995, Brooklyn Navy Yard Cogeneration Partners, L.P., 366 Madison Avenue, Suite 1103, New York, New York 10017, filed with the Federal Energy Regulatory Commission an application for determination of exempt wholesale generator status pursuant to Section 32(a)(1) of the Public Utility Holding Company Act of 1935, as amended by section 711 of the Energy Policy Act of 1992.

The applicant is a corporation that will be engaged directly and exclusively in owning and operating an eligible facility under construction in Brooklyn, New York. The facility will consist of a 315 MW (net) topping-cycle cogeneration facility fueled primarily by natural gas. The facility will include such interconnection components as are necessary to interconnect the facility with the facilities of the applicant's wholesale customers.

Comment date: October 3, 1995, in accordance with Standard Paragraph E

at the end of this notice. The Commission will limit its consideration of comments to those that concern the adequacy or accuracy of the application.

2. Pennsylvania Power & Light Company

[Docket No. ER95–1267–000]

Take notice that on August 31, 1995, Pennsylvania Power & Light Company (PP&L), tendered for filing supplemental information with respect to its adoption of certain accounting methods in compliance with the Commission's Statement of Policy issued December 17, 1993, in Docket No. PL93–1–000, *Post-Employment Benefits Other Than Pensions,* 61 FERC ¶ 61,330 (1992), *order on reh'g,* 65 FERC ¶ 61,035 (1993) concerning the treatment of post-retirement benefits other than pensions (PBOPs).

Comment date: September 27, 1995, in accordance with Standard Paragraph E at the end of this notice.

3. Pacific Gas and Electric Company

[Docket No. ER95–1338–000]

Take notice that on August 30, 1995, Pacific Gas and Electric Company (PG&E), tendered for filing an amendment to its July 3, 1995 filing in this docket of a rate change to Rate Schedule FERC No. 149 between PG&E and Lassen Municipal Utility District (Lassen). On July 3, 1995 PG&E submitted the following amendments to the September 22, 1993 Power and Transmission Services Agreement (Agreement) between Lassen and PG&E: 1) a First Amendment to the Agreement (First Amendment); 2) a revised Appendix A—Rates (Revised Appendix A) to the Agreement; and 3) a February 3, 1995 Letter Agreement that establishes the Power Service Demand rate under the Agreement.

At the request of the Commission Staff, PG&E is submitting revised cost support and workpapers to aid the Commission's review of the proposed rate change.

Copies of this filing have been served upon Lassen and the California Public Utilities Commission.

Comment date: September 27, 1995, in accordance with Standard Paragraph E at the end of this notice.

4. The Washington Water Power Company

[Docket No. ER95–1683–000]

Take notice that on September 1, 1995, The Washington Water Power Company (WWP), tendered for filing with the Federal Energy Regulatory Commission pursuant to 18 CFR 35.11 and 35.12a Transmission Service Agreement between WWP and Vaagen Brothers Lumber, Inc. WWP requests waiver of the prior notice requirement and requests an effective time and date of 0001 hours, September 1, 1995.

Comment date: September 27, 1995, in accordance with Standard Paragraph E at the end of this notice.

5. Florida Power & Light Company

[Docket No. ER95–1695–000]

Take notice that on September 5, 1995, Florida Power & Light Company (FPL), tendered for filing a proposed Service Agreement with MidCon Power Services Corp. for transmission service under FPL's Transmission Tariff No. 3.

FPL requests that the proposed Service Agreement be permitted to become effective on September 11, 1995, or as soon thereafter as practicable.

FPL states that this filing is in accordance with Part 35 of the Commission's Regulations.

Comment date: September 27 1995, in accordance with Standard Paragraph E at the end of this notice.

6. Northeast Utilities Service Company

[Docket No. ER95–1696–000]

Take notice that on September 5, 1995, Northeast Utilities Service Company (NU), tendered for filing a new Sale for Resale Tariff No. 7, which provides for wholesale sales by the NU System Companies to customers located outside of New England at market-based rates. NU is requesting an effective date of November 4, 1995.

Comment date: September 27, 1995, in accordance with Standard Paragraph E at the end of this notice.

7. Green Mountain Power Corporation

[Docket No. ER95–1697–000]

Take notice that on September 5, 1995, Green Mountain Power Corporation (GMP), tendered for filing an executed Service Agreement dated September 1, 1995 pursuant to which it has agreed to sell capacity and energy to LGE Power Marketing (LGE) in accordance with the terms and conditions of GMP's FERC Electric Tariff, Original Volume No. 2, and a Certificate of Concurrence to the filing by LGE. GMP has requested that the Commission waive its notice requirements in order to make the Service Agreement and Certificate of Concurrence effective as of September 6, 1995.

Comment date: September 27, 1995, in accordance with Standard Paragraph E at the end of this notice.

8. Pennsylvania Power & Light Company

[Docket No. ER95–1698–000]

Take notice that on September 5, 1995, Pennsylvania Power & Light Company (PP&L), tendered for filing with the Federal Energy Regulatory Commission four Service Agreements (the Agreements) between PP&L and (1) North American Energy Conservation, Inc., dated August 1, 1995; (2) Rainbow Energy Marketing Corp., dated August 11, 1995; (3) Phibro Inc., dated August 23, 1995; and (4) KCS Power Marketing, Inc., dated August 23, 1995.

The Agreements supplement a Short Term Capacity and Energy Sales umbrella tariff approved by the Commission in Docket No. ER95–782–000 on June 21, 1995.

In accordance with the policy announced in *Prior Notice and Filing Requirements Under Part II of the Federal Power Act,* 64 FERC ¶ 61,139, *clarified and reh'g granted in part and denied in part,* 65 FERC ¶ 61,081 (1993). PP&L requests the Commission to make the Agreement effective as of the date of execution of each, because service will be provided under an umbrella tariff and each service agreement is filed within 30 days after the commencement of service. In accordance with 18 CFR 35.11, PP&L has requested waiver of the sixty-day notice period in 18 CFR 35.3(e). PP&L has also requested waiver of certain filing requirements for information previously filed with the Commission in Docket No. ER95–782–000.

PP&L states that a copy of its filing was provided to the customers involved and to the Pennsylvania Public Utility Commission.

Comment date: September 27, 1995, in accordance with Standard Paragraph E at the end of this notice.

9. Florida Power & Light Company

[Docket No. ER95–1699–000]

Take notice that on September 5, 1995, Florida Power & Light Company (FPL), tendered for filing proposed service agreements with NorAm Energy Services, Inc. for transmission service under FPL's Transmission Tariff No. 2 and FPL's Transmission Tariff No. 3.

FPL requests that the proposed service agreements be permitted to become effective on September 11, 1995, or as soon thereafter as practicable.

FPL states that this filing is in accordance with Part 35 of the Commission's regulations.

Comment date: September 27, 1995, in accordance with Standard Paragraph E at the end of this notice.

Standard Paragraph

E. Any person desiring to be heard or to protest said filing should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, N.E.,

Washington, D.C. 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 18 CFR 385.214). All such motions or protests should be filed on or before the comment date. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a motion to intervene. Copies of this filing are on file with the Commission and are available for public inspection.

Lois D. Cashell,

Secretary.

[FR Doc. 95–23201 Filed 9–18–95; 8:45 am]

BILLING CODE 6717–01–P

[Docket No. CP85–221–051]

Frontier Gas Storage Co.; Notice of Sale Pursuant to Settlement Agreement

September 13, 1995.

Take notice that on September 7, 1995, Frontier Gas Storage Company (Frontier), c/o Reid & Priest, Market Square, 701 Pennsylvania Avenue, NW., Suite 800, Washington, D.C. 20004, in compliance with the provisions of the Commission's February 13, 1985, Order in Docket No. CP82–487–000, *et al.*, submitted an executed Service Agreement under Rate Schedule LVS–1 providing for the possible sale of up to a daily quantity of 50,000 MMBtu, not to exceed 5 Bcf for the term of the Agreement, of Frontier's gas storage inventory on an ''as metered'' basis to Western Gas Resources, Inc.

Under Subpart (b) of Ordering Paragraph (F) of the Commission's February 13, 1985, Order, Frontier is ''authorized to commence the sale of its inventory under such an executed service agreement fourteen days after filing the agreement with the Commission, and may continue making such sale unless the Commission issues an order either requiring Frontier to stop selling and setting the matter for hearing or permitting the sale to continue and establishing other procedures for resolving the matter.''

Any person desiring to be heard or to make a protest with reference to said filing should within 10 days of the publication of such notice in the Federal Register, file with the Federal Energy Regulatory Commission (825 North Capitol Street NE., Washington, D.C. 20426) a motion to intervene or protest in accordance with the requirements of the Commission's Rules of Practice and Procedures, 18 CFR 385.214 or 385.211. 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. 95–23138 Filed 9–18–95; 8:45 am]

BILLING CODE 6717–01–M

[Docket No. MG88–47–007]

Texas Gas Transmission Corporation; Notice of Filing

September 13, 1995.

Take notice that on September 7, 1995, Texas Gas Transmission Corporation (Texas Gas) submitted revised standards of conduct under Order Nos. 497 *et seq.*[1] and Order Nos. 566 *et seq.*[2] Texas Gas states that it is revising its standards of conduct to incorporate the changes required by Order Nos. 566 and 566–A. The modifications also reflect changes to Texas Gas's list of marketing affiliates and changes to its list of shared Directors.

Texas Gas states that copies of this filing have been mailed to all parties on the official service list compiled by the Secretary in this proceeding.

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 September 28, 1995. 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. 95–23139 Filed 9–18–95; 8:45 am]

BILLING CODE 6717–01–M

[1] Order No. 497, 53 FR 22139 (June 14, 1988) FERC Stats. & Regs. 1986–1990 ¶30,820 (1988); Order No. 497–A, *order on rehearing,* 54 FR 52781 (December 22, 1989), FERC Stats. & Regs. 1986–1990 ¶30,868 (1989); Order No. 497–B, *order extending sunset date,* 55 FR 53291 (December 28, 1990), FERC Stats. & Regs. 19861990 ¶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).

[2] 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,* 59 FR 52896 (October 20, 1994), 69 FERC ¶61,044 (October 14, 1994); Order No. 566–B, *order on rehearing,* 59 FR 65707 (December 21, 1994); 69 FERC ¶61,334 (December 14, 1994); *appeal docketed sub nom. Conoco, Inc. v. FERC,* D.C. Cir. No. 94–1745 (December 14, 1994).

Office of Hearings and Appeals

Proposed Implementation of Special Refund Procedures

AGENCY: Office of Hearings and Appeals, DOE.

ACTION: Notice of proposed implementation of special refund procedures.

SUMMARY: The Office of Hearings and Appeals (OHA) of the Department of Energy announces the proposed procedures for disbursement of $4,567,399.72 (plus accrued interest) in alleged or adjudicated crude oil overcharges obtained by the DOE from Malcolm Turner (Case No. VEF–0013), Revere Petroleum Corporation (Case No. VEF–0014), Granite Petroleum Corporation (Case No. VEF–0015), and Dalco Petroleum Corporation (Case No. VEF–0016). The OHA has tentatively determined that the funds obtained from these firms, plus accrued interest, be distributed in accordance with the DOE's Modified Statement of Restitutionary Policy in Crude Oil Cases, 51 Fed. Reg. 27899 (August 4, 1986).

DATE AND ADDRESSES: Comments must be filed in duplicate on or before October 19, 1995, and should be addressed to the Office of Hearings and Appeals, Department of Energy, 1000 Independence Avenue SW., Washington, D.C. 20585. All comments should conspicuously display a reference to Case Nos. VEF–0013, *et al.*

FOR FURTHER INFORMATION CONTACT: Richard W. Dugan, Associate Director, Office of Hearings and Appeals, 1000 Independence Avenue SW.,

Washington, D.C. 20585, (202) 586–2860.

SUPPLEMENTARY INFORMATION: In accordance with 10 C.F.R. 205.282(b), notice is hereby given of the issuance of the Proposed Decision and Order set forth below. The Proposed Decision and Order sets forth the procedures that the DOE has tentatively formulated to distribute a total of $4,567,399.72, plus accrued interest, remitted to the DOE by Malcolm Turner, Revere Petroleum Corporation, Granite Petroleum Corporation and Dalco Petroleum Corporation. The DOE is currently holding these funds in interest bearing escrow accounts pending distribution.

The OHA proposes to distribute these funds in accordance with the DOE's Modified Statement of Restitutionary Policy in Crude Oil Cases, 51 FR 27899 (August 4, 1986) (the MSRP). Under the MSRP, crude oil overcharge monies are divided among the federal government, the states, and injured purchasers of refined petroleum products. Refunds to the states will be distributed in proportion to each state's consumption of petroleum products during the price control period. Refunds to eligible purchasers will be based on the volume of petroleum products that they purchased and the extent to which they can demonstrate injury.

Because the June 30, 1995, deadline for crude oil refund applications has passed, we propose not to accept any new applications from purchasers of refined petroleum products for these funds. As we state in the Proposed Decision, any party who has previously submitted a refund application in the crude oil refund proceeding should not file another Application for Refund. The previously filed crude oil application will be deemed filed in all crude oil proceedings as the proceedings are finalized.

Any member of the public may submit written comments regarding the proposed refund procedures. Commenting parties are requested to submit two copies of their comments. Comments should be submitted within 30 days of publication of this notice in the Federal Register, and should be sent to the address set forth at the beginning of this notice. All comments received in these proceedings will be available for public inspection between the hours of 1:00 p.m. to 5:00 p.m., Monday through Friday, except federal holidays, in the Public Reference Room of the Office of Hearings and Appeals, located in Room 1E–234, 1000 Independence Avenue SW., Washington, D.C. 20585.

Dated: September 13, 1995.

George B. Breznay,

Director, Office of Hearings and Appeals.

Proposed Decision and Order of the Department of Energy

Implementation of Special Refund Procedures

Names of Firms:
Malcolm M. Turner
Revere Petroleum Corporation *et al.*
Granite Petroleum Corporation
Dalco Petroleum Corporation
Dates of Filing:
April 10, 1995
April 10, 1995
April 10, 1995
May 2, 1995
Case Numbers:
VEF–0013
VEF–0014
VEF–0015
VEF–0016
September 13, 1995.

In accordance with the procedural regulations of the Department of Energy (DOE), 10 CFR Part 205, Subpart V, the Office of General Counsel, Regulatory Litigation (OGC) (formerly the Economic Regulatory Administration (ERA), Office of Enforcement Litigation), filed four Petitions for the Implementation of Special Refund Procedures with the Office of Hearings and Appeals (OHA) on April 10, 1995, and May 2, 1995. The Petitions request that OHA formulate and implement procedures to distribute funds received by the DOE from Malcolm M. Turner (Turner), Revere Petroleum Corporation (Revere), Granite Petroleum Corporation (Granite), and Dalco Petroleum Corporation (Dalco), pursuant to court-approved settlements between the parties and the DOE, DOE consent orders or remedial orders. This Decision and Order sets forth the OHA's plan to distribute these funds.

I. Background

As indicated by the following summaries of the relevant enforcement proceedings, all of the funds that are subject to this Decision were obtained through enforcement actions involving alleged or adjudicated crude oil overcharges.

A. Malcolm Turner

Turner, the sole Director and President of Bayport Refining Co. (Bayport), was a reseller of crude oil during the period of petroleum price controls and was subject to regulations governing the pricing and allocation of crude oil set forth at 10 CFR Parts 211 and 212 of the Mandatory Petroleum Price and Allocation Regulations. As the result of an ERA audit of Turner's and Bayport's operations, the ERA issued a Proposed Remedial Order (PRO) on September 20, 1984, alleging that they violated the provisions of 10 CFR § 212.186, by charging prices for crude oil in excess of actual purchase prices without providing any service or other function traditionally and historically associated with the resale of crude oil during the period from September 1978 through December 1980. According to the PRO, those transactions resulted in overcharges amounting to $11,810,639.84. The PRO further alleged that during the period from December 1979 through December 1980, the Respondents violated the provisions of 10 CFR § 212.131 by the miscertification of crude oil. According to the PRO, those transactions resulted in overcharges amounting to $12,554,371.74. The OHA in large part affirmed the findings of the PRO and issued a Remedial Order (RO) to the Respondents on February 16, 1989. *Bayport Refining Co.*, 18 DOE ¶ 83,007, (1989). The RO was upheld by the Federal Energy Regulatory Commission (FERC) on October 4, 1993. *Bayport Refining Company and Malcolm M. Turner*, 65 FERC ¶ 61,021 (1993). Turner appealed to the United States District Court for the Northern District of Texas on March 31, 1994.[1] In January 1995, the court entered an Agreed Judgment resolving the issues addressed by the RO against Turner. Pursuant to the Agreed Judgment, Turner agreed to pay to the DOE the sum of $65,000. Turner has fulfilled his financial obligation to the DOE. As of May 31, 1995, the Bayport Consent Order fund contained $65,000 in principal plus accrued interest.[2]

B. Revere Petroleum Corp.

During the period of Federal petroleum price controls, Revere was engaged in crude oil reselling.[3] The firm was therefore subject to regulations governing the pricing of crude oil set forth at 10 CFR Parts 205, 210, 211, and 212 of the Mandatory Petroleum Price and Allocation Regulations. As a result of an ERA investigation of Revere's compliance with the price and allocation regulations, the ERA issued a PRO to Revere on January 18, 1983. However, on August 9, 1983, that PRO was amended by the ERA to include additional violations of 10 CFR § 212.186, alternative violations of 10 CFR § 212.183, and five additional parties as co-respondents of the PRO.[4] On May 29, 1992, the OHA issued the Amended PRO, with modifications, as an RO. *Revere Petroleum Corp.*, 22 DOE ¶ 83,004 (1992). The RO found Revere liable for violations of 10 CFR § 212.186 in connection with its resales of crude oil during the period April 1979 through March 1980. Revere appealed to FERC (Case No;. R092–4–00). However, subsequently, this enforcement proceeding was settled when Revere and DOE entered into a settlement on an ability-to-pay basis in order to resolve DOE's claims against the firm. Revere agreed to pay the DOE the sum of $50,000.00, plus a percentage of the

[1] Bayport, which was dissolved in November 1982, did not appeal the RO. While the matter was referred for enforcement of the RO against Bayport, no funds were ever collected from the corporation.

[2] The funds submitted by Turner pursuant to the Agreed Judgment are deposited in the Bayport Consent Order fund, No. 6AOX00329.

[3] References to Revere in this Decision include Richard E. Dobyns, President of Revere, during the price control period.

[4] Those five individuals were James J. Cross, M. Kemp McMillan, Gordon K. Walz, and Milton E. Walz, who entered into a separate Consent Order with the DOE in December 1987, and John E. Woolsey, who entered into a separate Consent Order with the DOE in September 1986.

proceeds of Revere's asset liquidation. As of May 31, 1995, Revere and the other respondents have paid to the DOE the sum of $1,310,140.13 in satisfaction of their obligations.[5] Although additional revenues may be collected, no good reason exists to delay implementing distribution of the current balance of the fund.

C. Granite Petroleum Corporation

Granite engaged in the reselling and marketing of crude oil during the period of petroleum price controls. The firm was therefore subject to regulations governing the pricing and allocation of crude oil set forth at 10 CFR Parts 211 and 212 of the Mandatory Petroleum Price and Allocation Regulations. The ERA conducted a detailed audit to determine Granite's compliance with the federal petroleum price and allocation regulations during the period from September 1, 1979 through January 27, 1981. As a result of the audit, on March 4, 1983, the ERA issued a PRO to the firm alleging violations of the crude oil price and allocation regulations (Case No. 640X00447). In September 1983, Granite and the DOE entered into a Consent Order which resolved a number of outstanding enforcement issues involving Granite. Under the terms of the settlement, Granite agreed to pay $200,000 in installment payments to the DOE.[6] As of May 31, 1995, Granite has paid to the DOE the sum of $176,698.85. Granite is currently delinquent in its payments to the DOE. Although we anticipate that additional sums may be collected from Granite, no good reason exists to forestall distribution of the current balance of the fund.

D. Dalco Petroleum Corporation

Dalco[7] was a reseller of crude oil during the period of price controls and was subject to regulations governing the pricing and allocation of crude oil set forth at 10 CFR Parts 211 and 212 of the Mandatory Petroleum Price and Allocation Regulations. As the result of an ERA audit, the ERA issued a PRO to Dalco on April 30, 1982, alleging that between March 1976 and September 1978, Dalco violated the DOE mandatory petroleum price regulations which governed the resale of domestic crude oil, pursuant to 10 CFR §§ 212.93, 212.10, 212.131, 205.202, 210.62(c), and 212.185, resulting in the illegal receipt of revenues. After the issuance of the PRO, but before a Statement of Objections was filed, Dalco filed for bankruptcy.[8] In August 1983, the Bankruptcy Court for the Northern District of Oklahoma issued an injunction which stayed the enforcement proceeding against the respondents. The bankruptcy court ultimately approved and allowed the DOE's claims against Dalco and as of May 31, 1995, Dalco has paid $3,015,560.74 to the DOE. Although the possibility exists that additional revenues will be obtained by the DOE in the Dalco bankruptcy proceeding, no reason exists to delay in implementing distribution of the current balance of the funds.[9]

II. Jurisdiction and Authority

The Subpart V regulations set forth general guidelines which may be used by the OHA in formulating and implementing a plan of distribution of fund received as a result of an enforcement proceeding. The DOE policy is to use the Subpart V process to distribute such funds. For a more detailed discussion of Subpart V and the authority of the OHA to fashion procedures to distribute refunds, *see Petroleum Overcharge Distribution and Restitution Act of 1986*, 15 U.S.C. §§ 4501 et seq.; *see also Office of Enforcement*, 9 DOE ¶ 82,508 (1981), and *Office of Enforcement*, 8 DOE ¶ 82,597 (1981).

We have considered the OGC's petitions that we implement Subpart V proceedings with respect to the Turner, Revere, Granite and Dalco funds and have determined that such proceedings are appropriate. This Proposed Decision and Order sets forth the OHA's tentative plan to distribute these funds. Before taking the actions proposed in this Decision, we intend to publicize our proposal and solicit comments from interested parties. Comments regarding the tentative distribution process set forth in this Proposed Decision and Order should be filed with the OHA within 30 days of its publication in the Federal Register.

III. Proposed Refund Procedures

A. Crude Oil Refund Policy

We propose to distribute the monies remitted pursuant to the Turner, Revere, Granite, and Dalco enforcement proceedings in accordance with DOE's Modified Statement of Restitutionary Policy in Crude Oil Cases (MSRP), 51 FR 27899 (August 4, 1986), which was issued as a result of the Settlement Agreement approved by the court in *The Department of Energy Stripper Well Exemption Litigation*, 653 F. Supp. 108 (D. Kan. 1986). Shortly after the issuance of the MSRP, the OHA issued an Order that announced that this policy would be applied in all Subpart V proceedings involving alleged crude oil violations. Order Implementing the MSRP, 51 FR 29689 (August 20, 1986) (the August 1986 Order).

Under the MSRP, 40 percent of crude oil overcharge funds will be disbursed to the federal government, another 40 percent to the states, and up to 20 percent may initially be reserved for the payment of claims to injured parties. The MSRP also specified that any funds remaining after all valid claims by injured purchasers are paid will be disbursed to the federal government and the states in equal amounts.

In April 1987, the OHA issued a Notice analyzing the numerous comments received in response to the August 1986 Order. 52 FR 11737 (April 10, 1987) (April 10 Notice). This Notice provided guidance to claimants that anticipated filing refund applications for crude oil monies under the Subpart V regulations. In general, we stated that all claimants would be required to (1) document their purchase volumes of petroleum products during the August 19, 1973 through January 27, 1981 crude oil price control period, and (2) prove that they were injured by the alleged crude oil overcharges. Applicants who were end-users or ultimate consumers of petroleum products, whose businesses are unrelated to the petroleum industry, and who were not subject to the DOE price regulations would be presumed to have been injured by any alleged crude oil overcharges. In order to receive a refund, end-users would not need to submit any further evidence of injury beyond the volume of petroleum products purchased during the period of price controls. *See City of Columbus Georgia*, 16 DOE ¶ 85,550 (1987).

The amount of money subject to this Proposed Decision is $4,567,399.72, plus accrued interest. In accordance with the MSRP, we propose initially to reserve 20 percent of those funds ($913,479.94 plus accrued interest) for direct refunds to applicants who claim that they were injured by crude oil overcharges. We propose to base refunds to claimants on a volumetric amount which has been calculated in accordance with the description in the April 10 Notice. That volumetric refund amount is currently $0.0016 per gallon. *See* 60 FR 15562 (March 24, 1995).

Applicants who have executed and submitted a valid waiver pursuant to one of the escrows established by the Stripper Well Settlement Agreement have waived their rights to apply for a crude oil refund under Subpart V. *See Mid-America Dairyman Inc.* v. *Herrington*, 878 F.2d 1448, 3 Fed. Energy Guidelines ¶ 26,617 (Temp. Emer. Ct. App. 1989); *In re Department of Energy Stripper Well Exemption Litigation*, 707 F. Supp. 1267, 3 Fed. Energy Guidelines ¶ 26,613 (D. Kan. 1987). Because the June 30, 1995, deadline for crude oil refund applications has passed, we propose not to accept any new applications from purchasers of refined petroleum products for these funds. *See Western Asphalt Service, Inc.*, 25 DOE ¶ _____, LEF–0047 (July 17, 1995). Instead, these funds will be added to the general crude oil overcharge pool used for direct restitution.[10]

B. Payments to the States and Federal Government

Under the terms of the MSRP, the remaining 80 percent of the alleged crude oil violation amounts subject to this Proposed Decision, or $3,653,919.78 plus accrued interest, should be disbursed in equal shares to the states and federal government, for indirect restitution. Refunds to the states will be in proportion to the consumption of petroleum products in each state during the

[5] Revere and all of the named individuals except Woolsey have satisfied their obligations to the DOE. Although Woolsey has made substantial payments to the DOE, he is delinquent in his payments, and the possibility exists that additional funds will be paid by him.

[6] Granite Petroleum Corporation and John E. Woolsey, President of Granite, are collectively referred to as Granite in the text. Both were parties to the Consent Order.

[7] References to Dalco in this Decision include W. Darryl Zang and Louis Porter, the firm's owners.

[8] Zang, Porter and Dalco filed for bankruptcy on August 16, 1982, June 15, 1983, and July 20, 1983 respectively.

[9] Porter has satisfied his obligations to the DOE under the PRO. Additional funds may be collected from the Dalco and Zang estates.

[10] A crude oil refund application is only required to submit one application for its share of all available crude oil overcharge funds. *See, e.g., Ernest A. Allerkamp*, 17 DOE § 85,079 at 88,176 (1988).

period of price controls. The share of ratio of the funds which each state will receive is contained in Exhibit H of the Stripper Well Settlement Agreement. When disbursed, these funds will be subject to the same limitations and reporting requirements as all other crude oil monies received by the states under the Stripper Well Agreement.

It Is Therefore Ordered That

The refund amounts remitted to the Department of Energy by Malcolm M. Turner, Revere Petroleum Corporation, Granite Petroleum Corporation, and Dalco Petroleum Corporation pursuant to their respective settlement agreements or judgments will be distributed in accordance with the foregoing Decision.

[FR Doc. 95–23230 Filed 9–18–95; 8:45 am]

BILLING CODE 6450–01–P

Office of Fossil Energy

[FE Docket Nos. 95–60–NG, 95–61–NG]

Phibro Inc.; Order Granting Blanket Authorization To Import and Export Natural Gas, Including Liquefied Natural Gas, From and To Canada and Mexico

AGENCY: Office of Fossil Energy, DOE.

ACTION: Notice of order.

SUMMARY: The Office of Fossil Energy of the Department of Energy gives notice that it has issued an order granting Phibro Inc. (Phibro) authorization to import up to 200 billion cubic feet (Bcf) of Canadian natural gas, including liquefied natural gas (LNG) and to import up to 200 Bcf of Mexican natural gas. Phibro is also authorized to export up to 200 Bcf of natural gas to Canada and to export up to 200 Bcf of natural gas to Mexico. Phibro's authorization is for a two-year term beginning on the date of first delivery of imported natural gas or LNG, or exported natural gas.

This order is available for inspection and copying in the Office of Fuels Programs Docket Room, 3F–056, Forrestal Building, 1000 Independence Avenue SW., Washington, D.C. 20585, (202) 586–9478. The docket room is open between the hours of 8:00 a.m. and 4:30 p.m., Monday through Friday, except Federal holidays.

Issued in Washington, D.C., September 11, 1995.

Clifford P. Tomaszewski,

Director, Office of Natural Gas, Office of Fuels Programs, Office of Fossil Energy.

[FR Doc. 95–23232 Filed 9–18–95; 8:45 am]

BILLING CODE 6450–01–P

[FE Docket No. 95–59–NG]

Universal Resources Corporation; Order Granting Blanket Authorization to Export Natural Gas to Canada

AGENCY: Office of Fossil Energy, DOE.

ACTION: Notice of order.

SUMMARY: The Office of Fossil Energy of the Department of Energy gives notice that it has issued an order granting Universal Resources Corporation blanket authorization to export up to 50 Bcf of natural gas to Canada. This authorization is for a period of two years beginning on the date of the first delivery.

This order is available for inspection and copying in the Office of Fuels Programs Docket Room, 3F–056, Forrestal Building, 1000 Independence Avenue, S.W., Washington, D.C. 20585, (202) 586–9478. The docket room is open between the hours of 8:00 a.m. and 4:30 p.m., Monday through Friday, except Federal holidays.

Issued in Washington, D.C. on September 5, 1995.

Clifford P. Tomaszewski,

Director, Office of Natural Gas, Office of Fuels Programs, Office of Fossil Energy.

[FR Doc. 95–23233 Filed 9–18–95; 8:45 am]

BILLING CODE 6450–01–P

Western Area Power Administration

Pacific Northwest-Pacific Southwest Intertie Project Transmission Service, Phoenix Area

AGENCY: Western Area Power Administration, DOE.

ACTION: Notice of sale of additional capacity on the Pacific Northwest-Pacific Southwest Intertie Project.

SUMMARY: The Western Area Power Administration (Western) is requesting comments on the proposed sale of firm transmission service available as a result of the completion of construction of the Mead-Phoenix and Mead-Adelanto Transmission Projects which are a part of the Pacific Northwest-Pacific Southwest Intertie Project (AC Intertie).

DATE: Comments from all interested parties will be accepted until October 19, 1995.

FOR FURTHER INFORMATION CONTACT: Mr. J. Tyler Carlson, Area Manager, Phoenix Area Office, Western Area Power Administration, P.O. Box 6457, Phoenix, AZ 85005–6457, Telephone: (602) 352–2521, Facsimile: (602) 352–2630.

SUPPLEMENTARY INFORMATION:

Background

The Mead-Phoenix Project (MPP) is an electrical transmission system that consists of 256 miles of 500-kV alternating current, convertible to direct current, transmission line constructed from the Perkins Switchyard, located next to Westwing Substation, northwest of Phoenix, Arizona; through Mead Substation, located south of Boulder City, Nevada; and on to Marketplace Switching Station. Mead-Adelanto Project (MAP) is an electrical transmission system that consists of 202 miles of 500-kV AC transmission line from Marketplace Substation to Adelanto Switching Station in southern California. The 500-kV Marketplace Switching Station will be constructed adjacent to and interconnected with the existing McCullough Switching Station in southern Nevada. As part of the MPP, a 1300 megavolt-ampere (MVA), 500/230-kV transformer will be added to the Mead Substation. Western will have approximately 525 MW of capacity entitlement on this transformer.

Marketing Issues

Western is requesting comments on the proposed sale of additional capacity in the AC Intertie created by the completion and availability of MPP and MAP. The quantity of marketable capacity will be limited by Western's entitlement to the available capacity. The additional capacity on the AC Intertie is anticipated to be available as of January 1, 1996. Western's contracted firm transmission service will begin after the MPP and MAP are released for commercial service.

Marketing Criteria

Western will be marketing the capacity from MPP and MAP by line segments in each direction. The following priority method will be used in selecting allotees for this additional capacity and will be based on requests for usage of each line segment as follows:

1. Perkins to Mead, Mead to Marketplace or Marketplace to Adelanto
   (a) Both directions, same amount
   (b) Both directions, different amounts
   (c) one direction only
2. Perkins to Marketplace or Mead to Adelanto
   (a) Both directions, same amount
   (b) Both directions, different amounts
   (c) one direction only
3. Perkins to Adelanto
   (a) Both directions, same amount
   (b) Both directions, different amounts
   (c) one direction only.

Where the priority of requests will be in the following order: 1(a), 1(b), 1(c); 2(a), 2(b), 2(c); 3(a), 3(b), 3(c).

Where if any one path is oversubscribed, the allocations will be prorated.

Marketable Resource

Point of receipt	Point of delivery	Capacity
Perkins Switchyard.	Mead Substation.	412 MW.
Mead Substation.	Perkins Switchyard.	412 MW.
Mead Substation.	Marketplace Switching Station.	580 MW.
Marketplace Switching Station.	Mead Substation.	580 MW.
Marketplace Switching Station.	Adelanto Switching Station.	100 MW.
Adelanto Switching Station.	Marketplace Switching Station.	100 MW.

Selection Process

Based on the comments received on this proposal, Western will furnish the terms, conditions, and procedures governing the selection of allotees in the next Federal Register notice to be published by mid-October 1995. The mid-October Federal Register notice will also provide a mechanism for applications of requests for transmission capacity.

Applicant deadline and Western's schedule will also be published in the mid-October Federal Register notice.

Other Issues

The proposed rate for the additional capacity resulting from the completion of MPP and MAP will be set forth in a public rate process currently under way in the Phoenix Area Office. The proposed rate will be based on Western's expectation that the Marketable Capacity used in the proposed rate calculation for the 500-kV transmission lines will be 668 MW. A rate for firm transmission service will be determined in the public rate process.

Determination Under Executive Order 12866

DOE has determined that this is not a significant regulatory action because it does not meet the criteria of Executive Order 12866 (58 FR 51735). Western has an exemption from centralized regulatory review under Executive Order 12866; accordingly, no clearance of this notice by the Office of Management and Budget is required.

Environmental Evaluation

Western will comply with the National Environmental Policy Act (NEPA) of 1969, 42 U.S.C. 4321 *et seq.*; Council On Environmental Quality (40 CFR Parts 1500–1508) and DOE NEPA regulations (10 CFR Parts 1500–1508) and DOE NEPA regulations (10 CFR Part 1021). Western has determined that this action is categorically excluded from the preparation of an environmental assessment or an environmental impact statement.

Issued in Golden, Colorado, September 7, 1995.

J. M. Shafer,

Administrator

[FR Doc. 95–23231 Filed 9–18–95; 8:45 am]

BILLING CODE 6450–01–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL–5297–8]

Agency Information Collection Activities Under OMB Review

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.)*, this notice announces that the Information Collection Request (ICR) abstracted below has been forwarded to the Office of Management and Budget (OMB) for review and comment. The ICR describes the nature of the information collection and its expected cost and burden; where appropriate, it includes the actual data collection instrument.

DATES: Comments must be submitted on or before September 27, 1995.

FOR FURTHER INFORMATION CONTACT: For further information, or a copy of this ICR, contact Sandy Farmer at (202) 260–2740, please refer to EPA #ICR 1230.08.

SUPPLEMENTARY INFORMATION:

Office of Air and Radiation

Title: New Source Review and Prevention of Significant Deterioration Permitting Programs (EPA ICR #1230.08; OMB #2060–0003). This ICR requests an 18 month renewal of the existing clearance while the Agency revises the underlying regulations at 40 CFR parts 51 and 52.

Abstract: New and modified stationary sources must supply information on estimated emissions, proposed control technology, and air quality impact when applying for a preconstruction permit. EPA or the State or local air pollution control agency uses the information in the permit application to ensure that all regulatory requirements are being met and that the new emissions, in conjunction with existing source emissions in the same area, will not interfere with the attainment or maintenance of the national ambient air quality standards.

The average annual burden to respondents for this collection of information is approximately 5,000 hours per year. This includes time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

Respondents: Owers or operators of new or modified sources of air pollution.

Estimated Number of Respondents: 20,410.

Estimated Total Annual Burden on Respondents: 1,006,070 hours.

Frequency of Collection: On occasion.

Send comments regarding the burden estimate, or any other aspect of this information collection, including suggestions for reducing the burden, (please refer to EPA ICR #1230.08 and OMB #2060–0003) to:

Sandy Farmer, EPA ICR #1230.08, U.S. Environmental Protection Agency, Information Policy Branch (2136), 401 M Street, SW, Washington, DC 20460.

and

Chris Wolz, OMB #2060–0003, Office of Management and Budget, Office of Information and Regulatory Affairs, 725 17th Street, NW., Washington, D.C. 20503.

Dated: September 13, 1995.

Joseph Retzer,

Regulatory Information Division.

[FR Doc. 95–23206 Filed 9–18–95; 8:45 am]

BILLING CODE 6560–50–M

[FRL–5298–2]

Notice of Open Meeting of the Office of Water, Environmental Protection Agency on Alternative Financing Options for Water Infrastructure

The Office of Water of the Environmental Protection Agency (EPA) will hold an open meeting on alternative financing options for water infrastructure. The meeting is scheduled for October 10, 1995, in the Conference Center of the Region II Office of EPA located at 290 Broadway in New York City. The meeting will run from 10:00 am to 5:00 pm.

This meeting is the fourth in a series to collect public input on alternative financing options to help pay for

wastewater and drinking water infrastructure. The study is being prepared by the Environmental Finance Center at the Maxwell School of Citizenship and Public Affairs at Syracuse University at the direction of EPA's Office of Wastewater Management (OWM), in response to a congressional request for an evaluation of alternative financing options for water and wastewater projects in EPA's FY 95 appropriations legislation.

The first three meetings have focused primarily on options for a wide variety of fee systems. This meeting will consider other financing options that include encouraging increased investments by the private sector in public purpose water infrastructure, and examining ways to lower the costs of public borrowing for water infrastructure.

Following a discussion among invited panel members, interested parties who wish to speak at the meeting will be allowed to do so. These parties are encouraged to notify the Syracuse University Environmental Finance Center by calling Ms. Ronda Garlow at (315) 443–5612. There will also be a sign-in list for speakers at the meeting. Ten minutes will be available for each presentation. Written comments in advance are encouraged. Please send all written material to: Victoria Kennedy, Syracuse University, Environmental Finance Center, 219 Maxwell Hall, Syracuse, NY 13244–1090.

Dated: September 13, 1995.

Michael B. Cook,

Director, Office of Wastewater Management.

[FR Doc. 95–23203 Filed 9–18–95; 8:45 am]

BILLING CODE 6560–50–M

FEDERAL COMMUNICATIONS COMMISSION

Public Safety Wireless Advisory Committee; Procedures for Contacts

AGENCIES: The National Telecommunications and Information Administration (NTIA), Larry Irving, Assistant Secretary for Communications and Information, and the Federal Communications Commission (FCC), Reed E. Hundt, Chairman.

ACTION: Notice of Establishment of Procedures for Oral or Written Contacts with the Chairman of the Public Safety Wireless Advisory Committee (PSWAC) or with any of its members.

SUMMARY: The NTIA and the FCC have established a Public Safety Wireless Advisory Committee to prepare a final report to advise the NTIA and the FCC on operational, technical and spectrum requirements of federal, state and local Public Safety entities through the year 2010. The Federal Advisory Committee Act, Public Law 92–463, as amended, requires public notice of all meetings of the PSWAC. This is to assure full public participation in the discussion of all matters of substance before the PSWAC.

We wish to assure that all contacts regarding the merits or substance of any PSWAC consideration which occur outside the scope of formal meetings are a matter of record. Therefore, the PSWAC will require that any person or entity that makes an oral or written presentation to the Chairman of the PSWAC (Philip L. Verveer) or any of the members of the PSWAC (Louis J. Freeh, Ronald K. Noble, Alan D. Bersin, William Bratton, Michael Freeman, Steven Proctor, Dennis C. Connors, and Fred Kuznik) must provide a document which summarizes that presentation. In the case of an oral communication, the document must be a memorandum reflecting who initiated the contact, which PSWAC officials were involved, and the substance of the conversation. In the case of a written contact, the document must be a copy of the letter or pleading constituting the written contact. The document must be labelled WTB–1.

DATES: This requirement is effective immediately.

ADDRESSES: Documents provided to the PSWAC for the public file should be sent to: John J. Borkowski, Designated Federal Official, Public Safety Wireless Advisory Committee, Private Wireless Division, Wireless Telecommunications Bureau, Federal Communications Commission, Washington, D.C. 20554.

SUPPLEMENTARY INFORMATION: All submissions concerning such contacts will be available for public inspection in a file designated WTB–1 maintained in the Private Wireless Division of the Wireless Telecommunications Bureau, Federal Communications Commission, in Room 8010, 2025 M Street NW.

FOR FURTHER INFORMATION CONTACT:

William Donald Speights, NTIA (202–482–1652), or John J. Borkowski, FCC (202–418–0680), Co-Designated Federal Officials of the Public Safety Wireless Advisory Committee. You may also obtain more information about the PSWAC from the Internet at the Public Safety Wireless Advisory Committee homepage (http://pswac.ntia.doc.gov.).

Federal Communications Commission.

Robert H. McNamara,

Chief, Private Wireless Division, Wireless Telecommunications Bureau.

[FR Doc. 95–23169 Filed 9–18–95; 8:45 am]

BILLING CODE 6712–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Designation of Geographic Shortage Areas for Waiver of Two-Year Home-Country Physical Presence Requirement, International Medical Graduates, Exchange Visitor Program

AGENCY: Office of the Secretary, DHHS.

ACTION: Notice of availability of information about areas with shortages of health care professionals.

FOR FURTHER INFORMATION CONTACT: Dr. Evan R. Arrindell, Acting Director, Division of Shortage Designation, Bureau of Primary Health Care, 4350 East-West Highway, Room 9–1D–1, Bethesda, Maryland 20814, (301) 594–0816.

SUPPLEMENTARY INFORMATION: Section 220 of the Immigration and Nationality Technical Corrections Act of 1994 (Pub. L. 103–416) amended the Immigration and Nationality Act (''the Act'') (8 U.S.C. 1182(e)) to add a new subsection (k) to Section 214 of that Act (8 U.S.C. 1184) concerning waiver of the 2-year foreign residence requirement for international medical graduates (''IMGs''). IMGs who were admitted to the United States on a J–1 visa in the exchange visitor program, or who acquired this status after admission to the United States, are subject to a 2-year home country residence and physical presence requirement. This means that they must reside and be physically present in their country of nationality or last residence abroad for an aggregate of at least 2 years following departure from the United States prior to acquiring lawful permanent resident status, unless they have been granted a waiver of this requirement.

Under section 212(e) of the Act, a waiver of the 2-year requirement may be granted by the Immigration and Naturalization Service (''INS'') upon favorable recommendation of the Director of the United States Information Agency (USIA) on the basis of: (a) Exceptional hardship to the applicant's U.S. citizen or permanent resident spouse or children; (b) persecution on account of race, religion, or political opinion; (c) a ''no objection'' statement issued by the applicant's

''home'' country; or (d) a request made to USIA by an interested U.S. Government agency to recommend a waiver to USIA because the applicant's work is important to the public interest.

The Immigration and Nationality Technical Corrections Act provided an additional basis for waiver of the 2-year requirement. A State Department of Public Health or its equivalent can request the Director of USIA to recommend that INS grant up to 20 waivers a year. Conditions for these requests are that: (a) in the case of an alien who is otherwise contractually obligated to return to a foreign country, the government of that country provides USIA with a written statement that it has no objection to the waiver; (b) the IMG demonstrates that he or she has a bona fide offer of full-time employment and will begin this employment within 90 days of receipt of a waiver, for a period totaling not less than 3 years; (c) the employment is in an area designated by the Secretary of Health and Human Services as having a shortage of health care professionals. Both INS and USIA have published in the Federal Register interim-final regulations, with requests for comments, setting forth procedures and requirements for obtaining State-requested waiver requests. 60 F.R. 26676 (May 18, 1995) and 60 F.R. 16785 (April 3, 1995).

Section 214(k)(1) of the Act (8 U.S.C. 1184) authorizes the Secretary of HHS to designate ''geographic area or areas * * * as having a shortage of health care professionals'' for purposes of the State-requested waiver. Notice is hereby given that both Health Professional Shortage Areas (''HPSAS'') and Medically Underserved Areas/Medically Underserved Populations (''MUAs/MUPs''), determined under Sections 332 and 330 of the Public Health Service Act, respectively, (42 U.S.C. 254e and 254c) are designated by the Secretary of HHS for purposes of 2-year home residency waiver requests by States under Section 214(k)(1) of the Act. HPSAs can be geographic areas, population groups, and health care facilities meeting regulatory criteria set forth at 42 CFR Part 5. Only physicians specialized in *primary care* (family practice, general internal medicine, pediatrics, and obstetrics and gynecology) are considered for physician shortage areas.

MUAs/MUPs are shortage areas and population groups designated pursuant to criteria set forth at 42 CFR § 51c.102(e) based on weighted values related to primary care physician ratios, infant mortality rates, the percentage of the population age 65 and over, and the percentage of the population below the poverty level. Whole counties and groups of contiguous counties can be designated.

The Bureau of Primary Health Care, Health Resources Services Administration publishes periodically a list of HPSAs in the Federal Register. The latest list was published on January 21, 1994 (59 F.R. 3412). This office also issues a list of MUAs/MUPs. Persons interested in obtaining this list or other information concerning HPSAs and MUAs/MUPs should contact: Dr. Evan R. Arrindell, Acting Director, Division of Shortage Designation, Bureau of Primary Health Care, 4350 East-West Highway, Room 9–1D–1 Bethesda, Maryland 20814 (phone: (301) 594–0816).

Dated: September 1, 1995.

Donna E. Shalala,

Secretary.

[FR Doc. 95–23199 Filed 9–18–95; 8:45 am]

BILLING CODE 4160–15–M

Food and Drug Administration

[Docket No. 93N–0293]

Guide to Food Labeling Regulations Implementing the Nutrition Labeling and Education Act of 1990; Questions and Answers; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a document entitled ''Food Labeling, Questions and Answers Volume II; A Guide for Restaurants and Other Retail Establishments'' that addresses various questions concerning the regulations that FDA issued to implement the Nutrition Labeling and Education Act of 1990 (the 1990 amendments). The agency has received a large number of inquiries about how these final rules are being implemented in restaurants and other retail establishments, and it has prepared ''Food Labeling, Questions and Answers Volume II; A Guide for Restaurants and Other Retail Establishments'' to respond generally to many of the questions that it has received. Answers to some of the most frequently asked questions are included as an appendix to this notice. This document is intended to facilitate compliance with the new rules.

DATES: Written comments may be submitted at anytime.

ADDRESSES: Copies of the document ''Food Labeling, Questions and Answers Volume II; A Guide for Restaurants and Other Retail Establishments'' will be available from the Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402, 202–512–1800. Please request order No. 017–012–00374–5. Submit written comments on ''Food Labeling, Questions and Answers Volume II; A Guide for Restaurants and Other Retail Establishments'' to the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857. Comments should be identified with the docket number found in brackets in the heading of this document. ''Food Labeling, Questions and Answers Volume II; A Guide for Restaurants and Other Retail Establishments'' and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

FOR FURTHER INFORMATION CONTACT: Michelle A. Smith, Center for Food Safety and Applied Nutrition (HFS–158), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–205–5099.

SUPPLEMENTARY INFORMATION: FDA has received a number of inquiries from industry, consumers, and others concerning how the regulations it has adopted, implementing the Nutrition Labeling and Education Act of 1990 (the 1990 amendments) apply to retail Food establishments, including restaurants. FDA has prepared a document entitled ''Food Labeling, Questions and Answers Volume II; A Guide for Restaurants and Other Retail Establishments'' to serve as general guidance on the regulations. This document provides answers to many of the questions that the agency has received. Answers to some of the most frequently asked questions are included as an appendix to this notice.

''Food Labeling, Questions and Answers Volume II; A Guide for Restaurants and Other Retail Establishments'' is intended only to be guidance to facilitate compliance with the regulations. It does not bind the agency, nor does it create or confer any rights, privileges, or benefits for or on any person. While ''Food Labeling, Questions and Answers Volume II; A Guide for Restaurants and Other Retail Establishments'' represents the best advice of FDA, it does not have the force and effect of law. The interpretations presented herein are obviously subject to the requirements of law both in the statute and in the regulations.

Interested persons may, submit written comments on ''Food Labeling, Questions and Answers Volume II; A Guide for Restaurants and Other Retail

Establishments'' to the Dockets Management Branch (address above). FDA will consider these comments in determining whether revisions to the document are warranted. Two copies of any comments should 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. The document and received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Appendix—Food Labeling: Questions and Answers, Volume II; A Guide for Restaurants and Other Retail Establishments— Sample Questions

The Guide presents answers to a range of questions, including questions about the application of exemptions and other special labeling provisions in restaurants, about the format for nutrition labeling when it is required, and about other issues concerning the nutrition labeling of retail foods. The Guide also responds to questions about the use of nutrient content claims and health claims on restaurant and other retail foods. It explains how to determine whether there is a reasonable basis for a claim, what foods to use as reference foods, and how to determine reference amounts.

Sample Questions

Question: How does FDA define ''restaurants''?

Answer: ''Restaurants'' include conventional full service restaurants and other establishments where food is sold for immediate, on-site consumption (e.g., institutional food service, delicatessens, and catering where there are facilities for immediate consumption on the premises) and establishments where foods are generally consumed immediately where purchased or while walking away (e.g., lunch wagons, cookie counters in a mall, and vending machines including similar foods sold from convenience stores); and food delivery systems or establishments where ready-to-eat foods are delivered to homes or offices for immediate consumption.

Question: If a restaurant makes a claim for one item, does it need to provide nutrition information for all the foods it serves?

Answer: No. The exemptions from nutrition labeling set out in §§ 101.9(j)(2)(i) through (iii) apply to individual food items that are served or sold in a restaurant or similar establishment, not to the establishment. A restaurant need only provide nutrition information for those items that bear a claim. The restaurant may voluntarily provide nutrition information for foods that do not bear a claim.

It should be noted that the January 6, 1993, final regulations implementing the NLEA currently apply to all forms of restaurant labeling *except for menus.* Thus, a claim on a menu does not trigger FDA's nutrition labeling or claims requirements. However, States are not prohibited from enforcing these requirements with respect to menus. Furthermore, in the Federal Register of June 15, 1993 (58 FR 33055), FDA published a proposal to remove the exemption for claims on menus. Should the agency publish a final regulation deleting the menu exemption, the requirements discussed herein for non-menu labeling (e.g., signs, posters, placards, brochures, banners, etc.) will apply to all forms of labeling, including menus.

Question: A restaurant serves a food that is commercially manufactured and packaged and labeled. The food is served to consumers in the form it was purchased by the restaurant, e.g., individual serving size packages of condiments are placed in a bowl for consumer use. Would FDA hold the restaurant that serves the food responsible if the label of the food does not meet FDA's requirements, for example, if a package of salad dressing bears a ''lowfat'' claim but fails to bear nutrition information?

Answer: FDA requires that the label of a food sold in packaged form identify conspicuously the name and place of business of the manufacturer, packer, or distributor (§ 101.5). The firm that is so identified is generally the firm that is responsible for insuring that the food is properly labeled.

Question: Does a restaurant have to use the Nutrition Facts format to provide nutrition information for a food that bears a claim?

Answer: No. FDA is not requiring full nutrition labeling for restaurant foods, nor is it requiring that nutrition information be presented in the Nutrition Facts format. Because restaurant foods tend to be prepared or sold differently from foods from other sources, FDA is providing flexibility for restaurants in how they determine the nutrient content of a food (e.g., using a cookbook, reliable nutrient data base, or other reasonable bases) and in how this information may be presented to consumers. Information on the nutrient amounts that are the basis for the claim (e.g., ''low fat, this meal provides less than 10 grams of fat'') may serve as the functional equivalent of complete nutrition labeling (§ 101.10).

Question: Does nutrition information have to appear on the same labeling that bears the claim?

Answer: No. Nutrition information for restaurant foods may appear on the same or different labeling from that which bears the claim. Nutrition information may be presented in various forms, including those specified in § 101.9 (Nutrition Facts), § 101.45 (e.g., displayed at point of purchase by an appropriate means, such as affixing it to the food, by posting a sign, or by making the information readily available in a brochure, notebook, or leaflet, in close proximity to the foods), and by other reasonable means, such as orally by waiters or waitresses. (The agency notes, however, that to ensure that the information is presented accurately by waitpersons the nutrition information should also be maintained in written form by the restaurant management.)

Question: When making a claim for a food, does a restaurateur have to have the food that bears the claim analyzed by a lab to determine its nutrient content?

Answer: No. A restaurant food may bear a nutrient content claim or health claim if the restaurateur has a ''reasonable basis'' for believing that the food meets the definition for the claim. If a restaurateur labels a food ''low fat,'' for example, he or she must have a reasonable basis for believing that the food complies with FDA's definition for ''low fat,'' i.e., that it contains no more than 3 g of fat per reference amount customarily consumed or, in the case of meals and main dishes, no more than 3 g of fat per 100 g.

Question: Will FDA require prior approval for labeling that bears a claim?

Answer: No. FDA does not have the authority to require prior approval of restaurant labeling that bears a nutrient content claim, health claim, or other nutrition information.

Question: Will restaurants be required to have claim bearing foods ''certified'' by a third party or an independent dietary professional?

Answer: No. FDA has provided broad flexibility in establishing the ''reasonable basis'' criterion for restaurant foods. Thus, while some restaurateurs may choose to work with a third party to modify recipes or revise labeling, there is no requirement to do so. Restaurants should be able to make their own determinations once they are familiar with the claims requirements.

Question: Many food service items are partially or wholly processed when they are purchased for use in a restaurant or similar establishment. Thus, it is difficult for the restaurant to keep track of the sodium content of foods. It may also be difficult for a restaurant to monitor the use of sodium in the cooking process and to develop recipes for ''low sodium'' foods that taste good. How will these problems be addressed in implementing the new requirements?

Answer: FDA does not intend to impose an unrealistic regime (e.g., to require exacting measurements or strict portion controls) in restaurants. However, the agency is requiring that a restaurant have a reasonable basis for believing that a food meets the nutrient requirements for a claim, and that it be able to provide reasonable assurance that the preparation of the food adheres to the basis for the claim. If a restaurateur has no knowledge of, or control over, the sodium content of a food, or some other aspect of its nutrient content, he/she should not attempt to make a sodium content or other claim about the nutrient levels in that food.

Question: What is a ''reference amount''? Do restaurants need to alter their serving size to be equal to the reference amount?

Answer: The reference amount or reference amount customarily consumed (RACC) is the amount of a food item customarily consumed per eating occasion as determined by FDA for the purpose of establishing realistic and consistent serving sizes for use in food labeling. Reference amounts for 139 different food categories are set out in 21 CFR 101.12. (Reference amounts for meat and poultry products are listed in 9 CFR 317.312.)

Restaurants do not need to alter the size of the portions they serve to be the same as the reference amount, nor does the serving size used in the labeling for a particular food need to be the same as the reference amount. However, in order to make certain nutrient content claims or health claims, an

individual food must meet the definition for the claim based on the amount of the subject nutrient in an amount of the food equal to its reference amount, e.g., a ''low fat'' food may contain up to 3 grams of fat per reference amount. When a food's reference amount is small (i.e., 30 g or less or 2 tablespoons or less), the food (e.g., a sauce or condiment) must also meet the requirements for the claim based on its nutrient content per 50 grams.

Question: Must a restaurant develop recipes for, analyze, and market, a reference food for every food that bears a relative claim?

Answer: No. The reference food may be the restaurant's regular product, or that of another restaurant, that has been offered for sale to the public on a regular basis for a substantial period of time. Nutrient values for a reference food may also be derived from such sources as a valid data base, an average of top national or regional brands, or a market basket norm (§ 101.13(j)(1)(ii)).

Dated: September 14, 1995

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 95–23242 Filed 9–18–95; 8:45 am]

BILLING CODE 4160–01–F

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 60 FR 30092, June 7, 1995) is amended to reflect the reorganization of the Office of the Director, National Institute of Allergy and Infectious Diseases (OD/NIAID). The reorganization consists of the following: (1) Retitle the Office of Financial Management (HNM12) to the Office of Financial Management and Technology Transfer (HNM12) and revise the functional statement; and (2) retitle the Office of Policy Analysis and Technology Transfer (HNM16) to the Office of Policy Analysis (HNM16) and revise the functional statement. This reorganization will enable the NIAID to better fulfill its mission by restructuring the OD/NIAID to better integrate related program areas and streamline operations.

Section HN–B, Organization and Functions is amended as follows:

(1) Under the heading *Office of Financial Management (HNM12),* delete the title and functional statement in their entirety and substitute the following:

Office of Financial Management and Technology Transfer (HNM12). (1) Is the principal organization that provides advice to the NIAID Director, Deputy Director, and senior staff on all financial management and technology transfer issues affecting the NIAID; (2) has functional responsibilities in financial management and technology transfer, and (3) is intricately involved in (a) program planning, (b) budget preparation and execution, (c) developing position papers for the NIAID Director and other senior staff, (d) managing NIAID's extensive technology transfer program, and (e) accelerating the transfer of NIAID technology to the private sector.

(2) Under the heading *Office of Policy Analysis and Technology Transfer (HNM16),* delete the title and functional statement in their entirety and substitute the following:

Office of Policy Analysis (HNM16). (1) Serves as principal advisor to the Institute Director, Deputy Director, and Division Directors regarding the planning, evaluation, and program, policy, and legislative analytical needs of the Institute; (2) provides support and serves as liaison to program managers in coordinating, integrating, and articulating long-range program goals and strategies; (3) is responsible for the development and coordination of the Institute's annual Planning and Reporting process; (4) maintains a continuing liaison with program planning, evaluation, and legislation counterparts in other ICDs in the OD/NIH; (5) advises Institute Task Forces to assure that the charge and work of the Task Forces are directed toward the projected planning and evaluation needs of the Institute; (6) conducts the intra-institute program assignments of all research, training, career and fellowship grant applications; (7) analyzes, interprets, and classifies the scientific content of research grants, contracts, and intramural research projects, and manages the scientific information data and coding of the Multi-Axis Coding System (MACS); (8) directs and coordinates all program evaluation activities, assessing the impact and focus of programs which are of major concern to the Institute; (9) advises on material for all stages related to Congressional budget presentations; (10) designs, develops and maintains the computer-based scientific and fiscal data collection, storage, and retrieval system for the Institute's contracts, grants, intramural research projects, fellowships and training awards; (11) directs and coordinates the legislative liaison, legislative tracking and analysis for the Institute; (12) manages the Executive Secretariat (controlled correspondence) functions for the Institute; and (13) serves as the focus for communications for trans-NIH concerns.

Dated: August 9, 1995.

Harold Varmus,

Director, NIH.

[FR Doc. 95–23135 Filed 9–18–95; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[NV–060–1990–01]

Notice of Availability for the Round Mountain Mill and Tailings Facility Draft Environmental Impact Statement and Notice of Comment Period and Public Meetings

AGENCY: Bureau of Land Management, Department of the Interior.

ACTION: Notice of availability for the Round Mountain Mill and Tailings Facility Draft Environmental Impact Statement (EIS), for the Smoky Valley Common Operation, Nye County, Nevada; and notice of comment period and public meetings.

SUMMARY: Pursuant to section 102(2)(C) of the National Environmental Policy Act, 40 CFR 1500–1508, and 43 CFR 3809, notice is given that the Bureau of Land Management (BLM) has prepared, with the assistance of a third-party consultant, a Draft EIS on the proposed Round Mountain Mill and Tailings Facility, and has made copies available for public and agency review.

DATES: Written comments on the Draft EIS must be submitted or postmarked to the BLM no later than November 22, 1995. Oral and/or written comments may also be presented at two public meetings, to be held:

October 17, 1995; 7 p.m.; Donald Simpson Community Center, Hadley, Nevada

October 18, 1995; 7 p.m.; Airport Plaza Hotel, 1981 Terminal Way, Reno, Nevada

ADDRESSES: Written comments on the Draft EIS should be addressed to: Bureau of Land Management, Battle Mountain District, Post Office Box 1420, Battle Mountain, Nevada 89820, Attn.: Christopher J. Stubbs, Round Mountain EIS Project Manager. A limited number of copies of the Draft EIS may be obtained at the same address. In addition, the Draft EIS and supporting documentation are available for review at the following locations: BLM, Battle Mountain District Office, Battle Mountain, Nevada; BLM, Nevada State Office, Reno, Nevada; and the Getchell Library, University of Nevada, Reno, Nevada.

FOR FURTHER INFORMATION CONTACT: Christopher J. Stubbs, Round Mountain EIS Project Manager, Bureau of Land Management, Post Office Box 1420, Battle Mountain, Nevada 89820, (702) 635–4000.

SUPPLEMENTARY INFORMATION: The Smoky Valley Common Operation has submitted a Plan of Operations Amendment for the construction, operation, and reclamation of a mill and tailings facility at the Round Mountain Mine. The mine currently consists of 4,767 acres of surface disturbance: 3,659 acres of land administered by the BLM, 515 acres of land administered by the Toiyabe National Forest, and 593 acres of patented land owned by the Smoky Valley Common Operation. The proposed facilities would comprise an expansion of the existing operation at the Round Mountain Mine to improve the recovery of gold from ore that is being mined from the existing open pit. Ancillary facilities would include a new primary crusher; a power line; fresh water, reclaim water, and tailings pipelines; and a septic system. The proposed facilities would be located on approximately 757 acres of public land administered by the BLM, Battle Mountain District Office, Tonopah Resource Area. Of this acreage, approximately 250 acres occur on public lands outside of the existing permit boundary. Construction is scheduled to begin in early 1996; operation of the mill and tailings facility would begin in 1997 and continue until 2008.

This Draft EIS analyzes the environmental impacts associated with the proposed mill and tailings facility and ancillary facilities, a range management alternative, an alternative tailings impoundment site, and the no action alternative. In addition, the Draft EIS analyzes potential impacts associated with pit dewatering and pit water quality, and the leach offload piles. Issues analyzed in the Draft EIS include geology and minerals, water resources, soils and watershed, vegetation, wildlife and fisheries, range resources, paleontological resources, cultural resources and Native American concerns, air quality, access and land use, recreation and wilderness, social and economic values, visual resources, noise, and hazardous materials.

A copy of the Draft EIS has been sent to all individuals, agencies, and groups who have expressed interest in the project or as mandated by regulation or policy. A limited number of copies are available upon request from the BLM at the address listed above.

Public participation has occurred during the EIS process. A Notice of Intent was filed in the Federal Register in August 1993, and an open scoping period was held for 120 days. Two public scoping meetings to solicit comments and ideas were held in November 1993, and a newsletter was issued to keep the public informed of the progress of the EIS. All comments presented to the BLM throughout the EIS process have been considered.

To assist the BLM in identifying and considering issues and concerns on the proposed action and alternatives, comments on the Draft EIS should be as specific as possible. It is also helpful if comments refer to specific pages or chapters in the document. Comments may address the adequacy of the Draft EIS and/or the merits of the alternatives formulated and discussed in the document. Reviewers may wish to refer to the Council on Environmental Quality Regulations for Implementing the Procedural Provisions of the National Environmental Policy Act at 40 CFR 1503.3 in addressing these points. After the comment period ends on the Draft EIS, comments will be analyzed and considered by the BLM in preparing the Final EIS.

Dated: September 12, 1995.

Jeffrey A. Weeks,

Acting District Manager.

[FR Doc. 95–23129 Filed 9–18–95; 8:45 am]

BILLING CODE 4310–HC–P

[WY–981–1640–00–370F; WYW129948]

Notice of Realty Action: Modified Competitive Bidding Sale of Public Lands in Washakie County, WY

AGENCY: Bureau of Land Management, Interior.

SUMMARY: The Bureau of Land Management (BLM) has determined that the public lands described below are suitable for disposal under sections 203 and 209 of the Federal Land Policy and Management Act of 1976 (FLPMA) (43 U.S.C. 1713, 1719).

Sixth Principal Meridian

T. 47 N. R. 92 W.

Sec. 23, W½NE¼SW¼, NW¼SE¼SW¼.

The land aggregates 30 acres more or less.

The BLM must receive fair market value for the land and any bid for less than fair market value will be rejected. The appraised value for the 30 acres is $45,000. The BLM may accept or reject any and all offers, or withdraw any land or interest in the land for sale if the sale would not be consistent with FLPMA or other applicable law.

DATES: All bids must be received in the Bighorn Basin Resource Area Office no later than 10:00 a.m., November 15, 1995.

ADDRESSES: Sealed bids may be handcarried to the Bighorn Basin Resource Area Office, 101 South 23rd Street, Worland, Wyoming, or mailed to the Bighorn Basin Resource Area Office, P.O. Box 119, Worland, Wyoming 82401–0119. The sealed bid envelope must be marked in the front lower-left corner with the words ''Public Land Sale, WYW129948, Sale held November 15, 1995. Sealed Bid—Do Not Open in Mail Room.''

FOR FURTHER INFORMATION CONTACT: Detailed information concerning the sale is available for review at the BLM office in Worland. For further information contact Karen Hepp, Range Management Specialist or Charles F. Wilkie, Area Manager, Bighorn Basin Resource Area, Bureau of Land Management, P.O. Box 119, Worland, Wyoming 82401–0119, (307)347–9871.

SUPPLEMENTARY INFORMATION: A bid will also constitute an application for conveyance of the unreserved mineral estate, excluding oil and gas resources. The mineral interests being offered have no known value. At the time of the sale, the bidder will be required to pay a $50 filing fee (in addition to their bid) for all unreserved mineral interests.

Sale of the above land will be conducted by modified competitive bidding. Timberline Feedlot Inc. will be allowed preference consideration to meet the high bid. The proposed sale is consistent with the Washakie Resource Management Plan and meets the sale criteria of 43 CFR 2710.0–3(a)(2). Disposal of this tract will serve to increase the economic development of the Worland area through the expansion of Timberline's feedlot.

All bidders must be United States citizens, 18 years of age or older, corporations subject to laws in the state of Wyoming, a state, state instrumentality or political subdivision authorized to hold property, or an entity legally capable of conveying and holding land or interests in land in Wyoming.

All sealed bids must be accompanied by a payment of not less than ten (10) percent of the total bid, plus a $50 filing fee for all unreserved mineral interests. Each bid must be accompanied by a certified check, postal money order, bank draft, or cashier's check made payable to the Bureau of Land Management.

The apparent high bidder and the designated bidder (Timberline Feedlot Inc.) will be notified immediately

following the opening of the sealed bids on November 15, 1995. If the designated bidder (Timberline Feedlot Inc.) fails to exercise their preference consideration to meet the highest bid within 30 days of the sale, the BLM will offer the lands to the high bidder. If the apparent high bidder is disqualified, the next highest qualified bid will be accepted. If Timberline Feedlot Inc. chooses not to meet the high bid and two (2) or more envelopes containing valid bids of the same amount are received, supplemental sealed bidding will be used to determine the high bid.

The successful bidder shall submit the remainder of the full bid price prior to the expiration of 180 days from the date of the sale. Failure to pay the remainder of the full bid price shall result in cancellation of the sale and the deposit shall be forfeited and disposed of as other receipts of the sale. Conveyance of the public land will except and reserve to the United States:

1. A right-of-way (ROW) thereon for ditches and canals constructed by the authority of the United States. Act of August 30, 1890 (43 U.S.C. 945).

2. All the oil and gas in the land so patented, and to it, or persons authorized by it, the right to prospect for, mine and remove such deposits from the same upon compliance with the conditions and subject to the provisions and limitations of the Act of July 17, 1914, as supplemented (30 U.S.C. 121–124).

Conveyance of the public land will also be subject to:

1. Oil and Gas Pipeline ROW WYW75340.
2. Road ROW WYW81772.
3. Federal Aid Highway ROW WYW0189320.
4. Power Transmission Line ROW WYW72986.
5. Surface Water Flowline ROW WYW75336.
6. Telephone/Telegraph ROW WYW68159.
7. Gas Pipeline and Road ROW WYW94115.
8. Telephone Line ROW WYW89760.

Publication of this notice in the Federal Register shall segregate the land from all forms of appropriation under the public land laws, including the general mining laws. The segregative effect will terminate upon issuance of the patent, 270 days from the date of the publication of this notice, or upon publication in the Federal Register of a notice of termination of segregation, whichever occurs first.

For a period of forty-five (45) days from the date of publication of this notice in the Federal Register, interested parties may submit comments to the District Manager, Worland District Office, Bureau of Land Management, P.O. Box 119, Worland, Wyoming 82401–0119. Any adverse comments will be evaluated by the State Director, who may sustain, vacate, or modify this realty action. In the absence of any action by the State Director, this realty action will become final.

Dated: September 8, 1995.

David Atkins,

Acting District Manager Worland, Wyoming.

[FR Doc. 95–23188 Filed 9–18–95; 8:45 am]

BILLING CODE 4310–22–P

Bureau of Reclamation

Central Valley Project Improvement Act, Review of Criteria for Evaluating Water Conservation Plans

SUMMARY: Section 3405(e) of the Central Valley Project Improvement Act (CVPIA) Title 34 of Public Law 102–575, requires Reclamation to develop criteria to evaluate water conservation plans for Central Valley Project contractors and to evaluate all the plans by that criteria, including plans required by Section 210 of the Reclamation Reform Act. The Act also requires Reclamation to review the criteria periodically, ''but no less than every three years.'' Reclamation finalized the Criteria for Evaluating Water Conservation Plans (Criteria) in April 1993. The Criteria must now be reviewed and revised, if necessary.

EFFECTIVE DATE: Comments should be provided to Reclamation by November 17, 1995.

ADDRESSES: Written comments should be mailed to the Bureau of Reclamation, Attention: Betsy Reifsnider, 2800 Cottage Way, MP–402, Sacramento, CA 95825.

FOR FURTHER INFORMATION CONTACT: Copies of the Criteria may be obtained by writing the Bureau of Reclamation, Attention: Betsy Reifsnider, 2800 Cottage Way, MP–402, Sacramento, CA 95825; or by calling Betsy at (916) 979–2388.

SUPPLEMENTARY INFORMATION: After considerable public input, Reclamation finalized the initial Criteria for Evaluating Water Conservation Plans (Criteria) in April 1993, and immediately began evaluating plans accordingly. As required by Section 3405(e), the Criteria must now be reviewed and updated if necessary to further promote the highest level of water use efficiency reasonably achievable by project contractors using best available cost-effective technology and best management practices.

As the first step in this review, Reclamation requests public comments on the contents of the April 1993 Criteria. The public is asked to note any problems with the existing Criteria, recommend any modifications which they believe Reclamation should make to the Criteria, and suggest new technology which has been shown to be cost effective in promoting water use efficiency.

Following review of the public comments received, Reclamation will consider whether to make changes to the existing Criteria. If changes are proposed, they will first be released as a draft for public review and comment. At that time, a series of public workshops will be held. Thereafter, changes will be finalized and revised Criteria issued by April 1996.

Dated: September 11, 1995.

Dan M. Fults,

Assistant Regional Director.

[FR Doc. 95–23197 Filed 9–18–95; 8:45 am]

BILLING CODE 4310–94–M

National Park Service

Pecos National Historical Park, Draft General Management Plan/ Development Concept Plan/ Environmental Impact Statement

AGENCY: National Park Service, Interior.

ACTION: Notice of availability of the Draft General Management Plan/ Development Concept Plan/ Environmental Impact Statement for Pecos National Historical Park, Santa Fe and San Miguel Counties, New Mexico.

SUMMARY: Pursuant to section 102(2)(c) of the National Environmental Policy Act of 1969, the National Park Service announces the availability of the Draft General Management Plan/Development Concept Plan/Environmental Impact Statement (GMP/DCP/EIS) for Pecos National Historical Park. This notice also announces public meetings for the purpose of receiving public comments on the Draft GMP/DCP/EIS.

On June 27, 1990, Congress repealed the act to establish Pecos National Monument and authorized the establishment of Pecos National Historical Park to include the former Pecos National Monument and 5,500 acres of the Forked Lightning Ranch. On November 8, 1990, Congress expanded Pecos National Historical Park to include the 682 acre Glorieta unit. The purpose of this Draft GMP/DCP/EIS is to set forth the basic management philosophy of the park and the overall approaches to resource management, visitor use, and facility development

that would be implemented over the next 10–15 years.

This Draft GMP/DCP/EIS describes and analyzes alternatives for the Pecos and Glorieta units of Pecos National Historical Park. Proposed action and no-action alternatives have been developed for each unit. In addition to the proposed action and no-action alternatives, two additional action alternatives have been developed for the Pecos unit; and one additional action alternative has been identified for the Glorieta unit. These alternatives propose future management and use options for the newly established Pecos National Historical Park. Under Pecos Unit Alternative A (no action), present use and management would continue. The primary interpretive focus would continue to be at the Pecos Pueblo/mission ruins complex, and no new visitor facilities would be developed. Under Pecos Unit Alternative B (the proposed action), two visitor staging areas would be developed—the Fogelson visitor center area and Kozlowski's Stage Stop. New visitor facilities would include trails and trailheads and interpretive exhibits. Under Pecos Unit Alternative C, three visitor staging areas would be developed—the Fogelson visitor center, Kozlowski's Stage Stop, and the Gateway overlook. Staging areas and associated facilities would have easy vehicle access. Under Pecos Unit Alternative D, visitors would enter the park from the south; and a new visitor center would be developed at the Gateway overlook area. Other visitor facilities would continue to be provided at Kozlowski's Stage Stop and the Fogelson visitor center. Under Glorieta Unit Alternative 1 (no-action), no new facilities would be provided. Glorieta Unit Alternative 2 (proposed action) would incorporate a staffed visitor contact facility and interpretive trails and exhibits at Pigeon's Ranch and an exterior interpretive exhibit at a pulloff overlooking Cañoncito. Glorieta Unit Alternative 3 would incorporate the same facilities as Alternative 2; however, the staffed contact station would be at a different location. The major impact topics assessed for the proposals and the alternatives are cultural and natural resources and the socioeconomic environment, including the local economy and National Park Service operations.

This Draft GMP/DCP/EIS was prepared in order to evaluate a range of alternatives and an assessment of impacts of these alternatives and to provide the public with an opportunity to comment. This document will be on public review for 60 days. The park would appreciate any comments on these alternatives or other ways to manage the park over the next 15 years.

DATES: Comments on the Draft GMP/DCP/EIS should be received no later than November 17, 1995. The dates and times for public meetings regarding the draft GMP/DCP/EIS can be obtained by contacting Pecos National Historical Park at 505–757–6414.

ADDRESSES: Comments on the Draft GMP/DCP/EIS should be submitted to Superintendent, Pecos National Historical Park, Post Office Drawer 418, Pecos, New Mexico 87552, telephone 505–757–6414.

SUPPLEMENTARY INFORMATION: Public reading copies of the Draft GMP/DCP/EIS will be available for review at the following locations: Office of Public Affairs, National Park Service, 1849 C Street, NW, Washington, D.C.; Department of the Interior Natural Resource Library, 1849 C Street, NW, Washington, D.C.; National Park Service, Southwest System Support Office, 1100 Old Santa Fe Trail, Santa Fe, New Mexico; Santa Fe Public Library Reference Desk, 145 Washington Avenue, Santa Fe, New Mexico; Pecos National Historical Park, Administrative Office, 2 miles south of Pecos, New Mexico on State Highway 63; and local public libraries. You may call the park at 505–757–6032 to arrange for a tour through October 15, 1995.

Dated: September 8, 1995.

Ernest W. Ortega,

Associate Regional Director.

[FR Doc. 95–23002 Filed 9–18–95; 8:45 am]

BILLING CODE 4310–70–M

Saint Croix Island International Historic Site Draft General Management Plan/Environmental Impact Statement; Intent

SUMMARY: This notice is to advise the public that the National Park Service is preparing a Draft General Management Plan (GMP)/Environmental Impact Statement (DEIS) for Saint Croix Island International Historic Site, Calais, Maine. The formal 30-day public scoping period for such effort begins October 1 and closes October 31, 1995. This scoping effort allows the public to help the National Park Service identify the most important issues to be addressed and the range of alternatives to be considered, proposed and evaluated in the Draft GMP/EIS.

A public information document is available. The purpose of the document is to invite public participation and to serve as an outline for discussion during public consultations. To ensure that the full range of issues are addressed and a full range of alternatives are identified and evaluated, comments and suggestions are invited from all interested parties. Written comments are welcome and must be postmarked no later than October 31, 1995. A public workshop will be held on Wednesday, October 25, 1995, at 7 pm, at the Washington County Technical College, River Road, U.S. Route 1, Calais, Maine.

SUPPLEMENTARY INFORMATION: The public information document briefly describes the significance of the site, the NPS planning process, preliminary management objectives, as well as an outline of preliminary ideas for the future of the site. No decision has been made regarding what the contents of the draft GMP/EIS will be or what alternatives will be proposed and evaluated in the draft GMP/EIS.

FOR FURTHER INFORMATION CONTACT: Superintendent, Acadia National Park, P.O. Box 177, Bar Harbor, Maine 04609, (207) 288–5472.

Dated: September 11, 1995.

Robert W. McIntosh,

Acting, Deputy Field Director.

[FR Doc. 95–23152 Filed 9–18–95; 8:45 am]

BILLING CODE 4310–70–P

Delta Region Preservation Commission; Meeting

AGENCY: National Park Service, Jean Lafitte National Historical Park and Preserve, Interior.

ACTION: Notice of meeting.

SUMMARY: Notice is hereby given in accordance with the Federal Advisory Committee Act that a meeting of the Delta Region Preservation Commission will be held at 7 p.m. at the following location and date.

DATES: October 18, 1995.

LOCATION: Beauregard House, Chalmette Unit, Jean Lafitte National Historical Park and Preserve, 8606 W. Saint Bernard Highway, Chalmette, Louisiana 70043.

FOR FURTHER INFORMATION CONTACT: Mr. Robert Belous, Superintendent, Jean Lafitte National Historical Park and Preserve, 365 Canal Street, Suite 3080, New Orleans, Louisiana 70130–1142, (504) 589–3882, extension 108.

SUPPLEMENTARY INFORMATION: The Delta Region Preservation Commission was established pursuant to section 907 of Pub. L. 95–625 (16 U.S.C. 203f), as amended, to advise the Secretary of the Interior in the selection of sites for inclusion in Jean Lafitte National Historical Park and Preserve, and in the

implementation and development of a general management plan and of a comprehensive interpretive program of the natural, historic, and cultural resources of the Region.

The matters to be discussed at this meeting include:

—Impanelment of New Members
—Old Business
—New Business
—Education Program
—General Park Update

The meeting will be open to the public. However, facilities and space for accommodating members of the public are limited, and persons will be accommodated on a first-come-first-served basis. Any member of the public may file a written statement concerning matters to be discussed with the Superintendent, Jean Lafitte National Historical Park and Preserve.

Minutes of the meeting will be available for public inspection four weeks after the meeting at the office of Jean Lafitte National Historical Park and Preserve.

Dated: September 6, 1995.

W. Thomas Brown,

Acting Field Director, Southeast Area.

[FR Doc. 95–23154 Filed 9–18–95; 8:45 am]

BILLING CODE 4310–70–M

Maine Acadian Culture Preservation Commission; Notice of Meeting

Notice is hereby given in accordance with the Federal Advisory Committee Act (PL 92–463) that the Maine Acadian Culture Preservation Commission will meet on Thursday, October 19, 1995. The meeting will convene at 7 PM in the cafeteria of Van Buren High School on Main Street (U.S. Route 1) in Van Buren, Aroostook County, Maine.

The eleven-member Maine Acadian Culture Preservation Commission was appointed by the Secretary of the Interior pursuant to the Maine Acadian Culture Preservation Act (PL 101–543). The purpose of the Commission is to advise the National Park Service with respect to:

- the development and implementation of an interpretive program of Acadian culture in the state of Maine; and
- the selection of sites for interpretation and preservation by means of cooperative agreements.

The Agenda for this meeting is as follows:

1. Review and approval of the summary report of the meeting held August 17, 1995.
2. Presentation: ''Where Two Worlds Met,'' early history of Saint Croix Island—Wayne Kerr, Heritage Presentation Specialist, Canadian Heritage (Parks Canada).
3. Reports of Maine Acadian Culture Preservation Commission working groups.
4. Report of the National Park Service planning team and project staff.
5. Opportunity for public comment.
6. Proposed agenda, place, and date of the next Commission meeting.

The meeting is open to the public. Further information concerning Commission meetings may be obtained from the Superintendent, Acadia National Park. Interested persons may make oral/written presentations to the Commission or file written statements. Such requests should be made at least seven days prior to the meeting to: Superintendent, Acadia National Park, PO Box 177, Bar Harbor, ME 04609–0177; telephone (207) 288–5472.

Robert W. McIntosh,

Acting Deputy Director, Northeast Field Area.

[FR Doc. 95–23151 Filed 9–18–95; 8:45 am]

BILLING CODE 4310–70–P

National Register of Historic Places; Notification of Pending Nominations

Nominations for the following properties being considered for listing in the National Register were received by the National Park Service before September 9, 1995. Pursuant to section 60.13 of 36 CFR Part 60 written comments concerning the significance of these properties under the National Register criteria for evaluation may be forwarded to the National Register, National Park Service, P.O. Box 37127, Washington, D.C. 20013–7127. Written comments should be submitted by October 4, 1995.

Carol D. Shull,

Keeper of the National Register.

CALIFORNIA

Madera County

Clark, Mary Andrews, Memorial Home, 306–336 S. Loma Dr., Los Angeles, 95001152

Mendocino County

Larsen Family House, 84 State St., Willits, 95001153

Napa County

Special Internal Revenue Bonded Warehouse, First District, No. 13, 1216 Church St., St. Helena, 95001154

Tulare County

Wilsonia Historic District, Roughly bounded by Pine Ln., Fern Ln., Hillcrest Rd., Sierra Ln., Kaweah Ln., Goddard Ln. and Park Rd., Wilsonia, 95001151

LOUISIANA

Iberia Parish

Erath, Auguste, Building, 333–335 W. St. Peter St., New Iberia, 95001156

Wormser's Department Store, 112 E. Main St., New Iberia, 95001158

MICHIGAN

Manistee County

Manistee Harbor, South Breakwater, Mouth of the Manistee R., at Lake Michigan, Manistee, 95001162

Ottawa County

Piers and Revetments at Grand Haven, Michigan, Mouth of Grand R., Grand Haven, 95001161

Van Buren County

Navigation Structures at South Haven Harbor, Michigan, Mouth of the Black R., at Lake Michigan, South Haven, 95001160

MINNESOTA

St. Louis County

United States Army Corps of Engineers Duluth Vessel Yard, Jct. of Ninth St., S. and Minnesota Ave., Duluth, 95001163

NORTH CAROLINA

Macon County

Satulah Mountain Historic District, Roughly bounded by NC 28, Satulah, Brooks, Worley, Warren and Old Walhalla Rd., Highlands, 95001155

OHIO

Portage County

Olin, Arvin, House, 1425 Ravenna Rd., Kent vicinity, 95001157

[FR Doc. 95–23131 Filed 9–18–95; 8:45 am]

BILLING CODE 4310–70–P

Notice of Inventory Completion for Native American Human Remains and Associated Funerary Objects in the Possession of the University of Nebraska State Museum, Anthropology Research Division, Lincoln, NE

AGENCY: National Park Service, Interior.

ACTION: Notice.

Notice is hereby given under the Native American Graves Protection and Repatriation Act, 25 U.S.C. 3003(d), of the completion of an inventory for Native American human remains and associated funerary objects from six sites in Nebraska currently in the possession of the University of Nebraska State Museum, Anthropology Research Division, Lincoln, NE.

A detailed inventory and assessment has been made by members of the professional staff of the University of Nebraska State Museum, in consultation with representatives of the Northern Ponca Tribe of Nebraska and the Southern Ponca Tribe of Oklahoma. Meetings with these tribal representatives have been held at the

Nebraska State Museum on eight occasions during 1993–1995, in addition to many phone conversations during this period.

During 1936–1938, the Nebraska State Archeological Survey conducted excavations of these six sites under the authority of the W.P.A. Official Project #165–81–8095, Work Project #3140. Under agreement with the W.P.A., the collections resulting from these excavations were accessioned by the University of Nebraska State Museum.

Human remains from the Ponca Fort Site (*Nanza*), Knox County, NE consist of sixty-six individuals. No known individuals were identified. A total of 5,310 cultural items are associated with these burials including: Wood (bark fragments, scraper, shaft smoother, shaft straightener); copper (beads, bracelets, bells, buttons, coils, neck rings, projectile points, rings, sheets, and cones); glass (beads, button), pipestone (bannerstone, pipe fragments), bone (bison tools, pendent, hair pipe bead); stone (grinding slab, unknown artifact); iron (ax, bracelets, projectile points, fragments); lead (bracelet, coils); leather fragments; shell (unmodified, gorgets).

The Ponca Fort Site's occupation by the Ponca Tribe is estimated as c. 1790–1800, based on associated cultural items and oral evidence of Ponca ethnohistoric informants in the 1930s (Wood 1965). The J.O. Dorsey ''Omaha Map'' (1884) indicated the presence of Ponca earthlodges on this site and Ponca ethnohistoric informant J. LaFleshe described ''curvilinear entrenchments'' and ''many earth-lodges'' inside the fort (Dorsey 1884). Prince Maximilian in 1832 described a uninhabited Ponca fort at this location. Cultural items found with the burials (such as copper fragments and trade beads), osteological evidence (such as copper staining, marked anterior dental wear, fair to good preservation, and morphological changes related to horseback riding), and the ethnohistoric evidence are consistent with Ponca occupation of the site.

Human remains from the Ponca Point Site (*Ma-azi*), Knox County, NE, consist of the remains of one infant. No known individuals were identified. Two associated funerary objects, consisting of one blue and one white glass bead, were found with this burial.

In 1966, Ponca tribal historian Peter LeClaire identified the Ponca Point site as ''*Ma-azi*'' or ''the burying place on the top of the ridge'' used by the Ponca in the historic period. Osteological evidence of red staining on the arm and rib and the two historic beads associated with this burial, the assessment of the site as protohistoric/historic Ponca, and Ponca ethnohistoric informants are consistent with Ponca occupation of this site.

Human remains from the Hogan Site, Knox County, NE consist of the remains of three individuals. No known individuals were identified. Two hundred eighty-one associated funerary objects include glass (beads), copper (button), and unidentified metal (pendant).

Describing this site in the *Report to the Chancellor* (1937), Bell reports that the Hogan site ''has been used as a burial ground until very recent times by the Ponca.'' Osteological evidence of red staining, good preservation, morphological changes related to horseback riding, and the associated funerary objects are consistent with Ponca occupation of this site.

Human remains from the Davis Site, Knox County, NE consist of the remains of nine individuals. No known individuals were identified. Two hundred and thirty-eight associated funerary objects include: Glass (beads, bottle); copper (bell, bracelets, buttons, bands, coils); iron (sheet, nails); pumice; wood (paper, post); tin (bowl, plate); textile (black cloth).

Reference is made to the Ponca living in this area as early as Truteau in 1795, Mackay in 1797, Clark in 1804, and Prince Maximilian in 1832. Ponca tribal members working on the site during excavations in 1937 identified these burials as Ponca. Osteological evidence of brachycephalic skulls, and associated cultural items are consistent with Ponca occupation of this site.

Human remains from the Minaric II Site (25KX9), Knox County, NE, consist of the remains of six individuals. No known individuals were identified. Sixty-eight associated funerary objects include: bone (antler fragments, antler scraper); pipestone (fragments); glass (beads); ceramics (sherds); copper (cones); sandstone abrader; and shells.

In 1938, Chief Birdhead identified the Minaric II Site as a Ponca village ''occupied by the lesser chiefs and the common people of the tribe.'' Chief Birdhead also said that his grandfather had lived in one of the houses on the bottom land. In 1966, Ponca tribal historian Peter LeClaire compiled a list of Ponca sites, and identified the Minaric II site as ''Farming Ground Village.'' Osteological evidence of copper staining, marked anterior dental wear, fair to good preservation, morphological changes related to horseback riding, and Ponca oral history are consistent with Ponca occupation of this site.

Human remains from the Minaric III Site, Knox County, NE, consist of the remains of one individual. No known individual was identified. Twenty-eight associated funerary objects include: glass (beads); metal (ring, copper necklace band); lithic (projectile point).

The archeological evidence of the Minaric III site, located between the Minaric II site and the Ponca Fort Site, indicates Ponca occupation during the historic period consistent with the surrounding Ponca sites. Osteological evidence of copper staining, marked anterior dental wear, good preservation, and the associated cultural items are consistent with Ponca occupation of this site.

Based on the above-mentioned information from these six sites, officials of the Nebraska State Museum have determined that, pursuant to 25 U.S.C. 3001 (2), there is a relationship of shared group identify which can be reasonably traced between these human remains and associated funerary objects and the Northern Ponca Tribe of Nebraska and the Southern Ponca Tribe of Oklahoma.

This notice has been sent to officials of the Northern Ponca Tribe of Nebraska and the Southern Ponca Tribe of Oklahoma. Representatives of any other Indian tribe that believes itself to be culturally affiliated with the human remains and associated funerary objects should contact Dr. Thomas Myers, Curator of Anthropology, University of Nebraska State Museum, Systematics Collections W436 Nebraska Hall, Lincoln, NE 68588–0544, telephone (402) 472–5033 before October 19, 1995. Repatriation of these human remains to the Northern Ponca Tribe of Nebraska and the Southern Ponca Tribe of Oklahoma may begin after this date if no additional claimants come forward.

Dated: September 13, 1995.

Francis P. McManamon,

Departmental Consulting Archeologist, Archeology and Ethnography Program.

[FR Doc. 95–23153; Filed 9–18–95; 8:45 am]

BILLING CODE 4310–70–F

DEPARTMENT OF JUSTICE

Information Collections Under Review

The Office of Management and Budget (OMB) has been sent the following collection(s) of information proposals for review under the provisions of the Paperwork Reduction Act (44 USC Chapter 35) and the Paperwork Reduction Reauthorization Act since the last list was published. Entries are grouped into submission categories, with each entry containing the following information:

(1) The title of the form/collection;

(2) The agency form number, if any, and the applicable component of the Department sponsoring the collection;

(3) Who will be asked or required to respond, as well as a brief abstract;

(4) An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond;

(5) An estimate of the total public burden (in hours) associated with the collection; and,

(6) An indication as to whether Section 3504(h) of Public Law 96–511 applies.

Comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the OMB reviewer, Mr. Jeff Hill on (202) 395–7340 and to the Department of Justice's Clearance Officer, Mr. Robert B. Briggs, on (202) 514–4319. If you anticipate commenting on a form/collection, but find that time to prepare such comments will prevent you from prompt submission, you should notify the OMB reviewer and the Department of Justice Clearance Officer of your intent as soon as possible. Written comments regarding the burden estimate or any other aspect of the collection may be submitted to Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, DC 20503, and to Mr. Robert B. Briggs, Department of Justice Clearance Officer, Systems Policy Staff/Information Resources Management/Justice Management Division Suite 850, WCTR, Washington, DC 20530.

Revision of a Currently Approved Collection

(1) Petition for Amerasians, Widow or Special Immigrant.

(2) Form: I–360. Immigration and Naturalization Service, United States Department of Justice.

(3) Primary: Individuals and Households. Other: None. The information collected on Form I–360 will be used by the Immigration and Naturalization Service to determine eligibility for the requested immigration benefit. The form serves the purpose of standardizing request for the benefit, and ensuring that basic information required to assess eligibility is provided by applicants.

(4) 11,000 responses per year at 2 hours per response.

(5) 22,000 annual burden hours.

(6) Not applicable under section 3504(h) of Public Law 96–511.

Public comment on this item is encouraged.

Dated: September 18, 1995.

Robert B. Briggs,

Department Clearance Officer, United States Department of Justice.

[FR Doc. 95–23155 Filed 9–18–95; 8:45 am]

BILLING CODE 4410–10–M

Information Collections Under Review

The Office of Management and Budget (OMB) has been sent the following collection(s) of information proposals for review under the provisions of the Paperwork Reduction Act (44 USC Chapter 35) and the Paperwork Reduction Reauthorization Act since the last list was published. Entries are grouped into submission categories, with each entry containing the following information:

(1) The title of the form/collection;

(2) The agency form number, if any, and the applicable component of the Department sponsoring the collection;

(3) Who will be asked or required to respond, as well as a brief abstract;

(4) An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond;

(5) An estimate of the total public burden (in hours) associated with the collection; and,

(6) An indication as to whether Section 3504(h) of Public Law 96–511 applies.

Comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the OMB reviewer, Mr. Jeff Hill on (202) 395–7340 and to the Department of Justice's Clearance Officer, Mr. Robert B. Briggs, on (202) 514–4319. If you anticipate commenting on a form/collection, but find that time to prepare such comments will prevent you from prompt submission, you should notify the OMB reviewer and the Department of Justice Clearance Officer of your intent as soon as possible. Written comments regarding the burden estimate or any other aspect of the collection may be submitted to Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, DC 20503, and to Mr. Robert B. Briggs, Department of Justice Clearance Officer, Systems Policy Staff/Information Resources Management/Justice Management Division suite 850, WCTR, Washington, DC 20530.

New Collection

(1) Trainer's Bureau/Trainer's Bureau Application Form.

(2) Form: None. Office of Victims of Crime, Office of Justice Programs, United States Department of Justice.

(3) Primary: Not-for-profit institutions. Other: State, Local or Tribal Government. The information requested is necessary for the Office for Victims of Crime to review request for training and provide a trainer that meets the needs of an agency or community seeking to improve the response to crime victims through providing consultation or training. Victims of Crime Act administrators, U.S. Attorneys and victim service providers across the nation will be given an opportunity to apply for needed training and technical assistance via this application.

(4) 150 responses per year at 2 hours per response.

(5) 300 annual burden hours.

(6) Not applicable under section 3504 (h) of Public Law 96–511.

Public comment on this item is encouraged.

Dated: September 13, 1995.

Robert B. Briggs,

Department Clearance Officer, United States Department of Justice.

[FR Doc. 95–23156 Filed 9–18–95; 8:45 am]

BILLING CODE 4410–18–M

DEPARTMENT OF LABOR

Employment and Training Administration

[TA–W–31,389]

Don Shapiro Industries, AKA Action West Jeans; El Paso, TX; Notice of Termination of Investigation

Pursuant to Section 221 of the Trade Act of 1974, an investigation was initiated on September 5, 1995 in response to a worker petition which was filed on September 5, 1995 on behalf of workers at Don Shapiro Industries (aka Action West Jeans), El Paso, Texas.

An active certification covering the petitioning group of workers remains in effect (TA–W–31,352). Consequently, further investigation in this case would serve no purpose, and the investigation has been terminated.

Signed in Washington, DC this 5th day of September, 1995.

Victor J. Trunzo,

Program Manager, Policy and Reemployment Services, Office of Trade Adjustment Assistance.

[FR Doc. 95–23185 Filed 9–18–95; 8:45 am]

BILLING CODE 4510–30–M

[TA–W–31,247]

Fina Oil and Chemical Company Exploration & Production Group Offshore Division at Various Locations in Texas; Certification Regarding Eligibility To Apply for Worker Adjustment Assistance

And Also Operating in The Following Other States:

TA–W–31,247A Louisiana
TA–W–31,247B Alabama
TA–W–31,247C Colorado
TA–W–31,247D Oklahoma

In accordance with Section 223 of the Trade Act of 1974 (19 U.S.C. 2273) as amended by the Omnibus Trade and Competitiveness Act of 1988 (Pub. L. 100–418), the Department of Labor herein presents the results of an investigation regarding certification of eligibility to apply for worker adjustment assistance.

In order to make an affirmative determination and issue a certification of eligibility to apply for adjustment assistance each of the group eligibility requirements of Section 222 of the Act must be met. It is determined in this case that all of the requirements have been met.

The investigation was initiated in response to a petition received on July 17, 1995 and filed on behalf of workers at Fina Oil and Chemical Company, at various locations in Texas, and also operating in the following other states: Louisiana, Alabama, Colorado & Oklahoma. The workers are engaged in occupations related to the production of crude oil and natural gas.

The investigation revealed that production and employment declined at the subject firm in 1994 and in January through June 1995. Company imports of crude oil increased in these same periods.

The investigation also disclosed that crude oil produced by the subject firm is marketed through normal retail channels and has been impacted by the high penetration of imports into the crude oil market.

U.S. imports of crude oil increased absolutely and relative to domestic shipments and consumption in 1994 and again in the twelve month period ending in May 1995. The ratio of imports to domestic production is over 102 percent.

Conclusion

After careful review of the facts obtained in the investigation, I conclude that increases of imports of articles like or directly competitive with crude oil and natural gas produced at Fina Oil and Chemical Company, at various locations in Texas, and also operating in the following other states: Louisiana, Alabama, Colorado and Oklahoma contributed importantly to the decline in sales or production and to the total or partial separation of workers of that firm. In accordance with the provisions of the Act, I make the following certification:

''All workers of Fina Oil and Chemical Company at various locations in Texas (TA–W–31,247) & operating in the following cited States, engaged in employment related to the production of crude oil and natural gas who became totally or partially separated from employment on or after October 8, 1994 through two years from the date of certification are eligible to apply for adjustment assistance under Section 223 of the Trade Act of 1974.''

TA–W–31,247A Louisiana
TA–W–31,247B Alabama
TA–W–31,247C Colorado
TA–W–31,247D Oklahoma

Signed in Washington, D.C. this 25th day of August, 1995

Victor J. Trunzo,

Program Manager, Policy and Reemployment Services, Office of Trade Adjustment Assistance.

[FR Doc. 95–23181 Filed 9–18–95; 8:45 am]

BILLING CODE 4510–30–M

Notice of Determinations Regarding Eligibility To Apply for Worker Adjustment Assistance and NAFTA Transitional Adjustment Assistance

In accordance with Section 223 of the Trade Act of 1974, as amended, the Department of Labor herein presents summaries of determinations regarding eligibility to apply for trade adjustment assistance for workers (TA–W) issued during the period of August and September, 1995.

In order for an affirmative to be made and a certification of eligibility to apply for worker adjustment assistance to be issued, each of the group eligibility requirements of Section 222 of the Act must be met.

(1) That a significant number or proportion of the workers in the workers' firm, or an appropriate subdivision thereof, have become totally or partially separated,

(2) That sales or production, or both, of the firm or subdivision have decreased absolutely, and

(3) That increases of imports of articles like or directly competitive with articles produced by the firm or appropriate subdivision have contributed importantly to the separations, or threat thereof, and to the absolute decline in sales or production.

Negative Determinations for Worker Adjustment Assistance

In each of the following cases the investigation revealed that criterion (3) has not been met. A survey of customers indicated that increased imports did not contribute importantly to worker separations at the firm.

TA–W–31,260; IBM Corp., Banks Manufacturing, Endicott, NY
TA–W–31,160; Noll Printing Co., Inc., Huntington, IN
TA–W–31,300; Omega News & Advertising, Inc., El Paso, TX

In the following cases, the investigation revealed that the criteria for eligibility have not been met for the reasons specified.

TA–W–31,301; Electron Wire, El Paso, TX
TA–W–31,316; Collegiate Pacific, Roanoke, VA
TA–W–31,353; Dura Convertible System, Adrian, MI
TA–W–31,295, TA–W–31,296; Portac, Inc. of Tacoma, Beaver, WA & Forks, WA
TA–W–31,286; Blairsville Machine Products Co., Blairsville, PA
TA–W–31,291; Lucas AU1, Hazleton Div., Hazleton, PA

Increased imports did not contribute importantly to worker separations at the firm.

TA–W–31,176; Handy & Harman, East Providence, RI

U.S. imports of gold declined in 1994 compared to 1993. The ratio of gold imports to domestic production declined in the same comparative periods.

TA–W–31,172; International Marine Carriers, Mineola, NY
TA–W–31,320; Associated Gas Services, Inc., (A subsidiary of Panhandle Eastern Corp.), Houston, TX

The workers' firm does not produce an article as required for certification under Section 222 of the Trade Act of 1974.

Affirmative Determinations for Worker Adjustment Assistance

The following certifications have been issued; the date following the company name and location for each determination references the impact date for all workers for such determination.

TA–W–31,214, TA–W–31,215, TA–W–31,216, TA–W–31,217; Buddy L., Inc., Lincoln St. Gloversville, NY, Patch Rd., Gloversville, NY Mayfield, NY and New York, NY: July 26, 1994.
TA–W–31,310; Cassaro Manufacturing Co., Carbondale, PA: July 24, 1994.

TA–W–31,308; American Safety Razor, Verona, VA: July 21, 1994.
TA–W–31,307; Exide Corp., Hamburg, PA: July 7, 1994.
TA–W–31,285; Red Level Fashions, Red Level, AL: July 7, 1994.
TA–W–31,319; American Standard, Inc., US Plumbing Products Div., Hamilton Township, NJ: July 27, 1994.
TA–W–31,293; Movie Star of Purvis, Purvis, MS: July 31, 1994.
TA–W–31,196; Cornik Fashion, Jersey City, NJ: May 16, 1994.
TA–W–31,311; Hillin-Simon/Prime Exploration, L.C., Midland, TX: August 25, 1995.
TA–W–31,161 & A; AEP Industries, Inc., South Hackensack, NJ and Moonachie, NJ: June 12, 1994.
TA–W–31,189; Cuddle Teen Frocks, Inc., New York, NY: June 21, 1994.
TA–W–31,195; Belden Wire & Cable Co (Formerly American Electric Cordsets Co), Cord Products Div., Bensenville, IL: June 15, 1994.
TA–W–31,197; H.H. Cutler Co., Statesboro, GA: June 1, 1994.
TA–W–31,233 & A; Jos J. Pietrafesa Co., Carrollton, GA & Liverpool, NY: July 7, 1994.
TA–W–31,347, TA–W–31,348, TA–W–31,349; Atlantic Oil Co., Glendale, CA, Bakersfield, CA and Sutter, CA: July 11, 1994.
TA–W–31,242; Fina Oil & Chemical Co., Exploration & Production Group, Dallas, TX: October 8, 1994.
TA–W–31,243, TA–W–31,244, TA–W–31,245, TA–W–31,246; Fina Oil & Chemical Co., South Louisiana Div., South Texas Div., East Texas Div., & West Texas Div. Located Through out the States of Texas & Louisiana: October 8, 1994.
TA–W–31,247; Fina Oil & Chemical Co., Offshore Div., With Locations in the States of Texas &, Operating in the Following Other States: A; Louisiana, B; Alabama, C; Colorado, D; Oklahoma: October 8, 1994.
TA–W–31,167, TA–W–31,168, TA–W–31,169; GCO Apparel Genesco, Bowdon, GA, Woodland, AL, Heflin, AL: June 13, 1994.
TA–W–31,324 & A; New Vision, Brooklyn, NY & New York, NY: August 1, 1994.
TA–W–31,299; P & M Tile, Inc., Mt. Gilead, NC: July 21, 1994.
TA–W–31,208; Delta Castings, Cooper, TX: June 19, 1994.
TA–W–31,234; Calvin Manufacturing Co., Tallapoosa, GA: July 7, 1994.
TA–W–31,222; Pamco Shoe Machinery Co., Inc., Lewiston, ME: June 22, 1994.
TA–W–31,254; Dexter Shoe Co., Milo Plant, Milo, ME: July 7, 1994.
TA–W–31,177; ITT Automotive, Tonawanda, NY: June 9, 1994.

Also, pursuant to Title V of the North American Free Trade Agreement Implementation Act (P.L. 103–182) concerning transitional adjustment assistance hereinafter called (NAFTA–TAA) and in accordance with Section 250(a) Subchapter D, Chapter 2, Title II, of the Trade Act as amended, the Department of Labor presents summaries of determinations regarding eligibility to apply for NAFTA–TAA issued during the month of August and September, 1995.

In order for an affirmative determination to be made and a certification of eligibility to apply for NAFTA–TAA the following group eligibility requirements of Section 250 of the Trade Act must be met:

(1) That a significant number or proportion of the workers in the workers' firm, or an appropriate subdivision thereof, (including workers in any agricultural firm or appropriate subdivision thereof) have become totally or partially separated from employment and either—

(2) That sales or production, or both, of such firm or subdivision have decreased absolutely,

(3) That imports from Mexico or Canada of articles like or directly competitive with articles produced by such firm or subdivision have increased, and that the increases in imports contributed importantly to such workers' separations or threat of separation and to the decline in sales or production of such firm or subdivision; or

(4) That there has been a shift in production by such workers' firm or subdivision to Mexico or Canada of articles like or directly competitive with articles which are produced by the firm or subdivision.

Negative Determinations NAFTA–TAA

In each of the following cases the investigation revealed that criteria (3) and (4) were not met. Imports from Canada or Mexico did not contribute importantly to workers' separations. There was no shift in production from the subject firm to Canada or Mexico during the relevant period.

NAFTA–TAA–00530; Omega News & Advertising, Inc., El Paso, TX
NAFTA–TAA–00370; Washington South Sound Services, Olympia, WA
NAFTA–TAA–00382; Titanium Metals Corp (TIMET), Tremont Div., Henderson, NV

In the following cases, the investigation revealed that the criteria for eligibility have not been met for the reasons specified.

NAFTA–TAA–00544; National Tea Co., In., DBA ''The Treal Superstore'', New Orleans, LA
NAFTA–TAA–00526; USDA Forest Service, Superior, MT

The investigation revealed that the workers of the subject firm do not produce an article within the meaning of Section 250(a) of the Trade Act, as amended.

Affirmative Determinations NAFTA–TAA

The following certifications have been issued; the date following the company name & location for each determination references the impact date for all workers for such determination.

NAFTA–TAA–00549; American Standard, Inc., U.S. Plumbing Products Div., Trenton, NJ: August 4, 1994.
NAFTA–TAA–00554; P&M Tile, Inc., Mount Gilead, NC: July 21, 1994.
NAFTA–TAA–00541; Gould Electronics, Inc., A.K.A. Gould Shawmut Marble Falls, TX: July 31, 1994.
NAFTA–TAA–00537; Vaagen Brothers Lumber, Inc., Colville, WA: July 22, 1994.
NAFTA–TAA–00539 &A, B; The 500 Fashion Group, Northampton, PA, Whitehall, PA & Philadelphia, PA: July 14, 1994.
NAFTA–TAA–00532; Anchor Glass Container Corp., Keyser, WV: July 14, 1994.
NAFTA–TAA–00555; AMCO Manufacturing Corp., Adrian Div., Adrian, MI: August 7, 1994.
NAFTA–TAA–00567; Roadware Corp., Kylertown, PA: August 10, 1994.

I hereby certify that the aforementioned determinations were issued during the months of August and September, 1995. Copies of these determinations are available for inspection in Room C–4318, U.S. Department of Labor, 200 Constitution Avenue NW., Washington, DC 20210 during normal business hours or will be mailed to persons who write to the above address.

Dated: September 7, 1995.

Victor J. Trunzo,

Program Manager, Policy & Reemployment Services, Office of Trade Adjustment Assistance.

[FR Doc. 95–23182 Filed 9–18–95; 8:45 am]

BILLING CODE 4510–30–M

Investigations Regarding Certifications of Eligibility To Apply for Worker Adjustment Assistance

Petitions have been filed with the Secretary of Labor under Section 221(a)

of the Trade Act of 1974 (''the Act'') and are identified in the Appendix to this notice. Upon receipt of these petitions, the Director of the Office of Trade Adjustment Assistance, Employment and Training Administration, has instituted investigations pursuant to Section 221(a) of the Act.

The purpose of each of the investigations is to determine whether the workers are eligible to apply for adjustment assistance under Title II, Chapter 2, of the Act. The investigations will further relate, as appropriate, to the determination of the data on which total or partial separations began or threatened to begin and the subdivision of the firm involved.

The petitioners or any other persons showing a substantial interest in the subject matter of the investigations may request a public hearing, provided such request is filed in writing with the Director, Office of Trade Adjustment Assistance, at the address show below, not later than September 29, 1995.

Interested persons are invited to submit written comments regarding the subject matter of the investigations to the Director, Office of Trade Adjustment Assistance, at the address shown below, not later than September 29, 1995.

The petitions filed in this case are available for inspection at the Office of the Director, Office of Trade Adjustment Assistance, Employment and Training Administration, U.S. Department of Labor, 200 Constitution Avenue NW., Washington, D.C. 20210.

Signed at Washington, D.C. this 5th day of September, 1995.

Victor J. Trunzo,

Program manager, Policy & Reemployment Services, Office of Trade Adjustment Assistance.

APPENDIX—PETITIONS INSTITUTED ON SEPTEMBER 5, 1995

TA–W	Subject firm (petitioners)	Location	Date of petition	Product(s)
31,385	Johnson Controls (UAW)	Louisville, KY	08/22/95	Batteries.
31,386	Huffy Bicycles (USWA)	Celina, OH	08/18/95	Bicycles and parts.
31,387	General Power Equip. Co (Wkrs)	Harvard, IL	07/14/95	Outdoor power products.
31,388	Acadia Polymers (Wkrs)	Clifton Forge, VA	08/14/95	Piston seals—auto industries.
31,389	Action West Jeans (Wkrs)	El Paso, TX	08/18/95	Jeans and jean products.
31,390	Bailey Corporation (Comp)	Portland, IN	08/18/95	Painted spoilers and trim components.
31,391	OshKosh B'Gosh (UFCW)	Marrowbone, KY	08/23/95	Jeans.
31,392	Exxon Chemical (Comp)	Casper, WY	08/18/95	Crude oil and natural gas.
31,393	Bethlehem Steel Corp (USWA)	Bethlehem, PA	08/22/95	Structural steel.
31,394	Bike Athletic Co. (UNITE)	Knoxville, TN	08/23/95	Sports apparel.
31,395	Great American Knitting (Comp)	Scotland Neck, NC	08/25/95	Men's and women's athletic white socks.
31,396	Nylomatic (Wkrs)	Fallsington, PA	08/24/95	Plastic injected molded parts.
31,397	Gold Medal, Inc. (Wkrs)	Crewe, VA	08/21/95	Bean bags, ottomans, cushions.
31,398	G III Fashions, Inc (Wkrs)	New York, NY	08/12/95	Leather outerwear.
31,399	AT&T Global Information (Wkrs)	Springfield, MA	08/03/95	Reprinted power supplies.
31,400	Motor Wheel Corp. (UAW)	Ypsilanti, MI	08/16/95	Vehicle wheel components.
31,401	Lanier Clothes (Comp)	Decherd, TN	08/21/95	Men's suits and sport coats.
31,402	Copper Range Co. (Comp)	White Pine, MI	08/21/95	Concentrate electro lytic cathode copper.
31,403	Liz Claiborne (Comp)	New York, NY	08/24/95	Ladies' apparel.
31,404	Lanier Clothes (Comp)	Winchester, TN	08/24/95	Men's suits, sportcoats.

[FR Doc. 95–23184 Filed 9–18–95; 8:45 am]

BILLING CODE 4510–30–M

[TA–W–30,941]

Miller Brewing Co., Fulton, NY; Amended Certification Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with Section 223 of the Trade Act of 1974 (19 USC 2273) the Department of Labor issued an Amended Certification Regarding Eligibility to Apply for Worker Adjustment Assistance on August 14, 1995, applicable to workers of Miller Brewing Company in Fulton, New York.

The Amended Certification revised the impact date to cover major layoffs that occurred in January 1994. Recent information revealed that layoffs also occurred in 1993. The Department is issuing another amended notice applicable to TA–W–30,941 to make the impact date one year prior to the date of the petition. The petition date for the subject case was April 13, 1994.

the amended notice applicable to TA–W–30,941 is hereby issued as follows:

All workers of Miller Brewing Company, Fulton, New York engaged in employment related to the production of beer who became totally or partially separated from employment on or after April 13, 1993 are eligible to apply for adjustment assistance under Section 223 of the Trade Act of 1994.

Signed at Washington, D.C., this 31st day of August, 1995.

Victor J. Trunzo,

Program Manager, Policy and Reemployment Services, Office of Trade Adjustment Assistance.

[FR Doc. 95–23186 Filed 9–18–95; 8:45 am]

BILLING CODE 4510–30–M

[TA–W–31,119]

Wirekraft Industries, Incorporated, Burcliff Industries Division, Cardington, OH; TA–W–31,119A, Wirekraft Industries, Incorporated, Burcliff Industries Division, South Bend, IN; and TA–W–31,119B, Wirekraft Industries, Incorporated, Burcliff Industries Division, Lakeville, IN; Amended Certification Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with Section 223 of the Trade Act of 1974 (19 USC 2273) the Department of Labor issued a Certification of Eligibility to Apply for Worker Adjustment Assistance on August 9, 1995, applicable to all workers of Wirekraft Industries, Incorporated, Burcliff Industries Division, located in Cardington, Ohio. The notice was published in the Federal

Register on August 24, 1995 (60 FR 44079).

The certification was amended August 18, 1995, to cover workers of the subject firm located in South Bend, Indiana. The notice will soon be published in the Federal Register.

New information received from the State Agency shows that worker separations have occurred at Wirekraft Industries, Incorporated, Burcliff Industries Division in Lakeville, Indiana. The workers produce electrical wire harnesses for appliances.

The intent of the Department's certification is to include all workers of Wirekraft Industries adversely affected by imports.

The amended notice applicable to TA–W–31,119 is hereby issued as follows:

All workers of the Burcliff Industries Division of Wirekraft Industries, Incorporated, Cardington, Ohio (TA–W–31,119), South Bend, Indiana (TA–W–31,119A), and Lakeville, Indiana (TA–W–31,119B) who became totally or partially separated from employment on or after May 26, 1994 are eligible to apply for adjustment assistance under Section 223 of the Trade Act of 1974.

Signed at Washington, D.C. this 7th day of September 1995.

Victor J. Trunzo,

Program Manager, Policy and Reemployment Services, Office of Trade Adjustment Assistance.

[FR Doc. 95–23183 Filed 9–18–95; 8:45 am]

BILLING CODE 4510–30–M

Public Meeting; Federal Committee on Apprenticeship

AGENCY: Employment and Training Administration, Labor.

ACTION: Notice.

Pursuant to section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463; 5 U.S.C. App. 1), notice is hereby given that the Federal Committee on Apprenticeship (FCA) will conduct an open meeting on October 1, 1995, at the Washington Hilton Hotel, 1919 Connecticut Avenue, NW., Washington, DC 20009.

The agenda will include:

12:00 a.m. Call to Order

Administrative Matters

- Meeting Logistics
- Approval of Minutes

Remarks: Assistant Secretary for ETA Bureau of Apprenticeship and Training Report

Work Group Reports and Recommendations

- Briefing on National Apprenticeship Conference
- Reauthorization/funding Carl Perkins Vocational Education Act
- Pilot test projects for promotion/expansion of registered apprenticeship
- National Registered Apprenticeship Award Program
- Regulatory Barriers to Expansion of Registered Apprenticeship
- Legislation affecting registered apprenticeship
- National Association of State and Territorial Apprenticeship Directors (NASTAD) Report
- National Association of Governmental Labor Officials (NAGLO) Report
- Public Comments
- Other Business

4:00 p.m. Adjournment

The agenda is subject to change due to time constraints and priority items which may come before the Committee between the time of this publication and the scheduled date of the FCA meeting.

Members of the public are invited to attend the proceedings. Individuals with disabilities should contact Marion M. Winters at (202) 219–5921, Ext. 114 no later than September 19, 1995, if special accommodations are needed.

Any member of the public who wishes to file written data, views or arguments pertaining to the agenda may do so by furnishing it to the Designated Federal Official at any time prior to the meeting. His address is: Mr. Anthony Swoope, Director, Bureau of Apprenticeship and Training, ETA, U.S. Department of Labor, 200 Constitution Avenue NW., Room N–4649 Washington, D.C. 20210.

Fifteen duplicate copies are needed for the members and for inclusion in the minutes of the meeting.

Any member of the public who wishes to speak at this meeting should so indicate the nature of intended presentation and the amount of time needed by furnishing a written statement to the Designated Federal Official by September 23, 1995. The Chairperson will announce at the beginning of the meeting the extent to which time will permit the granting of such requests.

Signed at Washington, D.C., this 13th day of September 1995.

Timothy M. Barnicle,

Assistant Secretary of Labor for Employment and Labor.

[FR Doc. 95–23187 Filed 9–18–95; 8:45 am]

BILLING CODE 4510–30–M

NUCLEAR REGULATORY COMMISSION

[Docket No. 50–286]

Power Authority of the State of New York; Indian Point Nuclear Generating Unit No. 3 Environmental Assessment and Finding of No Significant Impact

The U.S. Nuclear Regulatory Commission (the Commission) is considering issuance of a one time schedular exemption from the requirements of 10 CFR 50.71(e)(4) for the submittal of the periodic Final Safety Analysis Report (FSAR) update from Facility Operating License No. DPR–64, issued to the Power Authority of the State of New York (the licensee) for the Indian Point Nuclear Generating Unit No. 3 (IP3), located at the licensee's site in Westchester County, New York.

Environmental Assessment

Identification of the Proposed Action

The proposed schedular exemption would reschedule the required FSAR update from July 22, 1995, to December 27, 1995 (i.e. 6 months after restart from the extended shutdown). Title 10 of the Code of Federal Regulations (10 CFR), 10 CFR 50.71(e)(4) requires that FSAR revisions must be submitted annually or 6 months after a refueling outage provided the interval between updates does not exceed 2 years. In addition, 10 CFR 50.54(a)(3) requires that changes to the quality assurance program description that do not reduce commitments must be submitted to the NRC in accordance with the FSAR update requirements of 10 CFR 50.71(e).

The licensee shut down IP3 in February 1993 for a performance improvement outage. The plant was recently restarted on June 27, 1995. Although this extended shutdown was not a refueling outage, the number of facility changes made by the licensee during the shutdown equates it to one. As such, a one time FSAR update schedular exemption would enable the licensee to include most of the modifications, technical specifications amendments, and other changes completed during the extended shutdown in the next FSAR update.

The proposed action is in accordance with the licensee's application for exemption dated June 20, 1995.

The Need for the Proposed Action

The proposed schedular exemption is needed to permit the licensee to include most of the modifications, technical specifications amendments, and other changes completed during the extended shutdown in the next FSAR update.

Literal compliance with the FSAR update schedule of 10 CFR 50.71(e)(4) would result in an FSAR update which would be incomplete and not adequately reflect the actual design of the facility.

Environmental Impacts of the Proposed Action

The proposed action to allow the licensee an additional 6 months to update the IP3 FSAR is administrative in nature. The Commission has completed its evaluation of the proposed action and concludes that the probability or consequences of accidents will not increase, no changes are being made in the types of any effluents that may be released offsite, and there is no significant increase in the allowable individual or cumulative occupational radiation exposure. Accordingly, the Commission concludes that there are no significant radiological environmental impacts associated with the proposed action.

With regard to potential nonradiological impacts, the proposed action is administrative in nature and involves features located entirely within the restricted area as defined in 10 CFR Part 20. It does not affect nonradiological plant effluents and has no other environmental impact. Accordingly, the Commission concludes that there are no significant nonradiological environmental impacts associated with the proposed action.

Alternatives to the Proposed Action

Since the Commission has concluded there is no measurable environmental impact associated with the proposed action, any alternatives with equal or greater environmental impact need not be evaluated. However, as an alternative to the proposed action, the staff considered denial of the proposed action. Denial of the application would result in no change in current environmental impacts. The environmental impacts of the proposed action and the alternative action considered are the same.

Alternative Use of Resources

This action does not involve the use of any resources not previously considered in the ''Final Environmental Statement for the Indian Point Nuclear Generating Station Unit No. 3,'' dated February 1975.

Agencies and Persons Consulted

In accordance with its stated policy, on August 17, 1995, the staff consulted with the New York State official, Jack Spath of the New York State Energy Research and Development Authority, regarding the environmental impact of the proposed action. The State official had no comments.

Finding of No Significant Impact

Based upon the environmental assessment, the Commission concludes that the proposed action will not have a significant effect on the quality of the human environment. Accordingly, the Commission has determined not to prepare an environmental impact statement for the proposed action.

For further details with respect to the proposed action, see the licensee's letter dated June 20, 1995, which is available for public inspection at the Commission's Public Document Room, The Gelman Building, 2120 L Street NW., Washington, DC, and at the White Plains Public Library, 100 Martine Avenue, White Plains, New York.

Dated at Rockville, Maryland, this 12th day of September 1995.

For the Nuclear Regulatory Commission.

Ledyard B. Marsh,

Director, Project Directorate I–1, Division of Reactor Projects—I/II, Office of Nuclear Reactor Regulation.

[FR Doc. 95–23177 Filed 9–18–95; 8:45 am]

BILLING CODE 7590–01–P

Application for a License To Export a Utilization Facility

Pursuant to 10 CFR 110.70(b) ''Public notice of receipt of an application'', please take notice that the Nuclear Regulatory Commission has received the following application for an export license. Copies of the application are on file in the Nuclear Regulatory Commission's Public Document Room located at 2120 L Street, N.W., Washington, DC.

A request for a hearing or petition for leave to intervene may be filed within 30 days after publication of this notice in the Federal Register. Any request for hearing or petition for leave to intervene shall be served by the requestor or petitioner upon the applicant, the Office of the General Counsel, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555; the Secretary, U.S. Nuclear Regulatory Commission; and the Executive Secretary, U.S. Department of State, Washington, D.C. 20520.

In its review of the application for a license to export a utilization facility as defined in 10 CFR Part 110 and noticed herein, the Commission does not evaluate the health, safety or environmental effects in the recipient nation of the facility to be exported. The information concerning this application follows:

Name of applicant	ABB Combustion Engineering., Inc.	Description of facility	End use
Date of Application	10 August 1995	2 (Two) Nuclear Power Reactors/ 1000 MWe (ea) pressurized water reactors/Ulchin units 5 & 6.	Commercial Generation of Electricity.
Date Received	15 August 1995		
Application Number	XR 163		
Country of Destination	Republic of Korea		

Dated this 7th day of September 1995 at Rockville, Maryland.

For the Nuclear Regulatory Commission.

Ronald D. Hauber,

Director, Division of Nonproliferation, Exports and Multilateral Relations, Office of International Programs.

[FR Doc. 95–23180 Filed 9–18–95; 8:45 am]

BILLING CODE 7590–01–M

Generic Letter 88–20, Supplement 5, Individual Plant Examination of External Events for Severe Accident Vulnerabilities

AGENCY: Nuclear Regulatory Commission.

ACTION: Notice of issuance.

SUMMARY: The Nuclear Regulatory Commission (NRC) has issued Generic Letter 88–20, Supplement 5 to (1) notify all holders of operating licenses (except those licenses that have been amended to possession-only status) or construction permits for nuclear power reactors of modifications in the recommended scope of seismic reviews that are performed as part of individual plant examinations of external events (IPEEE) for the focused-scope and full-

scope plants and (2) provide guidance to licensees who wish to voluntarily modify their previously committed seismic IPEEE programs. This generic letter will be made available in the NRC Public Document Room. The information that was sent to the Committee to Review Generic Requirements, including the resolution of public comments received on this generic letter, will be made available in the NRC Public Document Room. This generic letter is also discussed in Commission information paper SECY–95–213 which will made available in the NRC Public Document Room.

DATES: The generic letter was issued on September 8, 1995.

ADDRESSES: Not Applicable.

FOR FURTHER INFORMATION CONTACT: John T. Chen (301) 415–6549.

SUPPLEMENTARY INFORMATION: None.

Dated at Rockville, MD, this 11th day of September, 1995.

For the Nuclear Regulatory Commission.

Alfred E. Chaffee,

Chief, Events Assessment and Generic Communications Branch, Division of Reactor Program Management, Office of Nuclear Reactor Regulation.

[FR Doc. 95–23175 Filed 9–18–95; 8:45 am]

BILLING CODE 7590–01–M

[Docket No. 50–278]

PECO Energy Co.; Notice of Consideration of Issuance of Amendment to Facility Operating License, Proposed No Significant Hazards Consideration Determination, and Opportunity for a Hearing

The U.S. Nuclear Regulatory Commission (the Commission) is considering issuance of an amendment to Facility Operating License No. DPR–56, issued to PECO Energy Company, et al., (the licensee), for operation of the Peach Bottom Atomic Power Station, Unit 3, located in York County, Pennsylvania.

The proposed amendment would delete License Condition 2.C(5) from Facility Operating License DPR–56 which restricts power levels to no less than seventy percent in the coastdown condition.

The amendment is being proposed on a exigent basis in accordance with 10 CFR 50.91(a)(6). On August 29, 1995, the licensee discovered that it was operating at sixty-two percent power in the coastdown condition in violation of License Condition 2.C(5). On August 30, 1995, in order to avoid an unwarranted plant shutdown, the licensee requested enforcement condition for this violation until such time as the staff could process a permanent change to the facility operating license that would delete License Condition 2.C(5). The NRC staff authorized enforcement discretion verbally on August 30, 1995 and in writing on September 1, 1995, by letter to Mr. George Hunger, PECO Energy Company. The amendment is being considered on an exigent basis in order to minimize the length of time the licensee is operating in violation of License Condition 2.C(5).

Pursuant to 10 CFR 50.91(a)(6) for amendments to be granted under exigent circumstances, the NRC staff must determine that the amendment request involves no significant hazards consideration. Under the Commission's regulations in 10 CFR 50.92, this means that operation of the facility in accordance with the proposed amendment would not (1) involve a significant increase in the probability or consequences of an accident previously evaluated; or (2) create the possibility of a new or different kind of accident from any accident previously evaluated; or (3) involve a significant reduction in a margin of safety. As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

1. The proposed change does not involve a significant increase in the probability or consequences of any accident previously evaluated.

Deletion of License Condition 2.C(5) is an administrative change that will not involve a significant increase in the probability or consequences of any accident previously evaluated. This license condition is more appropriately controlled by other licensing bases documents, which include the NRC approved GESTAR II analyses and the cycle specific reload licensing reports, and should not be part of the FOL. Accidentally, this FOL change will not alter any safety limits which ensure the integrity of fuel barriers, and will not result in any increase to onsite or offsite dose.

No physical changes are being made to the plant, nor are there any changes being made in the operation of the plant as a result of this change which could involve a significant increase in the probability or consequences of any accident previously evaluated. Additionally, this change will not alter the operation of equipment assumed to be available for the mitigation of accidents or transients.

2. The proposed change does not create the possibility of a new or different kind of accident from any previously evaluated.

Deletion of License Condition 2.C(5) is an administrative change that will not create the possibility of a new or different type of accident from any previously evaluated. Deletion of License Condition 2.C(5) is an administrative change that will not involve any changes to plant systems, structures or components (SCCs) which could act as new accident initiators. This change will not impact the manner in which SSCs are tested such that a new or different type of accident from any previously evaluated could be created.

3. The proposed change does not result in a significant reduction in the margin of safety.

No margins of safety are reduced as a result of the proposed deletion of License Condition 2.C(5). No safety limits will be changed as a result of this change. The proposed change does not involve a reduction in the margin of safety because this change is an administrative change which will not impact core limits or any other parameters that are used in the mitigation of a UFSAR design basis accident or transient. The change to the FOL does not introduce any hardware changes, and will not alter the intended operation of plant structures, systems or components utilized in the mitigation of UFSAR design basis accidents or transients. Additionally, this change will not introduce any new failure modes of plant equipment not previously evaluated.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

The Commission is seeking public comments on this proposed determination. Any comments received within 15 days after the date of publication of this notice will be considered in making any final determination.

Normally, the Commission will not issue the amendment until the expiration of the 15-day notice period. However, should circumstances change during the notice period, such that failure to act in a timely way would result, for example, in derating or shutdown of the facility, the Commission may issue the license amendment before the expiration of the 15-day notice period, provided that its final determination is that the amendment involves no significant hazards consideration. The final determination will consider all public and State comments received. Should the Commission take this action, it will publish in the Federal Register a notice of issuance. The Commission expects that the need to take this action will occur very infrequently.

Written comments may be submitted by mail to the Rules Review and Directives Branch, Division of Freedom of Information and Publications Services, Office of Administration, U.S. Nuclear Regulatory Commission, Washington, DC 20555, and should cite the publication date and page number of

this Federal Register notice. Written comments may also be delivered to Room 6D22, Two White Flint North, 11545 Rockville Pike, Rockville, Maryland, from 7:30 a.m. to 4:15 p.m. Federal workdays. Copies of written comments received may be examined at the NRC Public Document Room, the Gelman Building, 2120 L Street NW., Washington, DC.

The filing of requests for hearing and petitions for leave to intervene is discussed below.

By October 18, 1995, the licensee may file a request for a hearing with respect to issuance of the amendment to the subject facility operating license and any person whose interest may be affected by this proceeding and who wishes to participate as a party in the proceeding must file a written request for a hearing and a petition for leave to intervene. Requests for a hearing and a petition for leave to intervene shall be filed in accordance with the Commission's ''Rules of Practice for Domestic Licensing Proceedings'' in 10 CFR Part 2. Interested persons should consult a current copy of 10 CFR 2.714 which is available at the Commission's Public Document Room, the Gelman Building, 2120 L Street NW., Washington, DC, and at the local public document room located at the Government Publications Section, State Library of Pennsylvania, (Regional Depository) Education Building, Walnut Street and Commonwealth Avenue, Box 1601, Harrisburg, Pennsylvania 17105. If a request for a hearing or petition for leave to intervene is filed by the above date, the Commission or an Atomic Safety and Licensing Board, designated by the Commission or by the Chairman of the Atomic Safety and Licensing Board Panel, will rule on the request and/or petition; and the Secretary or the designated Atomic Safety and Licensing Board will issue a notice of hearing or an appropriate order.

As required by 10 CFR 2.714, a petition for leave to intervene shall set forth with particularity the interest of the petitioner in the proceeding, and how that interest may be affected by the results of the proceeding. The petition should specifically explain the reasons why intervention should be permitted with particular reference to the following factors: (1) The nature of the petitioner's right under the Act to be made a party to the proceeding; (2) the nature and extent of the petitioner's property, financial, or other interest in the proceeding; and (3) the possible effect of any order which may be entered in the proceeding on the petitioner's interest. The petition should also identify the specific aspect(s) of the subject matter of the proceeding as to which petitioner wishes to intervene. Any person who has filed a petition for leave to intervene or who has been admitted as a party may amend the petition without requesting leave of the Board up to 15 days prior to the first prehearing conference scheduled in the proceeding, but such an amended petition must satisfy the specificity requirements described above.

Not later than 15 days prior to the first prehearing conference scheduled in the proceeding, a petitioner shall file a supplement to the petition to intervene which must include a list of the contentions which are sought to be litigated in the matter. Each contention must consist of a specific statement of the issue of law or fact to be raised or controverted. In addition, the petitioner shall provide a brief explanation of the bases of the contention and a concise statement of the alleged facts or expert opinion which support the contention and on which the petitioner intends to rely in proving the contention at the hearing. The petitioner must also provide references to those specific sources and documents of which the petitioner is aware and on which the petitioner intends to rely to establish those facts or expert opinion. Petitioner must provide sufficient information to show that a genuine dispute exists with the applicant on a material issue of law or fact. Contentions shall be limited to matters within the scope of the amendment under consideration. The contention must be one which, if proven, would entitle the petitioner to relief. A petitioner who fails to file such a supplement which satisfies these requirements with respect to at least one contention will not be permitted to participate as a party.

Those permitted to intervene become parties to the proceeding, subject to any limitations in the order granting leave to intervene, and have the opportunity to participate fully in the conduct of the hearing, including the opportunity to present evidence and cross-examine witnesses.

If the amendment is issued before the expiration of the 30-day hearing period, the Commission will make a final determination on the issue of no significant hazards consideration. If a hearing is requested, the final determination will serve to decide when the hearing is held.

If the final determination is that the amendment request involves no significant hazards consideration, the Commission may issue the amendment and make it immediately effective, notwithstanding the request for a hearing. Any hearing held would take place after issuance of the amendment.

If the final determination is that the amendment request involves a significant hazards consideration, any hearing held would take place before the issuance of any amendment.

A request for a hearing or a petition for leave to intervene must be filed with the Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, DC 20555, Attention: Docketing and Services Branch, or may be delivered to the Commission's Public Document Room, the Gelman Building, 2120 L Street NW., Washington, DC, by the above date. Where petitions are filed during the last 10 days of the notice period, it is requested that the petitioner promptly so inform the Commission by a toll-free telephone call to Western Union at 1–(800) 248–5100 (in Missouri 1–(800) 342–6700). The Western Union operator should be given Datagram Identification Number N1023 and the following message addressed to John F. Stolz: petitioner's name and telephone number, date petition was mailed, plant name, and publication date and page number of this Federal Register notice. A copy of the petition should also be sent to the Office of the General Counsel, U.S. Nuclear Regulatory Commission, Washington, DC 20555, and to J. W. Durham, Sr., Esquire, Sr. V.P. and General Counsel, PECO Energy Company, 2301 Market Street, Philadelphia, Pennsylvania 19101, attorney for the licensee.

Nontimely filings of petitions for leave to intervene, amended petitions, supplemental petitions and/or requests for hearing will not be entertained absent a determination by the Commission, the presiding officer or the presiding Atomic Safety and Licensing Board that the petition and/or request should be granted based upon a balancing of the factors specified in 10 CFR 2.714(a)(1) (i)–(v) and 2.714(d).

For further details with respect to this action, see letter dated August 30, 1995, and the application for amendment dated September 1, 1995, which are available for public inspection at the Commission's Public Document Room, the Gelman Building, 2120 L Street NW., Washington, DC, and at the local public document room, located at the Government Publications Section, State Library of Pennsylvania, (Regional Depository) Education Building, Walnut Street and Commonwealth Avenue, Box 1601, Harrisburg, Pennsylvania 17105.

Dated at Rockville, MD, this 13th day of September 1995.

For the Nuclear Regulatory Commission.

John F. Stolz,

Director, Project Directorate I–2, Division of Reactor Projects—I/II, Office of Nuclear Reactor Regulation.

[FR Doc. 95–23176 Filed 9–18–95; 8:45 am]

BILLING CODE 7590–01–P

[Docket Nos. 50–338 and 50–339]

Virginia Electric & Power Company, North Anna Power Station Units 1 and 2; Exemption Amendment

I

The Virginia Electric and Power Company (VEPCO, the licensee) is the holder of Operating License No. NPF–4 which authorizes operation of North Anna Power Station Unit 1 and Operating License No. NPF–7 which authorizes operation of Unit 2. These operating licenses provide, among other things, that the North Anna Power Station is subject to all rules, regulations, and Orders of the Commission now or hereafter in effect.

The station comprises two pressurized water reactors at the Licensee's site located in Louisa County, Virginia.

II

By letter to the licensee dated November 6, 1986, Exemption 1 (among others) was approved by the NRC. Exemption 1 was from the technical requirements of Section III.G.3 of Appendix R to 10 CFR Part 50 to the extent that fire detection and fixed suppression systems were not installed throughout the Auxiliary, Fuel, and Decontamination Building (Fire Area 11). The original Safety Evaluation supporting Exemption 1 stated the charging pump cubicles had 3-hour fire-rated walls, and that the penetrations in these walls were sealed to a rating of 3 hours. By letter dated December 11, 1992, the licensee requested an addendum (exemption amendment) which revises the original Exemption 1 to account for non-fire-rated penetration seals and unprotected openings located in the south wall of the charging pump cubicles. The lack of penetration seals was identified in an NRC Inspection Report 50–338, 339/92–18 dated October 19, 1992.

The Commission's staff has evaluated the information provided by the licensee to support the addendum to Exemption 1. The Commission's Safety Evaluation relating to an Addendum to Exemption 1 From Certain Requirements of Appendix R to 10 CFR Part 50 is being issued concurrently with this exemption amendment. The Safety Evaluation concludes that the lack of fire-rated penetration seals in the south wall of the pump cubicles does not present an undue risk to the public health and safety and that special circumstances are present in that application of the regulation in the particular circumstances is not necessary to achieve the underlying purpose of the rule.

III

The underlying purpose of Section III.G.3 of Appendix R to 10 CFR Part 50 is to ensure that safe shutdown capability is maintained. Notwithstanding the lack of three hour rated penetration seals, the circumstances, as fully described in the Safety Evaluation, are such that the installation of fire detection and fixed suppression systems throughout Fire Area 11 is not necessary to provide reasonable assurance that safe shutdown capability is maintained.

Therefore, the staff concludes that ''special circumstances'' exist for the licensee's requested exemption amendment in that application of the regulation in these particular circumstances is not necessary to achieve the underlying purposes of Section III.G.3 of Appendix R to 10 CFR Part 50. The Commission hereby grants an amendment to Exemption 1 granted November 6, 1986, and authorizes the subject addendum (attached) to revise Exemption 1 to account for non-fire-rated penetrations in the south wall of the charging pump cubicles.

IV

Accordingly, the Commission has determined that, pursuant to 10 CFR Part 50.12(a), (1) the exemption amendment as described in Section II is authorized by law and will not present an undue risk to the public health and safety and is consistent with common defense and security, and (2) special circumstances are present for the exemption amendment in that application of the regulation in this particular circumstance is not necessary to achieve the underlying purposes of Appendix R to 10 CFR Part 50.

Pursuant to 10 CFR 51.32, the Commission has determined that the issuance of the exemption amendment will have no significant impact on the environment (60 FR 45747).

This exemption amendment is effective upon its issuance.

Dated at Rockville, Maryland this 12th day of September 1995.

For the Nuclear Regulatory Commission.

Ledyard B. Marsh,

Acting Director, Division of Reactor Projects—I/II, Office of Nuclear Reactor Regulation.

[FR Doc. 95–23174 Filed 9–18–95; 8:45 am]

BILLING CODE 7590–01–P

OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE

Notice of Meeting of the Trade Advisory Committee on Africa

AGENCY: Office of the United States Trade Representative.

ACTION: Notice that the September 28, 1995 meeting of the Trade Advisory Committee on Africa will be held from 11:00 a.m. to 2:00 p.m. The meeting will be closed to the public from 11:00 a.m. to 1:15 p.m. The meeting will be open to the public from 1:15 p.m. to 2:00 p.m.

SUMMARY: The Trade Advisory Committee on Africa will hold a meeting on September 28, 1995 from 11:00 a.m. to 2:00 p.m. The meeting will be closed from 11:00 a.m. to 1:15 p.m. when the meeting will include a review and discussion of current issues which influence U.S. trade policy. Pursuant to Section 2155(f)(2) of Title 19 of the United States Code, I have determined that this portion of the meeting will be concerned with matters the disclosure of which would seriously compromise the development by the United States Government of trade policy, priorities, negotiating objectives or bargaining positions with respect to the operation of any trade agreement and other matters arising in connection with the development, implementation and administration of the trade policy of the United States. The meeting will be open to the public and press from 1:15 p.m. to 2:00 p.m. when trade policy issues will be discussed. Attendance during this part of the meeting is for observation only. Individuals who are not members of the committee will not be invited to comment.

DATES: The meeting is scheduled for September 28, 1995, unless otherwise notified.

ADDRESSES: The meeting will be held at the Jefferson Hotel at 16th and M Street, Washington, D.C., unless otherwise notified.

FOR FURTHER INFORMATION CONTACT: Michaelle Burstin, Director of Public Liaison, Office of the United States Trade Representative, (202) 395–6120.

Michael Kantor,

United States Trade Representative.

[FR Doc. 95–23172 Filed 9–18–95; 8:45 am]

BILLING CODE 3190–01–M

POSTAL SERVICE

Privacy Act of 1974; System of Records

AGENCY: Postal Service.

ACTION: Notice of new system of records.

SUMMARY: The purpose of this document is to publish notice of a new Privacy Act system of records, USPS 120.154, Personnel Records—Employee Survey Process System Records. The new system contains a collection of statistical data compiled from surveys completed by employees on various topics and issues related to their employment. Some surveys within the system relate directly to individual managers or supervisors whose performance has been rated by the questionnaire respondents. Other surveys concern particular work locations rather than individual managers, but these surveys have the potential for being associated, though indirectly, with the particular manager or supervisor who is responsible for the work location.

DATES: This proposal will become effective without further notice October 30, 1995, unless comments are received on or before that date that result in a contrary determination.

ADDRESSES: Written comments on this proposal should be mailed or delivered to Payroll Accounting/Records, United States Postal Service, 475 L'Enfant Plaza SW, Room 8650, Washington, DC 20260–5242. Copies of all written comments will be available for public inspection and photocopying between 8 a.m. and 4:45 p.m., Monday through Friday, at the above address.

FOR FURTHER INFORMATION CONTACT: Betty E. Sheriff, (202) 268–2608.

SUPPLEMENTARY INFORMATION: The Postal Service has, in various stages of development, a number of employee survey processes that are intended to help improve postal operations, employee-management relations and communications, and the leadership skills of managers and supervisors. These survey processes involve the collection of data from employees by means of printed questionnaires or by telephone interviews, tabulation and analysis of the responses, and feedback of the results to the particular manager or supervisor concerned. The manager or supervisor is then expected to develop and implement plans for improvement based upon the problems identified by the responding employees. While intended primarily for developmental purposes, some information also may be used to evaluate a manager or supervisor's success in improving the survey results over time. Records maintained as a result of the data collection contain primarily statistical information and do not identify individual respondents. They are retrieved by reference to a particular manager, supervisor, or work location.

Two examples of surveys that relate to identifiable managers or supervisors are the ''Employee Feedback'' questionnaire, in which employees are asked to rate their supervisors, and the ''360 Degree Feedback'' instrument, which is completed by a manager, and his superiors, peers, and subordinates. Respondents to the 360 Degree questionnaire are asked to rate numerically the extent to which the manager has exhibited certain job-related behaviors. In all instances, respondents participate in these surveys voluntarily and anonymously. The results are tabulated and provided to the manager or supervisor in statistical form. The manager or supervisor is instructed how to use the information as a tool for improving his or her leadership skills. Survey results are reported and maintained by reference to the manager's or supervisor's name and social security number.

The Postal Service also periodically asks its employees to complete the Employee Opinion Survey. This survey contains questions that concern a particular work location rather than particular managers or supervisors. The questions cover general topics such as leadership and supervision, communication practices, treatment of employees, working conditions, and attention to quality. As with the other surveys, care is taken to preserve the anonymity of the employees surveyed. Managers and supervisors receive the results in the form of ratings for their own offices. They are instructed to analyze the results, share them with their employees, and prepare a list of strengths and opportunities for improvement from which an action plan may be developed and monitored. Because the results of the Employee Opinion Survey are reported and kept by work location, rather than by an individual manager or supervisor's name or other personal identifier, the information is not maintained or retrieved in a manner that prompts its establishment as a Privacy Act system of records. Since, however, there is the possibility, as noted above, that survey results for a specific work location may become associated with the responsible manager and may also be used in evaluating the manager's progress in implementing an action plan, the Postal Service deems it appropriate to include results of the Employee Opinion Survey in this system of records.

Maintenance of these records is not expected to have a significant effect on individual privacy rights. Individual respondents to the various surveys are assured anonymity. Information kept is limited to aggregate ratings and analyses associated with a particular work location or manager or supervisor. Managers and supervisors are provided the survey results that relate to themselves or to the work locations for which they are responsible. Because the survey results are intended for internal, developmental use, only three of the following Postal Service's general routine uses are being applied to this system of records: Disclosure to a Postal Service contractor, litigation, or storage. The information will be kept in a secured environment, with automated data processing (ADP) physical and administrative security and technical software applied to information on computer media. Contractors who maintain information collected by this system will be made subject to subsection (m) of the Privacy Act and be required to apply appropriate protections subject to audit and inspection by the Postal Inspection Service.

Pursuant to 5 U.S.C. 552a(e)(11), interested persons are invited to submit written data, views, or arguments on this proposal. A report of the following proposed system has been sent to Congress and to the Office of Management and Budget for their evaluation.

USPS 120.154

SYSTEM NAME:

Personnel Records—Employee Survey Process System Records, USPS 120.154.

SYSTEM LOCATIONS:

Human Resources at Headquarters, and at a contractor site.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Supervisors and managers who are rated under an employee survey process or have responsibility for a rated work location.

CATEGORIES OF RECORDS IN THE SYSTEM:

Work location, name and social security number of manager or supervisor, aggregate data and analyses of data, and national feedback reports.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

39 U.S.C. 401, 1001.

PURPOSE(S):

To improve the quality of postal services, employee-management

relations, and communication between managers and employees by soliciting employee feedback on job-related issues; to provide management and supervisors with information needed to improve their leadership skills; and to provide information for evaluating manager and supervisor performance.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

General routine use statements b, f, and g listed in the prefatory statement at the beginning of the Postal Service's published system notices apply to this system.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Paper and computer storage media.

RETRIEVABILITY:

Some survey information in the system is retrieved only by work location. Other information is retrieved by manager or supervisor name or social security number.

SAFEGUARDS:

Hardcopy records are maintained in a secured environment, with access limited to those individuals whose official duties require such access. Access to automated records is restricted by authorized user identification codes. Information on computer storage media maintained at a contractor site is protected by ADP physical security, technical software, and administrative security subject to audit and inspection by the Postal Inspection Service.

RETENTION AND DISPOSAL:

a. Employee Opinion Survey Process Records—Retain for 20 years. Destroy paper records by shredding or burning. Destroy computer records by erasure or degaussing.

b. Management Development Process Records: (1) Paper Survey Feeder Records—Cut off at the end of the calendar year and destroy by shredding or burning 3 years from cutoff date; (2) Computer Records—Retain for 20 years and then erase or degauss.

SYSTEM MANAGER(S) AND ADDRESS:

Vice President, Human Resources, United States Postal Service, 475 L'Enfant PLZ SW, Washington DC 20260–4200.

NOTIFICATION PROCEDURE:

Individuals wanting to know whether information about them is maintained in this system of records must address inquiries in writing to the system manager.

RECORD ACCESS PROCEDURES:

Requests for access must be made in accordance with the notification procedure above and the Postal Service Privacy Act regulations regarding access to records and verification of identity under 39 CFR 266.6.

CONTESTING RECORD PROCEDURES:

See Notification Procedure and Record Access Procedures above.

RECORD SOURCE CATEGORIES:

Postal employees.

Stanley F. Mires,

Chief Counsel, Legislative.

[FR Doc. 95–23134 Filed 9–18–95; 8:45 am]

BILLING CODE 7710–12–P

SECURITIES AND EXCHANGE COMMISSION

Forms Under Review by Office of Management and Budget

Agency Clearance Officer: Michael E. Bartell, (202) 942–8800.

Upon written request copy available from: Securities and Exchange Commission, Office of Filings and Information Services, Washington, D.C. 20549.

Extensions:

Form N–8A—File No. 270–135
Rule 6c–6—File No. 270–160
Proposed Rule 0–5—File No. 270–378

Notice is hereby given that pursuant to the Paperwork Reduction Act of 1980 (44 U.S.C. §§ 3501 *et seq.*), the Securities and Exchange Commission (''Commission'') has submitted requests for approval of extension for the following:

Form N–8A is the form that investment companies file with the Commission pursuant to Section 8(a) of the Investment Company Act of 1940 (''1940 Act''), which provides that an investment company may register by filing with the Commission a notification of registration. It is estimated that 610 respondents file form N–8A annually. The form requires approximately one hour of reporting per respondent annually.

Rule 6c–6 continues exemptive relief granted by Commission order to certain investment companies that responded to Internal Revenue Service Revenue Ruling 81–225 (September 25, 1981) by organizing new companies and substituting them for existing companies without prior Commission approval. No respondents incur a burden complying with the rule.

Proposed Rule 0–5 under the 1940 Act would establish an expedited review procedure for certain exemptive applications filed by registered investment companies with the Commission. It is estimated that 60 respondents may expend an estimated 300 total burden hours annually meeting the proposed requirements for receiving expedited review of their exemptive applications.

General comments regarding the estimated burden hours should be directed to the OMB Clearance Officer at the address below. Any comments concerning the accuracy of the estimated average burden hours for compliance with Commission rules and forms should be directed to Michael E. Bartell, Associate Executive Director, Office of Information Technology, Securities and Exchange Commission, 450 Fifth Street, N.W., Washington, D.C. 20549 and Clearance Officer, Project Numbers: 3235–0175 (Form N–8A), 3235–0245 (Rule 6c–6), and 3235–0432 (Proposed Rule 0–5), Office of Management and Budget, Room 3208, New Executive Office Building, Washington, D.C. 20503.

Dated: September 11, 1995.

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 95–23166 Filed 9–18–95; 8:45 am]

BILLING CODE 8010–01–M

[Rel. Nos. 33–7215; 34–36220]

Changes and Corrections to EDGAR Phase-In List

AGENCY: Securities and Exchange Commission.

ACTION: Notice.

SUMMARY: The Commission is publishing a list of changes and corrections to the EDGAR phase-in list for companies whose filings are processed by the Division of Corporation Finance.

FOR FURTHER INFORMATION CONTACT: Sylvia J. Reis, Assistant Director, CF EDGAR Policy, Division of Corporation Finance at (202) 942–2940.

SUPPLEMENTARY INFORMATION: In connection with the adoption of the final rules fully implementing the Electronic Data Gathering, Analysis, and Retrieval (''EDGAR'') system, on December 19, 1994 the Commission published a list of companies whose filings are processed by the Division of Corporation Finance to place registrants on notice as to when they would become subject to mandated electronic

filing.[1] The registrants were divided into ten groups, all of which will be phased in by May 1996. Rule 901 of Regulation S–T[2] provides that registrants may request a change to their assigned phase-in dates. Such requests may be granted pursuant to delegated authority. In addition, modifications are made to the list to reflect name changes, corporate restructurings, the addition of new entities, and similar factors.

Changes to the Division of Corporation Finance phase-in list are published from time to time in the SEC News Digest. The Commission today is publishing a comprehensive list of all changes in the Division of Corporation Finance phase-in group assignments made since the phase-in list was published in December 1994. This publication supersedes the last comprehensive list of changes published in the Federal Register on April 12, 1995 (Securities Act Release No. 7156). This procedure will be repeated from time to time, in order to further notify the public of changes to the list. A change to a company's phase-in date is of particular importance to persons or entities filing documents with respect to that company, since generally such persons must file electronically with the company become subject to mandated electronic filing.[3]

CHANGES FROM CORPORATION FINANCE EDGAR PHASE-IN LIST AS PUBLISHED IN SECURITIES ACT RELEASE NO. 7122

[December 19, 1994]

Name	CIK No.	Former group	New group
202 DATA SYSTEMS INC /PA/	718246	CF–08	REMOVE
3DO CO	898441	NONE	CF–10
3 D SYSTEMS CORP	910638	NONE	CF–10
625 LIBERTY AVENUE CORP	915893	NONE	CF–10
7TH LEVEL INC	920038	NONE	CF–10
A PLUS COMMUNICATIONS INC /TN/	908526	NONE	CF–10
AAA NET REALTY FUND XI LTD	924576	NONE	CF–10
AAMES CAPITAL CORP	913951	NONE	CF–10
AASCHE TRANSPORTATION SERVICES INC	927809	NONE	CF–10
ABBEY NATIONAL TREASURY SERVICES PLC/ENG	931061	NONE	CF–10
ABR INFORMATION SERVICES INC	920985	NONE	CF–10
ABSOLUTE ENTERTAINMENT INC	898739	NONE	CF–10
ABT BUILDING PRODUCTS CORP	902476	NONE	CF–10
ACACIA RESEARCH CORP	934549	CF–10	CF–08
ACCESS HEALTHNET INC/DE	911403	NONE	CF–10
ACCUGRAPH CORP	811703	CF–07	REMOVE
ACCUHEALTH INC	840401	CF–06	CF–10
ACCUSTAFF INC	924646	NONE	CF–10
ACME BOOT CO INC	918250	NONE	CF–10
ACME HOLDINGS INC	899824	NONE	CF–10
ACME METALS INC /DE/	002093	CF–04	CF–04
Change to ACME METALS INC /DE/	883702	CF–04	CF–04
ACORDIA INC /DE/	863881	NONE	CF–10
ACRES GAMING INC	912601	NONE	CF–10
ACR GROUP INC	711307	NONE	CF–07
ACT III BROADCASTING INC /DE/	914029	NONE	CF–10
ACT III CINEMAS INC	938342	NONE	CF–10
ACT MANUFACTURING INC	937971	NONE	CF–10
ACT NETWORKS INC	942132	NONE	CF–10
ACTIVE APPAREL GROUP INC	934795	NONE	CF–10
ADCO TECHNOLOGIES INC	934649	NONE	CF–10
ADFLEX SOLUTIONS INC	925743	NONE	CF–10
ADSONLY GROUP INC	943142	NONE	CF–10
ADTRAN INC	926282	NONE	CF–10
ADVANCED DEPOSITION TECHNOLOGIES INC	909963	NONE	CF–10
ADVANCED MEDIA INC	932779	NONE	CF–10
ADVANCED MEDICAL DYNAMICS INC	823314	CF–10	CF–10
Change to ADVANCED FINANCIAL INC	823314	CF–10	CF–10
ADVANCED SURGICAL INC	887893	NONE	CF–10
ADVANCED TECHNOLOGY MATERIALS INC	912841	NONE	CF–10
ADVANCED VOICE TECHNOLOGIES INC	932694	NONE	CF–10
ADVANTA MORTGAGE CONDUIT SERVICES INC	901833	NONE	CF–10
ADVOCAT INC	919956	NONE	CF–10
AEGIS CONSUMER FUNDING GROUP INC	932278	NONE	CF–10
AERO SERVICES INTERNATIONAL INC	350200	NONE	CF–06
AEROSPACE CREDITORS LIQUIDATING TRUST	908258	NONE	CF–10
AES CHINA GENERATING CO LTD	916792	NONE	CF–10
AES CORP	874761	NONE	CF–10
AETRIUM INC	908598	NONE	CF–10

[1] *See* Release No. 33–7122 (December 19, 1994) [59 FR 67752]. The timing for each phase-in group was included in that release as Appendix A, and the phase-in list as Appendix B. As is true with all rules of the Commission, persons making filings with the Commission are responsible for apprising themselves of their new obligations associated with filing on the EDGAR system. While the Commission attempts to contact registrants in each phase-in group by furnishing a copy of the EDGAR Filer Manual and EDGARLink software prior to phase-in, filers will not be relieved of their electronic filing obligations in the absence of such notification.

[2] 17 CFR 232.901.

[3] Rule 901(b) provides that a party making a filing pursuant to Section 13 or 14 of the Securities Exchange Act of 1934 [15 U.S.C. 78m or 78n, respectively] with respect to a registrant that has become subject to mandated electronic filing is required to submit that filing in electronic format. Consequently, persons filing a Schedule 13D or 13G, a proxy statement, or tender offer material with respect to an electronic filer are required to make such filings electronically.

CHANGES FROM CORPORATION FINANCE EDGAR PHASE-IN LIST AS PUBLISHED IN SECURITIES ACT RELEASE NO. 7122—Continued

[December 19, 1994]

Name	CIK No.	Former group	New group
AFC CABLE SYSTEMS INC	913360	NONE	CF–10
AFFILIATED NEWSPAPERS INVESTMENTS INC	918943	NONE	CF–10
AFFINITY GROUP INC	910560	NONE	CF–10
AFFYMAX N V	875133	CF–10	REMOVE
AFG RECEIVABLES CORP	927655	NONE	CF–10
AFGL INTERNATIONAL INC	914435	NONE	CF–10
AFP IMAGING CORP	319126	CF–06	CF–09
AFTERMARKET TECHNOLOGY CORP	933405	NONE	CF–10
AG ASSOCIATES INC	942124	NONE	CF–10
AG-CHEM EQUIPMENT CO INC	935503	NONE	CF–10
AGES HEALTH SERVICES INC	908516	NONE	CF–10
AG HOLDINGS INC /WA/	917300	NONE	CF–10
AGREE REALTY CORP	917251	NONE	CF–10
AGRI-NUTRITION GROUP LTD	922814	NONE	CF–10
AGRIPOST INC	313997	CF–06	REMOVE
AID AUTO STORES INC /DE/	937599	NONE	CF–10
AILEEN INC	002904	CF–06	CF–10
AIM GROUP INC	928032	NONE	CF–10
AIM TECHNOLOGY INC	928428	NONE	CF–10
AIRPORT SYSTEMS INTERNATIONAL INC	914398	NONE	CF–10
AIR TRANSPORTATION HOLDING COMPANY INC	353184	CF–07	CF–09
AK STEEL CORP	918192	NONE	CF–10
AK STEEL HOLDING CORP	918160	NONE	CF–10
ALABAMA NATIONAL BANCORPORATION	926966	NONE	CF–10
ALAFIRST BANCSHARES INC	870382	CF–10	REMOVE
Change to BNF BANCORP INC	870382	CF–10	REMOVE
ALAMO GROUP INC	897077	NONE	CF–10
ALASKA NORTHWEST PROPERTIES INC	313809	CF–07	CF–08
ALBEMARLE CORP	915913	NONE	CF–10
ALBION BANC CORP	899654	NONE	CF–10
ALCO HEALTH DISTRIBUTION CORP /DE/	855042	CF–10	CF–04
Change to AMERISOURCE DISTRIBUTION CORP	855042	CF–10	CF–04
ALDEN JOHN FINANCIAL CORP	822079	NONE	CF–10
ALDILA INC	902272	NONE	CF–10
ALERT CENTRE INC	915867	NONE	CF–10
ALL AMERICAN BOTTLING CORP	825811	NONE	CF–10
ALL AMERICAN TELEVISION INC	783265	CF–06	CF–06
Change to ALL AMERICAN COMMUNICATIONS INC	783265	CF–06	CF–06
ALLEGHENY GENERATING CO	774459	CF–08	CF–06
ALLEN ETHAN INC	003711	NONE	CF–10
ALLERGAN LIGAND RETINOID THERAPEUTICS INC	934592	NONE	CF–10
ALLIANCE FARMS COOPERATIVE ASSOCIATION	927536	NONE	CF–10
ALLIANCE SEMICONDUCTOR CORP/DE/	913293	NONE	CF–10
ALLIED DIGITAL TECHNOLOGIES CORP	933151	NONE	CF–10
ALLIED HOLDINGS INC	909950	NONE	CF–10
ALLIED LIFE FINANCIAL CORP	912154	NONE	CF–10
ALLISON ENGINE CO INC	916254	NONE	CF–10
ALLMINE INC	932008	NONE	CF–10
ALL PRO PRODUCTS INC	906600	NONE	CF–10
ALLSTATE CORP	899051	NONE	CF–10
ALL STATE PROPERTIES LP	745543	CF–07	CF–10
ALLTEL GEORGIA COMMUNICATIONS CORP	922328	NONE	CF–10
ALLTRISTA CORP	895655	NONE	CF–10
ALOE VERA NATUREL INC /MN/	917246	NONE	CF–10
ALPHA BETA CO	880800	NONE	CF–04
ALPHA BETA TECHNOLOGY INC	841168	NONE	CF–10
ALPHA HOSPITALITY CORP	906780	NONE	CF–10
ALTAI INC	796313	CF–07	CF–10
ALTERNATIVE RESOURCES CORP	920521	NONE	CF–10
ALUMAX INC	912600	NONE	CF–10
AMCON DISTRIBUTING CO	928465	NONE	CF–10
AMERIBANC INVESTORS GROUP	068336	CF–06	CF–09
AMERICAN APARTMENT COMMUNITIES INC	925927	NONE	CF–10
AMERICAN ASSET ADVISERS TRUST INC	913957	NONE	CF–10
AMERICAN BINGO & GAMING CORP	931683	NONE	CF–10
AMERICAN BUILDINGS CO /DE/	799208	NONE	CF–10
AMERICAN CINEMASTORES INC	908338	NONE	CF–10
AMERICAN CLASSIC VOYAGES CO	315136	NONE	CF–10
AMERICAN COMMUNICATIONS SERVICES INC	932140	NONE	CF–10

CHANGES FROM CORPORATION FINANCE EDGAR PHASE-IN LIST AS PUBLISHED IN SECURITIES ACT RELEASE NO. 7122—Continued

[December 19, 1994]

Name	CIK No.	Former group	New group
AMERICAN CORPORATE ACCRUALS INC	924641	NONE	CF–10
AMERICAN CREDIT OPTICAL INC /DE/	819913	CF–08	CF–08
Change to HALLMARK FINANCIAL SERVICES INC	819913	CF–08	CF–08
AMERICAN DIVERSIFIED GROUP INC	919742	NONE	CF–10
AMERICAN DRUG CO	922408	NONE	CF–10
AMERICAN EAGLE OUTFITTERS INC	919012	NONE	CF–10
AMERICAN ELECTRONIC COMPONENTS INC	920426	NONE	CF–10
AMERICAN EXPRESS MASTER TRUST SERIES 1993	921029	NONE	CF–10
AMERICAN FAMILY RESTAURANTS INC	925779	NONE	CF–10
AMERICAN FILM GROUP INC /FL/	932468	NONE	CF–10
AMERICAN FUEL CORP	912873	NONE	CF–10
AMERICAN HEALTHCARE INC/DE	704415	NONE	CF–10
Change to AMERICAN HEALTHCORP INC	704415	NONE	CF–10
AMERICAN HOMESTAR CORP	922812	NONE	CF–10
AMERICAN INCOME HOLDING INC	882322	CF–10	REMOVE
AMERICAN INTERNATIONAL CONSTRUCTION INC	933724	NONE	CF–10
AMERICAN INTERNATIONAL PETROLEUM CORP	799119	CF–06	CF–07
AMERICAN MIDLAND CORP	066052	CF–06	CF–09
AMERICAN MOBILE SATELLITE CORP	913665	NONE	CF–10
AMERICAN MORTGAGE INVESTORS TRUST II	914023	NONE	CF–10
AMERICAN MORTGAGE SECURITIES INC	863957	CF–10	REMOVE
AMERICAN OILFIELD DIVERS INC	906520	NONE	CF–10
AMERICAN ONCOLOGY RESOURCES INC /DE/	943061	NONE	CF–10
AMERICAN ONLINE INC	883780	NONE	CF–10
Change to AMERICAN ONLINE INC	883780	NONE	CF–10
AMERICAN PAGING INC	916065	NONE	CF–10
AMERICAN PREMIER GROUP INC	933537	CF–10	CF–04
AMERICAN PUBLISHING CO	868512	NONE	CF–10
AMERICAN QUALITY MANUFACTURING CORP	927237	NONE	CF–10
AMERICAN RADIO SYSTEMS CORP	943581	NONE	CF–10
AMERICAN RECREATION CO HOLDINGS INC	913773	NONE	CF–10
AMERICAN REPUBLIC REALTY FUND I	711512	CF–06	CF–08
AMERICAN RESTAURANT GROUP HOLDINGS INC	917540	NONE	CF–10
AMERICAN SENSORS INC	912090	NONE	CF–10
AMERICAN SOUTHWEST FINANCIAL SECURITIES CORP	912957	NONE	CF–10
AMERICAN TAX EXEMPT BOND TRUST	916824	NONE	CF–10
AMERICAN TECHNOLOGY CORP /DE/	924383	NONE	CF–10
AMERICAN TELECASTING INC/DE/	913271	NONE	CF–10
AMERICAN TOYS INC	912083	NONE	CF–10
AMERICAN VIDEO CLEARING HOUSE INC	837037	CF–09	REMOVE
AMERICAN WHITE CROSS INC	887622	NONE	CF–10
AMERICO LIFE INC	908139	NONE	CF–10
AMERIFED FINANCIAL CORP	874735	CF–10	REMOVE
AMERIGAS PARTNERS LP	932628	NONE	CF–10
AMERIGON INC	903129	NONE	CF–10
AMERILINK CORP	924774	NONE	CF–10
AMERISTAR CASINOS INC	912145	NONE	CF–10
AMERITECH CAPITAL FUNDING CORP	858662	NONE	CF–10
AMITY BANCSHARES INC /DE	879984	CF–10	REMOVE
AMNEX INC	793526	NONE	CF–10
AMPACE CORP	935678	NONE	CF–10
AMRECORP REALTY FUND II	745061	CF–09	CF–08
AMRECORP REALTY FUND III	776813	CF–09	CF–08
AMTRAN INC	898904	NONE	CF–10
AMTRUST CAPITAL CORP	934541	NONE	CF–10
AMWEST ENVIRONMENTAL GROUP INC	941813	NONE	CF–10
ANADIGICS INC	940332	NONE	CF–10
ANALYTICAL NURSING MANAGEMENT CORP	896262	NONE	CF–10
ANCHOR GAMING	914923	NONE	CF–10
ANCOR COMMUNICATIONS INC /MN/	920636	NONE	CF–10
ANDEAN DEVELOPMENT CORP	943184	NONE	CF–10
ANDOVER BANCORP INC	810589	CF–07	CF–08
ANDYNE COMPUTING LTD	930708	NONE	CF–10
ANESTA CORP /DE/	915916	NONE	CF–10
ANGELES HOUSING CONCEPTS INC	870561	CF–10	REMOVE
ANICOM INC	935802	NONE	CF–10
ANIKA RESEARCH INC	898437	NONE	CF–10
ANTEC CORP	908610	NONE	CF–10
ANTHEM ELECTRONICS INC /DE/	727120	CF–05	REMOVE

CHANGES FROM CORPORATION FINANCE EDGAR PHASE-IN LIST AS PUBLISHED IN SECURITIES ACT RELEASE NO. 7122—Continued

[December 19, 1994]

Name	CIK No.	Former group	New group
APARTMENT INVESTMENT & MANAGEMENT CO	922864	NONE	CF–10
APOGEE INC	915859	NONE	CF–10
APPAREL VENTURES INC	925866	NONE	CF–10
APPLIED CELLULAR TECHNOLOGY INC	924642	NONE	CF–10
APPLIED DIGITAL ACCESS INC	919048	NONE	CF–10
APPLIED INNOVATION INC	798399	NONE	CF–10
APPLIED SCIENCE & TECHNOLOGY INC	912842	NONE	CF–10
APPLIED VOICE TECHNOLOGY INC /WA/	931784	NONE	CF–10
APPLIX INC /MA/	932112	NONE	CF–10
APPS DENTAL INC	941553	NONE	CF–10
APOLLO GROUP INC	929887	NONE	CF–07
APROGENEX INC	907285	NONE	CF–10
APTARGROUP INC	896622	NONE	CF–10
AQUA CARE SYSTEMS INC /DE/	910566	NONE	CF–10
AQUAGENIX INC/DE	923604	NONE	CF–10
AQUAJET CORP	936807	NONE	CF–10
AQUILA GAS PIPELINE CORP	911535	NONE	CF–10
ARCH LEASING CORP	925555	NONE	CF–10
ARCH LEASING CORP TRUST	925556	NONE	CF–10
ARCH PETROLEUM INC	722144	CF–06	CF–06
Change to ARCH PETROLEUM INC /NEW/	320678	CF–06	CF–06
ARCSYS INC	943892	NONE	CF–10
ARDEN INDUSTRIAL PRODUCTS INC	916835	NONE	CF–10
ARDEN INTERNATIONAL KITCHENS INC	353575	CF–07	REMOVE
ARDOUR CORP	917860	NONE	CF–10
ARDUS CORP	941220	NONE	CF–10
ARETHUSA OFF SHORE LIMITED	867941	NONE	CF–10
ARGOSY GAMING CO	895385	NONE	CF–10
ARGUS PHARMACEUTICALS INC /DE/	854691	NONE	CF–10
ARIEL CORP	911167	NONE	CF–10
ARI HOLDINGS INC	792126	CF–06	CF–09
ARIL GROUP INC	765883	CF–08	REMOVE
ARIZONA CHARLIES INC	919565	NONE	CF–10
ARIZONA LAND INCOME CORP	830748	CF–06	CF–10
ARKANSAS BEST CORP /DE/	894405	NONE	CF–03
ARM FINANCIAL GROUP INC	910562	NONE	CF–10
ARRIS PHARMACEUTICAL CORP/DE/	913056	NONE	CF–10
ASANTE TECHNOLOGIES INC	913598	NONE	CF–10
ASB FINANCIAL CORP	915393	NONE	CF–10
ASCEND COMMUNICATIONS INC	921146	NONE	CF–10
ASECO CORP	896645	NONE	CF–10
ASPEN TECHNOLOGY INC /MA/	929940	NONE	CF–10
ASSISTED LIVING CONCEPTS INC	929994	NONE	CF–10
ASSOCIATED BUSINESS & COMMERCE INSURANCE CORP	928775	NONE	CF–10
ASSOCIATED COMMUNICATIONS CORP	230036	CF–05	REMOVE
ASSOCIATED ESTATES REALTY CORP	911635	NONE	CF–10
ASSOCIATED GROUP INC	931183	NONE	CF–10
ASTRO SCIENCES CORP	771642	NONE	CF–10
ASTRUM INTERNATIONAL CORP	914478	NONE	CF–10
ASV INC /MN/	926763	NONE	CF–10
ATC CAPITAL GROUP LTD	799900	NONE	CF–10
ATCHISON CASTING CORP	911115	NONE	CF–10
ATEL CASH DISTRIBUTION FUND VI LP	927569	NONE	CF–10
ATHENA ACQUISITIONS INC	929705	NONE	CF–10
ATLANTIC BEVERAGE CO INC	912609	NONE	CF–10
ATLANTIC COAST AIRLINES INC	904020	NONE	CF–10
ATLANTIC PROPERTIES LTD	943321	NONE	CF–10
ATLANTIS PLASTICS INC/FL	926196	NONE	CF–10
ATLAS AIR INC	941552	NONE	CF–10
ATLAS ENERGY FOR THE NINETIES PUBLIC NO 3 LTD	927804	NONE	CF–10
AUSPEX SYSTEMS INC	860749	NONE	CF–10
AUSTINS STEAKS & SALOON INC	930686	NONE	CF–10
AUTOCLAVE ENGINEERS INC	350067	CF–05	CF–06
AUTO BOND RECEIVABLES CORP	901179	NONE	CF–10
AUTOIMMUNE INC	879106	NONE	CF–10
AUTOMATED COMPLIANCE & TRAINING INC	850218	NONE	CF–10
AUTOMOBILE CREDIT FINANCE INC	891317	CF–10	CF–08
AUTOMOBLIE CREDIT FINANCE 1992–II	877665	CF–10	CF–08
AUTOMOBILE CREDIT FINANCE III	894373	CF–10	CF–08

CHANGES FROM CORPORATION FINANCE EDGAR PHASE-IN LIST AS PUBLISHED IN SECURITIES ACT RELEASE NO. 7122—Continued

[December 19, 1994]

Name	CIK No.	Former group	New group
AUTOMOBILE CREDIT FINANCE IV	905803	CF–10	CF–08
AUTOMOBILE CREDIT FINANCE V	916939	CF–10	CF–08
AUTOMOBILE CREDIT FINANCE VI	922053	CF–10	CF–08
AUTO ONE SECURITIZATION CORP	932131	NONE	CF–10
AVALON PROPERTIES INC	911536	NONE	CF–10
AVONDALE FINANCIAL CORP	908143	NONE	CF–10
AW COMPUTER SYSTEMS INC	319037	CF–08	CF–09
AXIS CAPITAL CORP	933978	NONE	CF–10
AYP CAPITAL INC	931750	NONE	CF–10
BABBAGES INC	833443	CF–05	REMOVE
BABY SUPERSTORE INC	927806	NONE	CF–10
BACK YARD BURGERS INC	901495	NONE	CF–10
BALDWIN BUILDERS	911642	NONE	CF–10
BALLARD MEDICAL PRODUCTS	723534	CF–06	CF–04
BALLY MANUFACTURING CORP	009435	CF–02	CF–02
Change to BALLY ENTERTAINMENT CORP	009435	CF–02	CF–02
BALLYS CASINO HOLDINGS INC	908611	NONE	CF–10
BALLYS GRAND INC /DE/	065297	NONE	CF–10
BALLYS HEALTH & TENNIS CORP	770944	NONE	CF–10
BALTIC INTERNATIONAL USA INC	918545	NONE	CF–10
BALTIMORE BANCORP	751926	CF–03	REMOVE
BANC ONE CREDIT CARD MASTER TRUST	930459	NONE	CF–10
BANC ONE STUDENT LOAN FUNDING CORP	925954	NONE	CF–10
BANCORP CONNECTICUT INC	921746	NONE	CF–10
BANCROFT PLAZA INC	909188	NONE	CF–10
BANK BUILDING CORP	907250	NONE	CF–10
BANK HOLDING CO	907584	NONE	CF–10
BANK JOS A CLOTHIERS INC /DE/	920033	NONE	CF–10
BANK MARYLAND CORP	819540	CF–05	CF–09
BANK OF KENTUCKY FINANCIAL CORP	934547	NONE	CF–10
BANK OF NEW YORK CO INC /NY/	904021	NONE	CF–10
BANK ONE COLUMBUS NA	930458	NONE	CF–10
BANK ONE TEXAS N A	905604	NONE	CF–10
BANK WEST FINANCIAL CORP	934598	NONE	CF–10
BANKATLANTIC BANCORP INC	921768	NONE	CF–10
BANYAN MORTGAGE INVESTORS L P III /IL/	802678	CF–05	REMOVE
BAOA INC	923771	NONE	CF–10
BARBERS HAIRSTYLING FOR MEN & WOMEN INC	926202	NONE	CF–10
BARRISTER INFORMATION SYSTEMS CORP	754128	CF–06	CF–09
BASQUE COUNTRY	928594	NONE	CF–10
BAY APARTMENT COMMUNITIES INC	915912	NONE	CF–10
BAY AREA HOLDINGS INC	060798	CF–08	CF–10
BAY AREA WAREHOUSE STORES INC	932721	NONE	CF–04
BCB FINANCIAL SERVICES CORP /PA/	920865	NONE	CF–10
BDM INTERNATIONAL INC /DE	870763	CF–10	CF–07
BEACH PATROL INC	924899	NONE	CF–10
BEACON PROPERTIES CORP	920114	NONE	CF–10
BEAZER HOMES USA INC	915840	NONE	CF–10
BECKER GAMING INC	920376	NONE	CF–10
BEDFORD BANCSHARES INC	921435	NONE	CF–10
BEI HOLDINGS LTD /DE/	225569	CF–05	CF–05
Change to AMRESCO INC	225569	CF–05	CF–05
BELCOR INC	099286	CF–06	CF–09
BELDEN & BLAKE CORP	734778	CF–06	CF–06
Change to BELDEN & BLAKE CORP /OH/	734778	CF–06	CF–06
BELL MARKETS INC	880801	NONE	CF–04
BELL MICROPRODUCTS INC	900708	NONE	CF–10
BELMONT HOMES INC	934651	NONE	CF–10
BENCHMARK BIOMEDICAL INC	918025	NONE	CF–10
BENEDEK BROADCASTING CORP	923027	NONE	CF–10
BENEFICIAL CALIFORNIA INC /DE/	917853	NONE	CF–10
BENIHANA NATIONAL CORP	715384	CF–06	CF–06
Change to BENIHANA INC	935226	CF–06	CF–06
BENSON FINANCIAL CORP	927717	NONE	CF–10
BERG ELECTRONICS INC	904899	NONE	CF–10
BERRY & BOYLE DEVELOPMENT PARTNERS III	841239	CF–10	CF–08
BERRY PLASTICS CORP	919463	NONE	CF–10
BEST POWER TECHNOLOGY INC	906054	CF–10	CF–08
BETTIS CORP /DE/	919964	NONE	CF–10

CHANGES FROM CORPORATION FINANCE EDGAR PHASE-IN LIST AS PUBLISHED IN SECURITIES ACT RELEASE NO. 7122—Continued

[December 19, 1994]

Name	CIK No.	Former group	New group
BEVERLY NATIONAL CORP	742275	CF–08	CF–09
BFP HOLDINGS CORP	924146	NONE	CF–10
BIG ENTERTAINMENT INC	912544	NONE	CF–10
BIG FLOWER PRESS INC	906306	NONE	CF–10
BIG SKY BANCORP INC	923285	NONE	CF–10
BIG SKY TRANSPORTATION CO	313522	CF–07	CF–09
BIG SMITH BRANDS INC	931688	NONE	CF–10
BIOCRYST PHARMACEUTICALS INC	882796	NONE	CF–10
BIOLASE TECHNOLOGY INC	811240	NONE	CF–10
BIOPLASTY INC	040944	CF–07	REMOVE
BIOSEPRA INC	919015	NONE	CF–10
BK I REALTY INC	783462	CF–09	CF–07
BK II PROPERTIES INC	783463	CF–09	CF–07
BK III RESTAURANTS INC	783464	CF–09	CF–07
BLACK HAWK GAMING & DEVELOPMENT CO INC	896495	NONE	CF–10
BLANCHE E W HOLDINGS INC	898438	NONE	CF–10
BLC FINANCIAL SERVICES INC	912737	NONE	CF–10
BLYTH INDUSTRIES INC	921503	NONE	CF–10
BLUE SKY MLS INC	939215	NONE	CF–07
BMC BANKCORP INC	702903	CF–05	REMOVE
BNSF CORP	934612	NONE	CF–04
BOARDWALK CASINO INC	915281	NONE	CF–10
BOCA RESEARCH INC	895642	NONE	CF–10
BOETTCHER WESTERN PROPERTIES II LTD	703152	CF–06	CF–08
BOETTCHER WESTERN PROPERTIES III LTD	716822	CF–06	CF–08
BOISE CASCADE OFFICE PRODUCTS CORP	938839	NONE	CF–10
BOLLE AMERICA INC /DE/	932422	NONE	CF–10
BOLLINGER INDUSTRIES INC	912894	NONE	CF–10
BOMBARDIER RECEIVABLES MASTER TRUST I	912542	NONE	CF–10
BORDEN CHEMICALS & PLASTICS OPERATING LIMITED PARTNERSHIP	933485	NONE	CF–10
BOONTON ELECTRONICS CORP	013191	CF–06	CF–10
BORDERS GROUP INC	940510	NONE	CF–10
BORG WARNER AUTOMOTIVE INC	908255	NONE	CF–10
BOS ENVIRONMENTAL INC	917134	NONE	CF–10
BOSTON CAPITAL TAX CREDIT FUND IV LP	913778	NONE	CF–10
BOSTON CHICKEN INC	894751	NONE	CF–10
BOSTON FINANCIAL APARTMENT PROPERTIES LTD	922319	NONE	CF–10
BOSTON FINANCIAL TAX CREDIT FUND VIII LP	911568	NONE	CF–10
BOSTON RESTAURANT ASSOCIATES INC	926295	NONE	CF–10
BOWLINE CORP	034682	CF–07	CF–08
BOYD BROS TRANSPORTATION INC	920907	NONE	CF–10
BOYD GAMING CORP	906553	NONE	CF–10
BRAE LAND CORP	940715	NONE	CF–10
BRANDT TECHNOLOGIES INC	896771	NONE	CF–10
BRASSIE GOLF CORP	916184	NONE	CF–10
BRAUVIN NET LEASE V INC	913762	NONE	CF–10
BREWER C HOMES INC	912153	NONE	CF–10
BRIDGEPORT MACHINES INC	931125	NONE	CF–10
BRIDGEVILLE FINANCIAL CORP	916299	NONE	CF–10
BRISTOL OAKS LP	930545	NONE	CF–10
BROADBAND TECHNOLOGIES INC /DE/	904898	NONE	CF–10
BROADCASTING PARTNERS INC	908663	NONE	CF–10
BROADCAST INTERNATIONAL INC	832411	CF–07	CF–09
BROCK CANDY CO	784275	CF–10	REMOVE
BROCK CONTROL SYSTEMS INC	897078	NONE	CF–10
BROCK EXPLORATION CORP	014399	CF–08	CF–10
BROCKWAY STANDARD HOLDINGS CORP	943897	NONE	CF–10
BRODERBUND SOFTWARE INC /DE/	812490	NONE	CF–10
BROOKS AUTOMATION INC	933974	NONE	CF–10
BROOKTREE CORP	764271	NONE	CF–10
BROWNE BOTTLING CO	825813	NONE	CF–10
BRYLANE INC	932698	NONE	CF–10
BRYLANE L P	912274	NONE	CF–10
BT ENERGY CORPORATION	716786	CF–07	CF–10
BTG INC /VA/	932279	NONE	CF–10
BUCKEYE CELLULOSE CORP	899597	NONE	CF–10
BUCKHEAD AMERICA CORP	909725	NONE	CF–10
BUDGET STORAGE ASSOCIATES I LP	790939	CF–08	REMOVE
BUGABOO CREEK STEAK HOUSE INC	919167	NONE	CF–10

CHANGES FROM CORPORATION FINANCE EDGAR PHASE-IN LIST AS PUBLISHED IN SECURITIES ACT RELEASE NO. 7122—Continued

[December 19, 1994]

Name	CIK No.	Former group	New group
BUILDING MATERIALS CORP OF AMERICA	927314	NONE	CF–10
BURGER KING INVESTORS MASTER LP	785994	CF–05	CF–05
Change to U S RESTAURANTS PROPERTIES MASTER LP	785994	CF–05	CF–05
BURLINGTON MOTOR HOLDINGS INC	912504	NONE	CF–10
BURLINGTON RESOURCES COAL SEAM GAS ROYALTY TRUST	906547	NONE	CF–10
BUSH BOAKE ALLEN INC	919998	NONE	CF–10
C & F FINANCIAL CORP	913341	NONE	CF–10
CABLEMAXX INC /DE	928507	NONE	CF–10
CABLEMAXX TEXAS INC	912891	NONE	CF–10
CAI WIRELESS SYSTEMS INC	914749	NONE	CF–10
CALA CO	880803	NONE	CF–04
CALA FOODS INC	838196	NONE	CF–04
CALCASIEU REAL ESTATE & OIL CO INC	352955	CF–08	CF–10
CALI REALTY L P	924901	NONE	CF–10
CALIFORNIA BELL INDUSTRIES INC	945489	NONE	CF–07
CALIFORNIA PETROLEUM TRANSPORT CORP	923649	NONE	CF–10
CALIFORNIA PRO SPORTS INC	899444	NONE	CF–10
CALIFORNIA PUBLIC EMPLOYEES RETIREMENT SYSTEM	919079	NONE	CF–10
CALLON PETROLEUM CO /DE/	942125	NONE	CF–10
CALPINE CORP	916457	NONE	CF–10
CAMBRIDGE SOUNDWORKS INC	919234	NONE	CF–10
CAMBRIDGE TECHNOLOGY PARTNERS MASSACHUSETTS INC	895462	NONE	CF–10
CAMCO INTERNATIONAL INC	913267	NONE	CF–10
CAMERA PLATFORMS INTERNATIONAL INC	775714	CF–07	CF–10
CAMERON ASHLEY INC	918858	NONE	CF–10
CAMERON FINANCIAL CORP /DE/	934884	NONE	CF–10
CAMPBELL STRATEGIC ALLOCATION FUND LP	910467	NONE	CF–10
CAMPO ELECTRONICS APPLIANCES & COMPUTERS INC	895693	NONE	CF–10
CANADIAN REYNOLDS METALS CO LTD	898442	NONE	CF–10
CANMAX INC /WY/	913659	NONE	CF–10
CANNONDALE CORP /DE/	930795	NONE	CF–10
CANTERBURY PARK HOLDING CORP	926761	NONE	CF–10
CAPCO AUTOMOTIVE PRODUCTS CORP	919549	NONE	CF–10
CAPITAL ONE FINANCIAL CORP	927628	NONE	CF–10
CAPITAL ONE MASTER TRUST	922869	NONE	CF–10
CAPITAL PREFERRED YIELD FUND III L P	914786	NONE	CF–10
CAPITAL RESOURCES REAL ESTATE PARTNERSHIP II	017294	CF–07	CF–08
CAPITOL QUEEN & CASINO INC	919566	NONE	CF–10
CAPITOL RESOURCES INC	017377	CF–08	REMOVE
CAPSTONE CAPITAL CORP	921767	NONE	CF–10
CAPSURE HOLDING CORP	837906	CF–06	CF–06
Change to CAPSURE HOLDINGS CORP	073313	CF–06	CF–06
CAPT CRAB INC	356622	CF–07	CF–07
Change to BAYPORT RESTAURANT GROUP INC	356622	CF–07	CF–07
CAPTEC FRANCHISE CAPITAL PARTNERS LP III	921794	NONE	CF–10
CARAUSTAR INDUSTRIES INC	825692	NONE	CF–10
CARBIDE GRAPHITE GROUP INC /DE	888918	NONE	CF–10
CARCO AUTO LOAN MASTER TRUST	873446	NONE	CF–07
CARDINAL REALTY SERVICES INC	903324	NONE	CF–10
CARDIVAN CO	919676	NONE	F–10
CAREADVANTAGE INC	937252	NONE	CF–10
CAREER HORIZONS INC	917673	NONE	CF–10
CAREERSTAFF UNLIMITED INC	922888	NONE	CF–10
CARELINE INC	912275	NONE	CF–10
CAREMARK INTERNATIONAL INC	890548	NONE	CF–10
CARENETWORK INC	867188	CF–10	REMOVE
CARLYLE GOLF INC	922867	NONE	CF–10
CARNEGIE BANCORP	915277	NONE	CF–10
CARROLLTON BANCORP	859222	NONE	CF–10
CASCADE FINANCIAL CORP	928911	NONE	CF–10
CASE CORP	922321	NONE	CF–10
CASE RECEIVABLES II INC	931152	NONE	CF–10
CASINO CASH INC	935702	NONE	CF–10
CASINO & CREDIT SERVICES INC	904902	NONE	CF–10
CASINO DATA SYSTEMS	898756	NONE	CF–10
CASINO MAGIC FINANCE CORP	914291	NONE	CF–10
CASINO RESOURCE CORP	899778	NONE	CF–10
CASINOS INTERNATIONAL INC	900138	NONE	CF–10
CASTLE GROUP INC	918543	NONE	CF–10

CHANGES FROM CORPORATION FINANCE EDGAR PHASE-IN LIST AS PUBLISHED IN SECURITIES ACT RELEASE NO. 7122—Continued

[December 19, 1994]

Name	CIK No.	Former group	New group
C ATS SOFTWARE INC	937266	NONE	CF–10
CBL & ASSOCIATES PROPERTIES INC	910612	NONE	CF–10
CB&T INC	357130	CF–08	CF–09
CCF HOLDING CO	943033	NONE	CF–10
C CUBE MICROSYSTEMS INC	919870	NONE	CF–10
CD RADIO INC	908937	NONE	CF–10
CDP TECHNOLOGIES INC	922520	NONE	CF–10
CDW COMPUTER CENTERS INC	899171	NONE	CF–10
CEC RESOURCES LTD	933435	NONE	CF–10
CECIL BANCORP INC	926865	NONE	CF–10
CELADON GROUP INC	865941	NONE	CF–10
CELEX GROUP INC	911323	NONE	CF–10
CELLEX BIOSCIENCES INC	704384	CF–07	CF–10
CELL GENESYS INC	865231	NONE	CF–10
CELLSTAR CORP	913590	NONE	CF–10
CELLTRONICS INC	740664	CF–07	CF–09
Change to R F INDUSTRIES LTD	740664	CF–07	CF–09
CENSTOR CORP /CA/	932094	NONE	CF–10
CENTENNIAL TECHNOLOGIES INC	919006	NONE	CF–10
CENTERPOINT PROPERTIES CORP	912893	NONE	CF–10
CENTEX CONSTRUCTION PRODUCTS INC	918646	NONE	CF–10
CENTRAL CAPITAL CORP /DE/	924707	NONE	CF–10
CENTRAL COAST BANCORP	921085	NONE	CF–10
CENTRAL EUROPEAN MEDIA ENTERPRISES LTD	925645	NONE	CF–10
CENTRAL MORTGAGE BANCSHARES INC /MO/	891286	NONE	CF–10
CENTRAL PENNSYLVANIA FINANCIAL CORP	769751	CF–05	REMOVE
CENTRAL RENTS INC	926845	NONE	CF–10
CENTRAL TRACTOR FARM & COUNTRY INC	928156	NONE	CF–10
CENTRAL VIRGINIA BANKSHARES INC	804561	NONE	CF–10
CENTURY CASINOS INC	911147	NONE	CF–10
CERPLEX GROUP INC	915870	NONE	CF–10
CFB BANCORP INC	932780	NONE	CF–10
CFS REAL ESTATE INVESTORS LTD	735585	CF–07	CF–10
CHAMPION CAPITAL CO L L C	931153	NONE	CF–10
CHAMPS ENTERTAINMENT INC	919862	NONE	CF–10
CHANCELLOR BROADCASTING CO	925744	NONE	CF–10
CHARTER FUNDING CORP	922919	NONE	CF–10
CHARTER FSB BANCORP INC	865160	CF–10	REMOVE
CHARTER GOLF INC	820774	CF–08	CF–08
Change to ASHWORTH INC	820774	CF–08	CF–08
CHARTWELL RE CORP	912047	NONE	CF–10
CHATEAU PROPERTIES INC	912393	NONE	CF–10
CHECKMATE ELECTRONICS INC	910320	NONE	CF–10
CHELMSFORD CAPITAL LTD	943657	NONE	CF–10
CHELSEA ATWATER INC /NV/	932127	NONE	CF–10
CHELSEA GCA REALTY INC	911215	NONE	CF–10
CHESAPEAKE ENERGY CORP	895126	NONE	CF–10
CHIC BY H I S INC	895519	NONE	CF–10
CHICAGO MINIATURE LAMP INC	942138	NONE	CF–10
CHICKS NATURAL INC	916303	NONE	CF–10
CHICOS FAS INC	897429	NONE	CF–10
CHILDROBICS INC	921685	NONE	CF–10
CHINA INTERNATIONAL TRUST & INVESTMENT CORP	908659	NONE	CF–10
CHS ELECTRONICS INC	924374	NONE	CF–10
CIBER INC	918581	NONE	CF–10
CIDCO INC	917639	NONE	CF–10
CIMA LABS INC	833298	NONE	CF–10
CINEMA RIDE INC	925956	NONE	CF–10
CINEMARK MEXICO USA INC	910280	NONE	CF–10
CINERGI PICTURES ENTERTAINMENT INC	922519	NONE	CF–10
CINTECH TELE MANAGEMENT SYSTEMS INC	926038	NONE	CF–10
CIRCLE K CORP /DE/	936287	NONE	CF–10
CITATION CORP /AL/	924648	NONE	CF–10
CITIBANK SOUTH DAKOTA NA STAN CRED CARD MAS TR I SER 1995–2	941709	NONE	CF–10
CITIBANK SOUTH DAKOTA NA STAN CRED CARD MAS TR I SER 1995–3	941707	NONE	CF–10
CITIBANK SOUTH DAKOTA NA STAN CRED CARD MAS TR I SER 1995–4	941702	NONE	CF–10
CIT GROUP SECURITIZATION CORP II	931494	NONE	CF–10
CITISAVE FINANCIAL CORP	942790	NONE	CF–10
CITYFED FINANCIAL CORP	744765	NONE	CF–10

CHANGES FROM CORPORATION FINANCE EDGAR PHASE-IN LIST AS PUBLISHED IN SECURITIES ACT RELEASE NO. 7122—Continued

[December 19, 1994]

Name	CIK No.	Former group	New group
CITY OF SEOUL	926302	NONE	CF–10
CKF BANCORP INC	930203	NONE	CF–10
CLAIRES STORES INC	034115	CF–05	CF–04
CLARK USA INC /DE/	898444	NONE	CF–10
CLASSICS INTERNATIONAL ENTERTAINMENT INC	894789	NONE	CF–10
CLEAN X PRESS INC /CO/	894847	NONE	CF–10
CLUB CORP INTERNATIONAL	929455	NONE	CF–10
CMAC INVESTMENT CORP	890926	NONE	CF–10
CMC INDUSTRIES INC	913270	NONE	CF–10
CMG INFORMATION SERVICES INC	914712	NONE	CF–10
CMI INDUSTRIES INC	911221	NONE	CF–10
CMS ENERGY MICHIGAN LIMITED PARTNERSHIP	937910	NONE	CF–05
CMS NOMECO OIL & GAS CO	946036	NONE	CF–07
CNB HOLDINGS INC	912566	NONE	CF–10
CNL AMERICAN PROPERTIES FUND INC	922981	NONE	CF–10
CNL FINANCIAL CORP	021193	CF–08	REMOVE
CNL INCOME FUND XV LTD	913057	NONE	CF–10
CNL INCOME FUND XVII LTD	943718	NONE	CF–10
CNL INCOME FUND XVIII LTD	943730	NONE	CF–10
COASTAL FINANCIAL CORP /DE/	935930	NONE	CF–10
COASTWIDE ENERGY SERVICES INC	913851	NONE	CF–10
COBRA GOLF INC	910072	NONE	CF–10
COBRA INDUSTRIES INC	911505	NONE	CF–10
COCENSYS INC	895034	NONE	CF–10
COCONUT CODE INC /FL/	908181	NONE	CF–10
COGENCO INTERNATIONAL INC	730729	NONE	CF–10
COGENTRIX ENERGY INC	917711	NONE	CF–10
COHERENT COMMUNICATIONS SYSTEMS CORP	921147	NONE	CF–10
COHESANT TECHNOLOGIES INC	928420	NONE	CF–10
COHO ENERGY INC	908797	NONE	CF–10
COIN BILL VALIDATOR INC	933020	NONE	CF–10
COLD METAL PRODUCTS INC	918653	NONE	CF–10
COLDWELL BANKER CORP	914067	NONE	CF–10
COLE KENNETH PRODUCTIONS INC	921691	NONE	CF–10
COLEMAN HOLDINGS INC	910387	NONE	CF–10
COLEMAN WOOD PRODUCTS INC	921429	NONE	CF–10
COLEMAN WORLDWIDE CORP	901038	NONE	CF–10
COLE TAYLOR FINANCIAL GROUP INC	721059	NONE	CF–10
COLONIAL PROPERTIES TRUST	909111	NONE	CF–10
COLOROCS CORP /GA/	789990	NONE	CF–10
COLUMBIA BANCORP	834105	NONE	CF–10
COLUMBIA HEALTHCARE CORP	860730	CF–01	CF–01
Change to COLUMBIA HCA HEALTHCARE CORP	860730	CF–01	CF–01
COLUMBUS REALTY TRUST	913602	NONE	CF–10
COMBINED COMPANIES INTERNATONAL CORP	911521	NONE	CF–10
COMCAST UK CABLE PARTNERS LTD	919957	NONE	CF–10
COMMONWEALTH ALUMINUM CORP	934747	NONE	CF–10
COMMONWEALTH INCOME & GROWTH FUND I	913141	NONE	CF–10
COMMONWEALTH INCOME & GROWTH FUND II	938322	NONE	CF–10
COMMONWEALTH INDUSTRIES CORP	022626	CF–05	CF–09
COMMUNICATIONS CENTRAL INC	914249	NONE	CF–10
COMMUNITY BANK SHARES OF INDIANA INC	933590	NONE	CF–10
COMMUNITY BANCSHARES INC /TN/	763585	CF–08	REMOVE
COMMUNITY BANKSHARES INC /GA/	927478	NONE	CF–10
COMMUNITY BANKSHARES INC /SC/	894508	NONE	CF–10
COMMUNITY FINANCIAL CORP /DE/	850606	NONE	CF–07
COMMUNITY FINANCIAL CORP /IL/	934858	NONE	CF–10
COMMUNITY INVESTORS BANCORP INC	930277	NONE	CF–10
COMMUNITY MEDICAL TRANSPORT INC	925602	NONE	CF–10
COMPUTER LEARNING CENTERS INC	943206	NONE	CF–10
COMPUTER MARKETPLACE INC	900475	NONE	CF–10
COMSTOCK TAILINGS CO INC	917558	NONE	CF–10
COM VU CORP	714281	CF–08	REMOVE
CONCENTRA CORP	933091	NONE	CF–10
CONCEPT TECHNOLOGIES GROUP INC	916485	NONE	CF–10
CONCORDE GAMING CORP	215503	CF–08	CF–09
CONCORD HEALTH GROUP INC	896499	NONE	CF–10
CONCORD HOLDING CORP	916610	NONE	CF–10
CONDEV LAND FUND II LTD	828744	CF–07	CF–10

CHANGES FROM CORPORATION FINANCE EDGAR PHASE-IN LIST AS PUBLISHED IN SECURITIES ACT RELEASE NO. 7122—Continued

[December 19, 1994]

Name	CIK No.	Former group	New group
CONDEV LAND GROWTH FUND 86 LTD	795280	CF–07	CF–10
CONGOLEUM CORP	023341	NONE	CF–10
CONGRESS STREET PROPERTIES INC	745770	CF–06	REMOVE
CONNECTICUT GENERAL REALTY INVESTORS L P	356456	CF–06	REMOVE
CONNECTICUT GENERAL REALTY INVESTORS II LP	716008	CF–06	REMOVE
CONSEP INC	914978	NONE	CF–10
CONSOLIDATED CAPITAL GROWTH FUND	201529	CF–05	CF–08
CONSOLIDATED CAPITAL INSTITUTIONAL PROPE 3	768890	CF–05	CF–08
CONSOLIDATED CAPITAL PROPERTIES III	317331	CF–05	CF–08
CONSOLIDATED CAPITAL PROPERTIES IV	355804	CF–09	CF–08
CONSOLIDATED CAPITAL PROPERTIES V	725614	CF–05	CF–08
CONSOLIDATED CAPITAL PROPERTIES VI	755908	CF–06	CF–08
CONSOLIDATED GRAPHICS INC /TX/	921500	NONE	CF–10
CONSOLIDATED ROYAL MINES INC	933157	NONE	CF–10
CONSOLIDATED STAINLESS INC	909726	NONE	CF–10
CONSO PRODUCTS CO	914448	NONE	CF–10
CONSULTING GROUP MANAGED FUTURES FUND LP	923660	NONE	CF–10
CONTEMPRI HOMES INC	897926	NONE	CF–10
CONTINENTAL AMERICAN TRANSPORTATION INC	866457	NONE	CF–10
CONTINENTAL CABLEVISION INC	355069	NONE	CF–04
CONTINENTAL CHOICE CARE INC	922488	NONE	CF–10
CONTINENTAL WASTE INDUSTRIES INC	876035	NONE	CF–07
CONTISECURITIES ASSET FUNDING CORP	917819	NONE	CF–10
CONVERGENT SOLUTIONS INC /NY/	811870	CF–06	REMOVE
CONVERSE INC	716934	NONE	CF–10
CONVERSION INDUSTRIES INC	766849	NONE	CF–10
COOPER CAMERON CORP	941548	NONE	CF–10
COOPERATIVE BANKSHARES INC	923529	NONE	CF–10
COPART INC	900075	NONE	CF–10
COPELCO CAPITAL FUNDING CORP II	930299	NONE	CF–10
CORNERSTONE IMAGING INC	909276	NONE	CF–10
CORPORATE ASSET BACKED CORP	916791	NONE	CF–10
CORPORATE PROPERTY ASSOCIATES 12 INC	912046	NONE	CF–10
CORRPRO COMPANIES INC /OH/	907072	NONE	CF–10
CORVITA CORP	925174	NONE	CF–10
COTY INC /DE/	939919	NONE	CF–10
COUNTRY STAR RESTAURANTS INC	911220	NONE	CF–10
COUNTY SEAT INC	933035	NONE	CF–10
COUNTY SEAT STORES INC	910112	NONE	CF–10
COVENANT TRANSPORT INC	928658	NONE	CF–10
CP FUNDING CORP	929701	NONE	CF–10
CP LTD PARTNERSHIP	931917	NONE	CF–10
CRA MANAGED CARE INC	942136	NONE	CF–10
CREATIVE COMPUTERS INC	937941	NONE	CF–10
CREATIVE MEDICAL DEVELOPMENT INC	919045	NONE	CF–10
CREATIVE PROGRAMMING & TECHNOLOGY VENTURES	913160	NONE	CF–10
CREE RESEARCH INC /NC/	895419	NONE	CF–10
CRESCENT AIRWAYS CORP	910614	NONE	CF–10
CRESCENT REAL ESTATE EQUITIES INC	918958	NONE	CF–10
CRESTMONT FINANCIAL CORP	864901	CF–10	REMOVE
CRONOS GLOBAL INCOME FUND XIV LP	891332	CF–10	CF–08
CRONOS GLOBAL INCOME FUND XV LP	912605	CF–10	CF–08
CROP GROWERS CORP	921584	NONE	CF–10
CROSSMANN COMMUNITIES INC	911644	NONE	CF–10
CROWN AMERICAN REALTY TRUST	905134	NONE	CF–10
CROWN LABORATORIES INC /DE/	847385	NONE	CF–10
CROWN PACIFIC PARTNERS L P	930735	NONE	CF–10
CRW FINANCIAL INC /DE	943809	NONE	CF–10
CSA INCOME FUND LIMITED PARTNERSHIP I–C	764628	CF–07	CF–09
CSA INCOME FUND LIMITED PARTNERSHIP I–D	764629	CF–07	CF–09
CSA INCOME FUND LIMITED PARTNERSHIP II	809224	CF–08	CF–09
CSA INCOME FUND LIMITED PARTNERSHIP III	831890	CF–08	CF–09
CSA INCOME FUND IV LIMITED PARTNERSHIP	858801	CF–08	CF–09
CSB FINANCIAL GROUP INC	940006	NONE	CF–10
CSC INDUSTRIES INC	806400	CF–04	CF–10
CS FIRST BOSTON STRUCTURED PRODUCTS CORP	920031	NONE	CF–10
CSI COMPUTER SPECIALISTS INC	923141	NONE	CF–10
CSL LIGHTING MANUFACTURING INC	916068	NONE	CF–10
CSX TRADE RECEIVABLES CORP	911703	NONE	CF–10

CHANGES FROM CORPORATION FINANCE EDGAR PHASE-IN LIST AS PUBLISHED IN SECURITIES ACT RELEASE NO. 7122—Continued

[December 19, 1994]

Name	CIK No.	Former group	New group
CUMBERLAND FEDERAL BANCORPORATION INC	830315	CF–09	REMOVE
CURTIS MATHES HOLDING CORP	755229	NONE	CF–10
CVD EQUIPMENT CORP	766792	CF–07	CF–10
CVD FINANCIAL CORP	906549	NONE	CF–10
CWMBS INC	906410	NONE	CF–10
CYBERONICS INC	864683	NONE	CF–10
CYCLO 3 PSS CORP	895319	NONE	CF–10
CYCLODEXTRIN TECHNOLOGIES DEVELOPMENT INC	922247	NONE	CF–10
CYPRUS AMAX FINANCE CORP	925132	NONE	CF–10
CYRIX CORP	867105	NONE	CF–10
CYTEC INDUSTRIES INC/DE/	912513	NONE	CF–10
CZECH INDUSTRIES INC /DE/	899627	NONE	CF–10
DADE INTERNATIONAL INC	942307	NONE	CF–10
DAIMLER BENZ AUTO GRANTOR TRUST 1993–A	911423	NONE	CF–10
DAIMLER BENZ VEHICLE RECEIVABLES CORP	924381	NONE	CF–10
DAIMLER BENZ VEHICLE TRUST 1994–A	924382	NONE	CF–10
DAINE INDUSTRIES INC	824845	CF–08	CF–10
DAINE INCOME PROPERTIES–86	813367	CF–09	REMOVE
DAINE PENSION INVESTORS 84	726370	CF–09	REMOVE
DAINE PENSION INVESTORS 85	756765	CF–09	REMOVE
DAIN REAL ESTATE PARTNERS I LP	715764	CF–09	REMOVE
DAKOTA EQUITIES LTD	915401	NONE	CF–10
DAKTRONICS INC /SD/	915779	NONE	CF–10
DAL TILE INTERNATIONAL INC	906611	NONE	CF–10
DAN RIVER INC /GA/	914384	NONE	CF–10
DARDEN RESTAURANTS INC	940944	NONE	CF–10
DARLING INTERNATIONAL INC	916540	NONE	CF–10
DATA SOUTH COMPUTER CORP	722582	CF–06	REMOVE
DATA SYSTEMS NETWORK CORP	926849	NONE	CF–10
DATASTREAM SYSTEMS INC	938481	NONE	CF–10
DAVE & BUSTERS INC	943823	NONE	CF–10
DAVEL COMMUNICATIONS GROUP INC	911016	NONE	CF–10
DAVIDSON & ASSOCIATES INC	897722	NONE	CF–10
DAVIN ENTERPRISES INC	815017	CF–08	CF–10
DB PAN AMERICAN ENERGY CORP	095626	CF–09	CF–08
Change to SUNBASE ASIA INC	095626	CF–09	CF–08
DDI PHARMACEUTICALS INC	109657	CF–07	CF–07
Change to OXIS INTERNATIONAL INC	109657	CF–07	CF–07
DEANE HOMES	932788	NONE	CF–10
DEARBORN BANCORP INC /MI/	895541	NONE	CF–10
DEBARTOLO REALTY CORP	912045	NONE	CF–10
DECATHLON ADVISORS LP	850340	CF–10	REMOVE
DECKERS OUTDOORS CORP	910521	NONE	CF–10
DEFAULT PROOF CREDIT CARD SYSTEM INC /FL/	803260	NONE	CF–10
DEFLECTA SHIELD CORP /DE/	914605	NONE	CF–10
DELAWARE MANAGEMENT HOLDINGS INC	921739	NONE	CF–10
DELPHI FILM ASSOCIATES	700579	CF–09	REMOVE
DENVER & EPHRATA TELEPHONE & TELEGRAPH CO	903269	NONE	CF–10
DENVER BANKSHARES INC	923214	NONE	CF–10
DEPARTMENT 56 INC	902270	NONE	CF–10
DESKTOP DATA INC	858912	NONE	CF–08
DETROIT DIESEL CORP	910058	NONE	CF–10
DEVELOPED TECHNOLOGY RESOURCES INC	890725	NONE	CF–10
DHB CAPITAL GROUP INC /NY/	899166	NONE	CF–10
D H MARKETING & CONSULTING INC	933954	NONE	CF–10
DIAGNOSTIC HEALTH SERVICES INC /DE/	895659	NONE	CF–10
DIAL CALL COMMUNICATIONS INC	918645	NONE	CF–10
DIALOGIC CORP	899042	NONE	CF–10
DIAMETRICS MEDICAL INC	895380	NONE	CF–10
DIAMOND CABLE COMMUNICATIONS PLC	929649	NONE	CF–10
DIAMOND SHAMROCK OFFSHORE PARTNERS L P	773350	CF–04	REMOVE
DIASENSE INC /PA/	895650	NONE	CF–10
DIASYS CORP	916380	NONE	CF–10
DICKINSON HOLDING CORP	918963	NONE	CF–10
DIMAC CORP	820999	NONE	CF–10
DIMAC DIRECT INC	916399	NONE	CF–10
DIMECO INC	898037	NONE	CF–10
DIMON INC	939930	NONE	CF–10
DIPLOMAT CORP	910319	NONE	CF–10

CHANGES FROM CORPORATION FINANCE EDGAR PHASE-IN LIST AS PUBLISHED IN SECURITIES ACT RELEASE NO. 7122—Continued

[December 19, 1994]

Name	CIK No.	Former group	New group
DIRECT CONNECT INTERNATIONAL INC	840815	CF–08	CF–10
DISCOVER CARD TRUST 1993–A	896244	NONE	CF–10
DISCOVER CARD TRUST 1993–B	896245	NONE	CF–10
DISCOVERY ZONE INC	900392	NONE	CF–10
DIVERSIFIED FUTURES TRUST I	926805	NONE	CF–10
DIY HOME WAREHOUSE INC	899595	NONE	CF–10
DOAK PHARMACAL CO INC	029386	CF–08	REMOVE
DOLLAR TREE STORES INC	935703	NONE	CF–10
DOMINGUEZ SERVICES CORP	860673	CF–10	CF–07
DOMTAR GYPSUM INC	924780	NONE	CF–10
DORSEY TRAILERS INC	924117	NONE	CF–10
DOUBLE EAGLE PETROLEUM & MINING CO	029834	CF–08	CF–10
DOUBLETREE CORP	923472	NONE	CF–10
DOVATRON INTERNATIONAL INC	899047	NONE	CF–10
DOVE AUDIO INC	930436	NONE	CF–10
DOWNEY FINANCIAL CORP	935063	NONE	CF–10
DR STRUCTURED FINANCE CORP	909750	NONE	CF–10
DRYPERS CORP	894232	NONE	CF–10
DSP COMMUNICATIONS INC	934545	NONE	CF–10
DSP GROUP INC /DE/	915778	NONE	CF–10
DT INDUSTRIES INC	918999	NONE	CF–10
DTE HOLDINGS INC	936340	NONE	CF–10
DUAL DRILLING CO /DE/	907245	NONE	CF–10
DUALSTAR TECHNOLOGIES CORP	929546	NONE	CF–10
DUFF & PHELPS CREDIT RATING CO	928599	NONE	CF–10
DUNNS SUPPLY STORE INC	916357	NONE	CF–10
DURACRAFT CORP	911561	NONE	CF–10
DW BANKSHARES INC	916715	NONE	CF–10
DWFCM INTERNATIONAL ACCESS FUND LP	914747	NONE	CF–10
EAGLE EXPLORATION CO	030906	CF–08	CF–10
EAGLE FINANCE CORP	921863	NONE	CF–10
EASCO INC /DE/	938145	NONE	CF–10
EASTERN AMERICAN NATURAL GAS TRUST	895474	NONE	CF–10
EASTERN STAINLESS CORP	836437	CF–07	REMOVE
Change to EASTERN STAINLESS CORP /VA/	843867	CF–07	REMOVE
EASTMAN CHEMICAL CO	915389	NONE	CF–10
EASTOVER CORP	036207	CF–06	REMOVE
EAST PEORIA REAL ESTATE INC	909122	NONE	CF–10
EAST TEXAS FINANCIAL SERVICES INC	929646	NONE	CF–10
ECCS INC	900619	NONE	CF–10
ECHO BAY FINANCE CORP	887864	CF–07	CF–10
ECHO BAY MINES LTD	722080	CF–07	CF–10
ECHOSTAR COMMUNICATIONS CORP	920425	NONE	CF–10
EDELBROCK CORP	929037	NONE	CF–10
EDISON THOMAS INNS INC	808219	CF–06	CF–07
EDUCATIONAL INSIGHTS INC	919570	NONE	CF–10
EIA TECHNOLOGIES	920385	NONE	CF–10
EIGHT HOLDINGS INC	858365	CF–10	REMOVE
ELSON INDUSTRIES INC /DE/	032032	CF–05	REMOVE
ELECTRIC FUEL CORP	916529	NONE	CF–10
ELECTROCOM AUTOMATION INC	881404	CF–10	REMOVE
ELECTROGRAPH SYSTEMS INC	722641	CF–08	REMOVE
ELECTRONIC CLEARING HOUSE INC	721773	CF–07	CF–08
ELECTRONIC FAB TECHNOLOGY CORP	916797	NONE	CF–10
ELECTRONIC RETAILING SYSTEMS INTERNATIONAL INC	898747	NONE	CF–10
ELECTRONICS COMMUNICATIONS CORP	926366	NONE	CF–10
ELECTROPHARMACOLOGY INC	934849	NONE	CF–10
ELEK TEK INC	908613	NONE	CF–10
ELEPHANT & CASTLE GROUP INC	899849	NONE	CF–10
ELLETT BROTHERS INC	902055	NONE	CF–10
ELETRAX SYSTEMS INC	797448	NONE	CF–10
ELTRON INTERNATIONAL INC	915910	NONE	CF–10
EMCARE HOLDINGS INC	900083	NONE	CF–10
EMC FUNDING CORP TWO	906276	NONE	CF–10
EMERGING ALPHA CORP	904147	NONE	CF–10
EMERGING BETA CORP	904144	NONE	CF–10
EMERGING DELTA CORP	904145	NONE	CF–10
EMERGING GAMMA CORP	904146	NONE	CF–10
EMMIS BROADCASTING CORP	783005	NONE	CF–10

CHANGES FROM CORPORATION FINANCE EDGAR PHASE-IN LIST AS PUBLISHED IN SECURITIES ACT RELEASE NO. 7122—Continued

[December 19, 1994]

Name	CIK No.	Former group	New group
EMPHESYS FINANCIAL GROUP INC	916356	NONE	CF–10
EMPIRE OF CAROLINA INC	312840	NONE	CF–10
EMPLOYEE SOLUTIONS INC	904897	NONE	CF–10
EMPRESS RIVER CASINO FINANCE CORP	918648	NONE	CF–10
ENCAD INC	913599	NONE	CF–10
ENERGY BIOSYSTEMS CORP	895677	NONE	CF–10
ENERGY CONVERSION DEVICES INC	032878	CF–06	CF–10
ENERGY MANAGEMENT CONCEPTS INC	937815	NONE	CF–10
ENSERCH EXPLORATION INC	931006	NONE	CF–10
ENSERCH EXPLORATION PARTNERS LTD	764625	CF–03	REMOVE
ENTERGY CORP /DE/	893928	CF–03	REMOVE
Change to ENTERGY CORP /DE/	065984	CF–01	CF–01
ENTERPRISE FEDERAL BANCORP INC	922036	NONE	CF–10
ENTERTAINMENT MEDIA ACQUISITION CORP	917079	NONE	CF–10
ENTREE CORP	814579	CF–06	CF–05
ENVIROMETRICS INC /DE/	917253	NONE	CF–10
ENVIRONMENTAL RESOURCES & DISPOSAL INC	919997	NONE	CF–10
ENVIRONMENT ONE CORP	033081	CF–07	CF–08
ENVIROPUR WASTE REFINING & TECHNOLOGY INC	895947	NONE	CF–10
EOTT ENERGY PARTNERS LP	917464	NONE	CF–10
EPIC DESIGN TECHNOLOGY INC /CA/	929457	NONE	CF–10
EPIC HEALTHCARE GROUP INC /DE/	841940	CF–10	REMOVE
EP TECHNOLOGIES INC	896978	NONE	CF–10
EQCC RECEIVABLES CORP	897897	NONE	CF–10
EQUALNET HOLDING CORP	936163	NONE	CF–10
EQUITEC 80 REAL ESTATE INVESTORS	314887	CF–09	REMOVE
EQUITEC 82 REAL ESTATE INVESTORS	701437	CF–09	REMOVE
EQUITEC LEASING INVESTORS 9	798050	CF–09	REMOVE
EQUITEC VENTURE LEASING INVESTORS A	747409	CF–09	REMOVE
EQUITEC VENTURE LEASING INVESTORS B	747410	CF–09	REMOVE
EQUITY CORP INTERNATIONAL	928155	NONE	CF–10
EQUITY INNS INC	916530	NONE	CF–10
EQUITY MARKETING INC	911151	NONE	CF–10
EQUITY RESIDENTIAL PROPERTIES TRUST	906107	NONE	CF–10
EQUIVANTAGE ACCEPTANCE CORP	933505	NONE	CF–10
EQUUS GAMING CO LP	928423	NONE	CF–10
ERNST HOME CENTER INC	924635	NONE	CF–10
ERP OPERATING LTD PARTNERSHIP	931182	NONE	CF–10
ESKIMO PIE CORP	787520	NONE	CF–10
ESMOR CORRECTIONAL SERVICES INC	914670	NONE	CF–10
ESQUIRE COMMUNICATIONS LTD	898015	NONE	CF–10
ESQUIRE RADIO & ELECTRONICS INC	033541	CF–06	REMOVE
ESSEX FINANCIAL PARTNERS LP	847325	CF–05	CF–10
Change to ESSEX BANCORP INC /NEW	847325	CF–05	CF–10
ESSEX HOSPITALITY ASSOCIATES III LP	911217	NONE	CF–10
ESSEX PROPERTY TRUST INC	920522	NONE	CF–10
ETI/US/INC	859369	CF–10	REMOVE
EUROPEAN GATEWAY ACQUISITION CORP	908517	NONE	CF–10
EVANS SYSTEMS INC	904901	NONE	CF–10
EVANS WITHYCOMBE RESIDENTIAL INC	925267	NONE	CF–10
EVERGREEN BANCSHARES INC	930199	NONE	CF–10
EXCALIBUR INDUSTRIES	201779	CF–08	CF–10
EXPERT SOFTWARE INC	939730	NONE	CF–10
EXPRESSAIR MESSENGER INC	926299	NONE	CF–10
EXSTAR FINANCIAL CORP	893963	NONE	CF–10
EXTREME TECHNOLOGIES INC	907166	NONE	CF–10
EYE CARE CENTERS OF AMERICA INC	759896	NONE	CF–10
FACTORY STORES OF AMERICA INC	899757	NONE	CF–10
FAILURE GROUP INC	851520	NONE	CF–10
FAIRFIELD MANUFACTURING CO INC	904543	NONE	CF–10
FALCON BUILDING PRODUCTS INC	923286	NONE	CF–10
FALCON HOLDING GROUP LP	900346	NONE	CF–10
FALLEYS INC /KS/	835678	NONE	CF–04
FAMILY DENTAL CENTER SERVICE CO OF AMERICA	935869	NONE	CF–10
FAMILY GOLF CENTERS INC	929941	NONE	CF–10
FARMERS NATIONAL BANCORP /MD/	700850	CF–04	REMOVE
FARREL CORP	034645	NONE	CF–10
FBD HOLDING CO INC	942595	NONE	CF–10
F & C BANCSHARES INC	878671	CF–10	REMOVE

CHANGES FROM CORPORATION FINANCE EDGAR PHASE-IN LIST AS PUBLISHED IN SECURITIES ACT RELEASE NO. 7122—Continued

[December 19, 1994]

Name	CIK No.	Former group	New group
FCC RECEIVABLES CORP	940182	NONE	CF–10
FCS LABORATORIES INC	719130	CF–07	CF–10
FEATHERLITE MFG INC	928064	NONE	CF–10
FED ONE BANCORP INC	929549	NONE	CF–10
FEDERAL AFFORDABLE HOUSING CORP	911356	NONE	CF–10
FEDERAL MORTGAGE MANAGEMENT INC	909962	NONE	CF–10
FEDERATED DEPARTMENT STORES INC	034945	CF–02	REMOVE
FED ONE BANCORP INC	929549	NONE	CF–10
FEI CO	914329	NONE	CF–10
FELCOR SUITE HOTELS INC	923603	NONE	CF–10
FENTURA BANCORP INC	919865	NONE	CF–10
FERRELLGAS PARTNERS L P	922358	NONE	CF–10
FERTECH ENVIRONMENTAL SERVICES INC	933090	NONE	CF–10
FF BANCORP INC	885727	CF–10	REMOVE
FF HOLDINGS CORP	838448	NONE	CF–10
FFLC BANCORP INC	912738	NONE	CF–10
FFVA FINANCIAL CORP	924285	NONE	CF–10
FIBERONICS INTERNATIONAL INC	724968	CF–05	REMOVE
FIBERSTARS INC /CA/	924168	NONE	CF–10
FIDELITY FINANCIAL BANKSHARES CORP	937688	NONE	CF–10
FIDELITY LEASING INCOME FUND V LP	830660	CF–09	CF–08
FIDELITY LEASING INCOME FUND VI LP	846471	CF–10	CF–08
FIDELITY LEASING INCOME FUND VII LP	858661	CF–10	CF–08
FIDELITY LEASING INCOME FUND VIII LP	870742	CF–10	CF–08
FIDELITY MEDICAL INC	320017	CF–07	CF–09
FINANCECO AUTO RECEIVABLES CORP	920207	NONE	CF–10
FINANCIAL BANCORP INC	855932	NONE	CF–10
FINANCIAL SECURITY ASSURANCE HOLDINGS LTD	913357	NONE	CF–10
FINANCIAL SERVICES ACQUISITION CORP /DE/	931707	NONE	CF–10
FINANCING FOR SCIENCE INTERNATIONAL INC	914244	NONE	CF–10
FINGERHUT RECEIVABLES INC	921751	NONE	CF–10
FINISHMASTER INC	917321	NONE	CF–10
FINLAY ENTERPRISES INC /DE	878731	NONE	CF–10
FINLAY FINE JEWELRY CORP	898684	NONE	CF–10
FIREFOX COMMUNICATIONS INC	942167	NONE	CF–10
FIRST ALERT INC	918960	NONE	CF–10
FIRST ALLIANCE CORP /KY/	910603	NONE	CF–10
FIRST ASHLAND FINANCIAL CORP	934793	NONE	CF–10
FIRST BANCSHARES INC /MO/	912967	NONE	CF–10
FIRST BANKSHARES INC /GA/	925944	NONE	CF–10
FIRSTBANK PUERTO RICO	932625	NONE	CF–10
FIRST BANKS INC	710507	NONE	CF–10
FIRST BELL BANCORP INC	932697	NONE	CF–10
FIRST CENTRAL BANCSHARES INC	897979	NONE	CF–10
FIRST CHESAPEAKE FINANCIAL CORP	899164	NONE	CF–10
FIRST CHOICE HEALTH NETWORK INC	922622	NONE	CF–10
FIRST CITY BANCORPORATION OF TEXAS INC	828678	CF–09	CF–09
Change to FIRSTCITY FINANCIAL CORP	828678	CF–09	CF–09
FIRST COMMUNITY BANCSHARES INC/GA/	825351	CF–08	REMOVE
FIRST COMMUNITY CORP /SC/	932781	NONE	CF–10
FIRST COMMUNITY CORP /TN/	924960	NONE	CF–10
FIRST DEPOSIT NAT BK FIRST DEP MAS TR ASST BK CER SER 1993–1	909823	NONE	CF–10
FIRST DEPOSIT NAT BK FIRST DEP MAS TR ASST BK CER SER 1993–2	909826	NONE	CF–10
FIRST DEPOSIT NATL BK FIRST DEP MA TR ASS BK CERT SER 1994–1	926216	NONE	CF–10
FIRST FAMILY FINANCIAL CORP	927313	NONE	CF–10
FIRST FEDERAL BANCORPORATION /MN/	933461	NONE	CF–10
FIRST FEDERAL BANCSHARES OF EAU CLAIRE INC	920526	NONE	CF–10
FIRSTFED NORTHERN KENTUCKY BANCORP INC	877867	CF–10	REMOVE
FIRST FIDELITY ACCEPTANCE CORP	789874	NONE	CF–10
FIRST INDEPENDENCE CORP /DE/	908486	NONE	CF–10
FIRST INDUSTRIAL REALTY TRUST INC	921825	NONE	CF–10
FIRST KENT FINANCIAL CORP	920770	NONE	CF–10
FIRST MERCHANTS ACCEPTANCE CORP	926296	NONE	CF–10
FIRST MERCURY FINANCIAL CORP	929186	NONE	CF–10
FIRST MIDWEST FINANCIAL INC	907471	NONE	CF–10
FIRST MISSOURI BANCSHARES INC	916526	NONE	CF–10
FIRST MUTUAL FINANCIAL INC	934738	NONE	CF–10
FIRST NATIONWIDE HOLDINGS INC	928358	NONE	CF–10
FIRST NORTH AMERICAN NATIONAL BANK	928596	NONE	CF–10

CHANGES FROM CORPORATION FINANCE EDGAR PHASE-IN LIST AS PUBLISHED IN SECURITIES ACT RELEASE NO. 7122—Continued

[December 19, 1994]

Name	CIK No.	Former group	New group
FIRST OF AMERICA BANK MICHIGAN NA	934842	CF–10	CF–07
FIRST OF AMERICA BANK NORTHEAST ILLINOIS NA	934841	NONE	CF–10
FIRST OPTION HEALTH PLAN OF NEW JERSEY INC	919868	NONE	CF–10
FIRST OZAUKEE CAPITAL CORP	920612	NONE	CF–10
FIRST SAVINGS BANCORP OF LITTLE FALLS INC	902435	NONE	CF–10
FIRST SOUTHERN BANCSHARES INC	934302	NONE	CF–10
FIRST SUNBELT BANKSHARES INC	802776	CF–06	REMOVE
FIRST WASHINGTON REALTY TRUST INC	926861	NONE	CF–10
FIRST WESTERN FINANCIAL CORP	037059	CF–07	REMOVE
FISCHER IMAGING CORP	750901	NONE	CF–10
FISHER SCIENTIFIC INTERNATIONAL INC	880430	NONE	CF–10
FISHKILL NATIONAL CORP	749923	CF–06	REMOVE
FLAIR CORP	913953	NONE	CF–10
FLAMEMASTER CORP	037358	CF–07	CF–10
FLORES & RUCKS INC /DE/	930550	NONE	CF–10
FLORIDA AUTOMOBILE FINANCE CORP	926297	NONE	CF–10
FLORIDA WEST AIRLINES INC	836190	NONE	CF–10
FLORISTS TRANSWORLD DELIVERY INC	935870	NONE	CF–10
FLORSHEIM SHOE CO /DE/	928908	NONE	CF–10
FLOYD VALLEY PACKING CO	037727	CF–08	REMOVE
FLUOROSCAN IMAGING SYSTEMS INC	923855	NONE	CF–10
FNBH BANCORP INC	943119	NONE	CF–10
FOAMEX INTERNATIONAL INC	912908	NONE	CF–10
FOAMEX-JPS AUTOMOTIVE LP	927584	NONE	CF–10
FOCAL CORP	915461	NONE	CF–10
FOCUS SURGERY INC	909727	NONE	CF–10
FOHP INC	937817	NONE	CF–10
FOILMARK INC	914066	NONE	CF–10
FOOD 4 LESS GM INC	886141	NONE	CF–10
FOOD 4 LESS HOLDINGS INC /CA	898470	NONE	CF–10
FOOD 4 LESS HOLDINGS INC /DE	936523	NONE	CF–04
FOOD 4 LESS MERCHANDISING INC	880824	NONE	CF–04
FOOD 4 LESS OF CALIFORNIA INC	880823	NONE	CF–04
FOOD 4 LESS OF SOUTHERN CALIFORNIA INC	880825	NONE	CF–04
FOOD COURT ENTERTAINMENT NETWORK INC	940800	NONE	CF–10
FOOD TRENDS ACQUISITION CORP	923134	NONE	CF–10
FOR HIRE INC	935000	NONE	CF–10
FORECAST GROUP LP	915350	NONE	CF–10
FORE SYSTEMS INC /DE/	920000	NONE	CF–10
FORREST CITY FINANCIAL CORP	922288	NONE	CF–10
FORTE COMPUTER EASY INC	940034	NONE	CF–10
FOTOBALL USA INC	922251	NONE	CF–10
FOUNTAIN POWERBOAT INDUSTRIES INC	764858	NONE	CF–06
FOURTH SHIFT CORP	905724	NONE	CF–10
FPA MEDICAL MANAGEMENT INC	920173	NONE	CF–10
FRANCOR FINANCIAL INC	726317	CF–06	REMOVE
FRANKFORD CORP	700714	CF–07	REMOVE
FRANKFORT FIRST BANCORP INC	930182	NONE	CF–10
FRANKLIN OPHTHALMIC INSTRUMENTS CO INC	898630	NONE	CF–10
FRAWLEY CORP	038824	CF–06	CF–10
FREDERICKSBURG NATIONAL BANCORP INC	707177	CF–07	REMOVE
FREMONT CORP	038981	NONE	CF–10
FRESH AMERICA CORP	921614	NONE	CF–10
FRIEDMANS INC	911004	NONE	CF–10
FRIENDLY ICE CREAM INC	930588	NONE	CF–10
FRIENDLYS HOLDING CO INC	932090	NONE	CF–10
FRONTIER AIRLINES INC /CO/	921929	NONE	CF–10
FRONTIER NATURAL GAS CORP	901611	NONE	CF–10
FRONTIER OIL & GAS CO /DE	906350	NONE	CF–10
FRONTIER OIL EXPLORATION CO	907649	NONE	CF–10
FROST HANNA ACQUISITION GROUP INC	906598	NONE	CF–10
FROST HANNA MERGERS GROUP INC	916844	NONE	CF–10
FSA MUNICIPAL ASSET BACKED CORP	930647	NONE	CF–10
FSB FINANCIAL CORP	920856	NONE	CF–10
FSF FINANCIAL CORP	924370	NONE	CF–10
FTP SOFTWARE INC	912548	NONE	CF–10
FUELCELL CORP OF AMERICA	924638	NONE	CF–10
FULCRUM TECHNOLOGIES INC	912152	NONE	CF–10
FUND AMERICA INVESTORS CORP II	895730	NONE	CF–10

CHANGES FROM CORPORATION FINANCE EDGAR PHASE-IN LIST AS PUBLISHED IN SECURITIES ACT RELEASE NO. 7122—Continued

[December 19, 1994]

Name	CIK No.	Former group	New group
FUSION SYSTEMS CORP	920029	NONE	CF–10
FUTUREBIOTICS INC	922200	NONE	CF–10
G&L REALTY CORP	912240	NONE	CF–10
G/O INTERNATIONAL INC	928447	NONE	CF–10
GALLERY RODEO INTERNATIONAL	837852	NONE	CF–10
GALVESTON HOUSTON CO	039838	CF–05	REMOVE
GAME FINANCIAL CORP	920106	NONE	CF–10
GARDEN FRESH RESTAURANT CORP /DE/	942133	NONE	CF–10
GARDEN STATE NEWSPAPERS INC	918944	NONE	CF–10
GARDNER DENVER MACHINERY INC	916459	NONE	CF–10
GARMENT GRAPHICS INC	895641	NONE	CF–10
GARTNER GROUP INC	749251	NONE	CF–10
GASONICS INTERNATIONAL CORP	918647	NONE	CF–10
GATES FA DISTRIBUTING INC	827838	CF–05	REMOVE
GATEWAY BANCORP INC/KY	931066	NONE	CF–10
GATEWAY BANCORP INC /NY	758029	CF–05	CF–10
GATEWAY INDUSTRIES INC /CA/	725876	CF–07	CF–10
GB PROPERTY FUNDING CORP	912906	NONE	CF–10
GC COMPANIES INC	912295	NONE	CF–10
GEERLINGS & WADE INC	922810	NONE	CF–10
GENCARE HEALTH SYSTEMS INC	879028	CF–10	REMOVE
GENEMEDICINE INC	907111	NONE	CF–10
GENERAL ACCEPTANCE CORP /IN/	937965	NONE	CF–10
GENERAL CELLULAR CORP	831104	CF–09	REMOVE
GENERAL CHEMICAL GROUP INC	929697	NONE	CF–10
GENERAL DEVICES INC	040528	CF–07	CF–09
GENERAL GROWTH PROPERTIES INC	895648	NONE	CF–10
GENERAL MAGIC INC	933524	NONE	CF–10
GENERAL MEDIA INC	920771	NONE	CF–10
GENERAL MEDICAL CORP /VA	880123	NONE	CF–10
GENERAL TEXTILES	899690	NONE	CF–10
GENMAR HOLDINGS INC	823619	NONE	CF–10
GENZYME DEVELOPMENT PARTNERS LP	856312	NONE	CF–10
GENZYME TRANSGENICS CORP	904973	NONE	CF–10
GEO ENVIRONMENTAL RESOURCES INC	914553	NONE	CF–10
GEONEX CORP	796318	CF–06	CF–08
GEORGIA BANK FINANCIAL CORP /GA	880116	NONE	CF–10
GEOWORKS /CA/	922285	NONE	CF–10
GF BANCORP INC	906787	NONE	CF–10
GFSB BANCORP INC	942129	NONE	CF–10
GIANT CEMENT HOLDING INC	922405	NONE	CF–10
GILLETT HOLDINGS INC	812011	NONE	CF–10
GILMAN & CIOCIA INC	914142	NONE	CF–10
GILMER FINANCIAL SERVICES INC	930540	NONE	CF–10
GLENDALE BANCORPORATION/NJ	769800	CF–08	REMOVE
GLEN ROCK STATE BANCORP INC	921906	NONE	CF–10
GLENBOROUGH REALTY TRUST INC	929454	NONE	CF–10
GLENGATE APPAREL INC	916394	NONE	CF–10
GLIMCHER REALTY TRUST	912898	NONE	CF–10
GLOBAL CAPITAL ACCESS CORP	943941	NONE	CF–10
GLOBAL INDUSTRIES LTD	895663	NONE	CF–10
GLOBALINK INC	899679	NONE	CF–10
GLOBAL MARKET INFORMATION INC	922811	NONE	CF–10
GLOBALSTAR TELECOMMUNICATIONS LTD	933401	NONE	CF–10
GLOBAL TELECOMMUNICATION SOLUTIONS INC	925004	NONE	CF–10
GLOBAL TELEMEDIA INTERNATIONAL INC	789562	CF–08	CF–09
GLOBUS CELLULAR & USER PROTECTION LTD	939402	NONE	CF–10
GLYKO BIOMEDICAL LTD	908401	NONE	CF–10
GMAC 1990–A GRANTOR TRUST	868571	CF–01	REMOVE
GM HOLDINGS INC	916486	NONE	CF–10
GMI 94 LLC	928729	NONE	CF–10
GNAC CORP	311905	NONE	CF–10
GNC ENERGY CORP	043398	CF–07	CF–10
GNC INC	936512	NONE	CF–10
GOLD CAPITAL CORP /CO/	919626	NONE	CF–10
GOLDEN INTERSTATE MEDICAL MANAGEMENT INC	911225	NONE	CF–10
GOLDEN STAR RESOURCES LTD	903571	NONE	CF–10
GOLDEN SYSTEMS INC	911876	NONE	CF–10
GOLDEN TRIANGLE ROYALTY & OIL INC	042284	CF–08	CF–09

CHANGES FROM CORPORATION FINANCE EDGAR PHASE-IN LIST AS PUBLISHED IN SECURITIES ACT RELEASE NO. 7122—Continued

[December 19, 1994]

Name	CIK No.	Former group	New group
GOLF ENTERPRISES INC /DE/	921756	NONE	CF–10
GOOD IDEAS ENTERPRISES INC	916714	NONE	CF–10
GOODRICH PETROLEUM CORP	943861	NONE	CF–10
GORAN CAPITAL INC	925600	NONE	CF–10
GOVERNMENT EXPORT TRUST SERIES 1993–1	898313	NONE	CF–10
GRAHAM INCOME FUND 82A	400001	CF–07	REMOVE
GRAND GAMING CORP	911760	NONE	CF–10
GRANITE DEVELOPMENT PARTNERS LP	925171	NONE	CF–10
GRAPHIX ZONE INC	915684	NONE	CF–10
GREAT AMERICAN BACKRUB STORE INC	934006	NONE	CF–10
GREAT AMERICAN BANCORP INC	943064	NONE	CF–10
GREAT AMERICAN BROADCASTING CORP	849143	CF–10	REMOVE
GREAT AMERICAN COOKIE CO INC	920110	NONE	CF–10
GREAT AMERICAN CORP	043271	CF–07	REMOVE
GREAT AMERICAN INVESTMENT NETWORK INC	901514	NONE	CF–10
GREATER ROME BANCSHARES INC	928484	NONE	CF–10
GREAT LAKES AVIATION LTD	914397	NONE	CF–10
GREAT PINES WATER CO INC	906285	NONE	CF–10
GREAT TRAIN STORE CO	924380	NONE	CF–10
GREAT WESTERN AIR INC	909232	NONE	CF–10
GREEN MOUNTAIN COFFEE INC	909954	NONE	CF–10
GREENBRIER COMPANIES INC	923120	NONE	CF–10
GREENFIELD INDUSTRIES INC /DE/	906419	NONE	CF–10
GREENMAN TECHNOLOGIES INC	932699	NONE	CF–10
GREENSTONE INDUSTRIES INC	922862	NONE	CF–10
GREENWICH AIR SERVICES INC	891461	NONE	CF–10
GREENWOOD RESOURCES INC /CO/	718474	CF–07	CF–09
Change to PACKAGING RESEARCH CORP	718474	CF–07	CF–09
GREG MANNING AUCTIONS INC	895516	NONE	CF–10
GRIFFIN REAL ESTATE FUND II	319716	CF–06	CF–08
GRIFFIN REAL ESTATE FUND IV	728526	CF–06	CF–08
GRIFFIN REAL ESTATE FUND V	760451	CF–06	CF–08
GRIFFIN REAL ESTATE FUND VI	783452	CF–06	CF–08
GRIFFITH CONSUMERS CO /DE/	935814	NONE	CF–10
GRIFFITH CONSUMERS CO /MD/	801937	CF–09	REMOVE
GRILL CONCEPTS INC	895041	NONE	CF–10
GROVE REAL ESTATE ASSET TRUST	920776	NONE	CF–10
GROW BIZ INTERNATIONAL INC	908315	NONE	CF–10
GROWTH ENVIRONMENTAL INC	913890	NONE	CF–10
GRYPHON HOLDINGS INC	912558	NONE	CF–10
GS FINANCIAL PRODUCTS US LP	914720	NONE	CF–10
GS TECHNOLOGIES OPERATING CO INC	925906	NONE	CF–10
GUARANTY BANCSHARES CORP	768536	CF–06	REMOVE
GUARANTY STATE BANCORP	900342	NONE	CF–10
GUIDANT CORP	929987	NONE	CF–10
GUILFORD PHARMACEUTICALS INC	918066	NONE	CF–10
GUINNESS TELLI-PHONE CORP	940036	NONE	CF–10
GULF & SOUTHERN FINANCIAL CORP	774555	CF–06	REMOVE
GUTHRIE SAVINGS INC	925533	NONE	CF–10
GWC CORP	779244	CF–03	REMOVE
GWINNETT BANCSHARES INC	858862	CF–10	REMOVE
HAAGEN ALEXANDER PROPERTIES INC	913292	NONE	CF–10
HAGGAR CORP	892533	NONE	CF–10
HALLMARK HEALTHCARE CORP	765052	CF–04	REMOVE
HALLWOOD HOLDINGS INC	874238	CF–10	CF–08
Change to OAKHURST CAPITAL INC	874238	CF–10	CF–08
HALLWOOD INDUSTRIES INC	046535	CF–06	CF–08
Change to STEEL CITY PRODUCTS INC	046535	CF–06	CF–08
HAMILTON FINANCIAL SERVICES CORP	899161	NONE	CF–10
HAMMONS JOHN Q HOTELS LP	916536	NONE	CF–10
HANCOCK JOHN REAL ESTATE L P	708319	CF–06	REMOVE
HANCOCK JOHN REALTY INCOME FUND III LP	842741	CF–09	CF–07
HAPPINESS EXPRESS INC	923662	NONE	CF–10
HARBOR INVESTMENT CORP	874386	CF–10	REMOVE
HARBOUR CAPITAL CORP	897082	NONE	CF–10
HARBOUR INTERMODAL LTD	933649	NONE	CF–10
HARMONEY STREET CAPITAL INC	830488	CF–09	CF–09
Change to NETWORK LONG DISTANCE INC	830488	CF–09	CF–09
HARRAHS JAZZ CO	916611	NONE	CF–10

CHANGES FROM CORPORATION FINANCE EDGAR PHASE-IN LIST AS PUBLISHED IN SECURITIES ACT RELEASE NO. 7122—Continued

[December 19, 1994]

Name	CIK No.	Former group	New group
HARRIER INC	789847	CF–07	CF–09
HARRIS CHEMICAL NORTH AMERICA INC	910711	NONE	CF–10
HARRIS COMPUTER SYSTEMS CORP	927133	NONE	CF–10
HARRYS FARMERS MARKET INC	899755	NONE	CF–10
HARVARD FUTURES FUND LLC	932093	NONE	CF–10
HARVEST E-XPRESS INC	937601	NONE	CF–10
HARVEST HOME FINANCIAL CORP	919624	NONE	CF–10
HARVEY ENTERTAINMENT CO	904350	NONE	CF–10
HARVEY UNIVERSAL INC	911671	NONE	CF–10
HARVEYS CASINO RESORTS	914022	NONE	CF–10
HASKEL INTERNATIONAL INC	918022	NONE	CF–10
HAUPPAUGE DIGITAL INC	930803	NONE	CF–10
HAYWOOD BANCSHARES INC	940941	NONE	CF–10
HB COMMUNICATIONS ACQUISITION CORP	900029	NONE	CF–10
HCA HOSPITAL CORPORATION OF AMERICA	846489	CF–10	REMOVE
HCIA INC	935001	NONE	CF–10
HDS NETWORK SYSTEMS INC	894743	NONE	CF–10
HEALTHCARE AMERICA INC	914627	NONE	CF–10
HEALTH CARE PROPERTIES II L P	760689	CF–06	REMOVE
HEALTH & COMMUNITY LIVING INC	904919	NONE	CF–10
HEALTHDYNE TECHNOLOGIES INC	900307	NONE	CF–10
HEALTH MANAGEMENT SYSTEMS INC	861179	NONE	CF–10
HEALTHPLAN SERVICES CORP	942319	NONE	CF–10
HEALTH POWER INC /DE/	917674	NONE	CF–10
HEALTHWISE OF AMERICA INC	912955	NONE	CF–10
HEALTHY PLANET PRODUCTS INC	768260	CF–08	CF–07
HEARTLAND FINANCIAL USA INC	920112	NONE	CF–10
HEARTLAND GROUP OF COMPANIES INC	909108	NONE	CF–10
HEARTLAND WIRELESS COMMUNICATIONS INC	917707	NONE	CF–10
HEILEMAN G BREWING CO INC	914982	NONE	CF–10
HELEN OF TROY LTD	916789	NONE	CF–10
HELICON GROUP LP	915767	NONE	CF–10
HELLO DIRECT INC /DE/	937265	NONE	CF–10
HEMASURE INC	919745	NONE	CF–10
H.E.R.C. PRODUCTS INC	919010	NONE	CF–10
HERITAGE OAKS BANCORP	921547	NONE	CF–10
HF BANCORP INC	941547	NONE	CF–10
HFC REVOLVING CORP	923147	NONE	CF–10
HI RISE RECYCLING SYSTEMS INC	906605	NONE	CF–10
HI SHEAR TECHNOLOGY CORP	918027	NONE	CF–10
HIGH HOPES INC	800181	CF–08	REMOVE
HIGHWAYMASTER COMMUNICATIONS INC	944400	NONE	CF–10
HIGHWOODS PROPERTIES INC	921082	NONE	CF–10
HILITE INDUSTRIES INC	915197	NONE	CF–10
HIRSCH INTERNATIONAL CORP	915909	NONE	CF–10
HMN FINANCIAL INC	921183	NONE	CF–10
HMO AMERICA INC	742415	CF–07	REMOVE
HOLLY PRODUCTS INC	909753	NONE	CF–10
HOLLY RESIDENTIAL PROPERTIES INC	900340	CF–10	REMOVE
HOLLYWOOD ENTERTAINMENT CORP	905895	NONE	CF–10
HOLMES PROTECTION GROUP INC	926764	NONE	CF–10
HOLNAM INC	860602	CF–02	REMOVE
HOME BANCORP/IN	916822	NONE	CF–10
HOME BUILDING BANCORP INC	930594	NONE	CF–10
HOMECAPITAL INVESTMENT CORP	320545	NONE	CF–10
HOME EXPRESS INC /DE/	934597	NONE	CF–10
HOME FINANCIAL CORP/DE	921151	NONE	CF–10
HOME NATIONAL CORP/MA	715128	CF–04	REMOVE
HOME PROPERTIES OF NEW YORK INC	923118	NONE	CF–10
HOME STATE HOLDINGS INC	906524	NONE	CF–10
HOMEOWNERS FINANCIAL CORP	932268	NONE	CF–10
HOMETOWN BUFFET INC	910558	NONE	CF–10
HORIZON BANCORP INC	931332	NONE	CF–10
HORIZON CELLULAR TELEPHONE CO LP	898675	NONE	CF–10
HORIZON FINANCIAL SERVICES CORP	920600	NONE	CF–10
HORIZON MENTAL HEALTH MANAGEMENT INC	935007	NONE	CF–10
HORIZON OUTLET CENTERS INC	911645	NONE	CF–10
HOSIERY CORP OF AMERICA INC	934383	NONE	CF–10
HOSSS STEAK & SEA HOUSE INC	937258	NONE	CF–10

CHANGES FROM CORPORATION FINANCE EDGAR PHASE-IN LIST AS PUBLISHED IN SECURITIES ACT RELEASE NO. 7122—Continued

[December 19, 1994]

Name	CIK No.	Former group	New group
HOTEL INVESTORS CORP	316206	CF–04	CF–04
Change to STARWOOD LODGING CORP	316206	CF–04	CF–04
HOTEL INVESTORS TRUST	048595	CF–04	CF–04
Change to STARWOOD LODGING TRUST	048595	CF–04	CF–04
HOULIHANS RESTAURANT GROUP INC	909723	NONE	CF–10
HOUSEHOLD AFFINITY FUNDING CORP	906327	NONE	CF–10
HOUSEHOLD FINANCE CORP HOUSEHOLD AFFINITY CRED CARD MAS TR I	906328	NONE	CF–10
HOUSEHOLD RECEIVABLES FUNDING CORP	877655	NONE	CF–10
HOUSEHOLD RECEIVABLES FUNDING CORP II	894153	NONE	CF–10
HOUSTON OIL TRUST	355118	CF–05	REMOVE
HOUSTON SAM RACE PARK LTD	911082	NONE	CF–10
HRSI FUNDING INC	880283	NONE	CF–10
HUB GROUP INC	940942	NONE	CF–10
HUDSON RESOURCES INC	924710	NONE	CF–10
HUDSON TECHNOLOGIES INC /NY	925528	NONE	CF–10
HUGOTON ENERGY CORP	914144	NONE	CF–10
HUMPHREY HOSPITALITY TRUST INC	929545	NONE	CF–10
HUNGARIAN TELECONSTRUCT CORP	905428	NONE	CF–10
HUNTCO INC	905722	NONE	CF–10
HUNTER RESOURCES INC	031063	CF–08	CF–09
HUNTSMAN CORP	918763	NONE	CF–10
HWCC TUNICA INC	927801	NONE	CF–10
HYPERMEDIA COMMUNICATIONS INC	894680	NONE	CF–10
IBS FINANCIAL CORP	925780	NONE	CF–10
ICHI-BON INVESTMENT CORP	935730	NONE	CF–10
ICN BIOMEDICALS INC	798166	CF–04	REMOVE
ICN PHARMACEUTICALS INC	930184	NONE	CF–10
ICN PHARMACEUTICALS INC /DE/	049601	CF–03	REMOVE
ICON HEALTH & FITNESS INC	934798	NONE	CF–10
ICU MEDICAL INC /DE	883984	NONE	CF–10
IDAHO CO	809365	CF–08	CF–10
IDEON GROUP INC	943097	NONE	CF–10
IDM CORP	932143	NONE	CF–10
IDM ENVIRONMENTAL CORP	909792	NONE	CF–10
IEA INCOME FUND VI	774482	CF–09	CF–08
IEA INCOME FUND VII	803511	CF–09	CF–08
IEA INCOME FUND VIII	821097	CF–09	CF–08
IEA INCOME FUND IX LP	836972	CF–09	CF–08
IEA INCOME FUND X LP	853735	CF–10	CF–08
IEA INCOME FUND XI LP	867640	CF–10	CF–08
IEA INCOME FUND XII LP	879045	CF–10	CF–08
IEA MARINE CONTAINER FUND II	315806	CF–09	CF–08
IEA MARINE CONTAINER INCOME FUND III	350202	CF–09	CF–08
IEA MARINE CONTAINER INCOME FUND IV	357047	CF–09	CF–08
IEA MARINE CONTAINER INCOME FUND V-A	727047	CF–09	CF–08
IEA MARINE CONTAINER INCOME FUND V-B	727048	CF–09	CF–08
IEC FUNDING CORP	934665	NONE	CF–10
IGEN INC /CA/	916304	NONE	CF–10
ILLINOVA CORP	914755	NONE	CF–10
ILM I LEASE CORP	932091	NONE	CF–10
ILM II LEASE CORP	932092	NONE	CF–10
IMAC MERGER SUBSIDIARY INC	932124	NONE	CF–10
IMAGE INDUSTRIES INC	905435	NONE	CF–10
IMAGE SENSING SYSTEMS INC	943034	NONE	CF–10
IMAGE SYSTEMS CORP	049852	NONE	CF–10
IMAGEX SERVICES INC	927798	NONE	CF–10
IMAX CORP	921582	NONE	CF–10
IMCLONE SYSTEMS INC /DE	765258	NONE	CF–10
IMMO FINANCE CORP	919605	NONE	CF–10
IMMUNE RESPONSE CORP	817785	NONE	CF–10
IMPERIAL GOVERNMENT INCOME TRUST SERIES I	900472	NONE	CF–10
IMPERIAL INDUSTRIES INC	049930	CF–07	CF–10
IMREG INC	730757	CF–07	CF–10
IMSCO INC /MA/	924396	NONE	CF–10
IN BRAND CORP	909278	NONE	CF–10
INCO HOMES CORP	897432	NONE	CF–10
INCONTROL INC	871629	NONE	CF–10
INDEPENDENT AMERICAN PARTICIPATING INCOME FUND LP	760688	CF–07	CF–10
INDEPENDENT BANCORP OF ARIZONA INC	915305	NONE	CF–10

CHANGES FROM CORPORATION FINANCE EDGAR PHASE-IN LIST AS PUBLISHED IN SECURITIES ACT RELEASE NO. 7122—Continued

[December 19, 1994]

Name	CIK No.	Former group	New group
INDEPENDENT BANKS OF VIRGINIA INC	719731	CF–08	CF–09
Change to HERITAGE BANKSHARES INC /VA	719731	CF–08	CF–09
INDEPENDENT RESEARCH AGENCY FOR LIFE INSURANCE INC	354242	NONE	CF–10
INDIANA WIRELESS LTD	932982	NONE	CF–10
INDIANTOWN COGENERATION FUNDING CORP	927630	NONE	CF–10
INDUSTRIAL BANCORP INC	942899	NONE	CF–10
INDUSTRIAL SCIENTIFIC CORP	906108	NONE	CF–10
INDUSTRIAL TRAINING CORP	764867	NONE	CF–10
INFOMED HOLDINGS INC	896157	NONE	CF–10
INFORMATION AMERICA INC /GA	879772	CF–10	REMOVE
INFORMATION SOLUTIONS INC	723574	CF–07	CF–07
Change to IMAGE SOFTWARE INC	723574	CF–07	CF–07
INFORMATION STORAGE DEVICES INC /CA/	932980	NONE	CF–10
INFOSAFE SYSTEMS INC	894738	NONE	CF–10
INFOSOFT INTERNATIONAL INC	917471	NONE	CF–10
INHALE THERAPEUTIC SYSTEMS	906709	NONE	CF–10
INITIAL ACQUISITION CORP	899394	NONE	CF–10
INLAND GOLD & SILVER CORP /WA/	811038	CF–07	CF–07
Change to INLAND RESOURCES INC	717754	CF–07	CF–07
INLAND MONTHLY INCOME FUND III INC	923284	NONE	CF–10
INNERDYNE INC	822084	NONE	CF–10
INNERSPACE INC	891162	NONE	CF–10
INNKEEPERS USA TRUST/FL	926866	NONE	CF–10
INNODATA CORP	903651	NONE	CF–10
INNOVATIVE GAMING CORP OF AMERICA	897795	NONE	CF–10
INNOVIR LABORATORIES INC	901099	NONE	CF–10
INOVISION CORP	775526	CF–05	CF–10
INPHYNET MEDICAL MANAGEMENT INC	925170	NONE	CF–10
INSCI CORP	878612	NONE	CF–10
INSET INDUSTRIES INC	929140	NONE	CF–10
INSIGHT ENTERPRISES INC	932696	NONE	CF–10
INSITUFORM SOUTHEAST CORP	799096	CF–06	CF–09
Change to ENVIROQ CORP	799096	CF–06	CF–09
INTEGRACARE INC	912081	NONE	CF–10
INTEGRATED COMMUNICATION NETWORK INC	927856	NONE	CF–10
INTEGRATED RESOURCES INC	050857	CF–09	REMOVE
INTEGRITY MUSIC INC	922865	NONE	CF–10
INTELLICORP INC	730169	CF–06	CF–10
INTEL OVERSEAS CORP	768545	CF–10	CF–07
INTERACTIVE FLIGHT TECHNOLOGIES INC	932021	NONE	CF–10
INTERACTIVE GROUP INC	943354	NONE	CF–10
INTERACTIVE MEDIA TECHNOLOGIES INC	850510	CF–08	CF–10
INTERCONTINENTAL TRAVEL SERVICES INC	858449	CF–10	REMOVE
INTERCOUNTY BANCSHARES INC	908837	NONE	CF–10
INTERFILM INC	911216	NONE	CF–10
INTERGROUP HEALTHCARE CORP /DE	876718	CF–10	REMOVE
INTERIM SERVICES INC	914536	NONE	CF–10
INTERIORS INC	921563	NONE	CF–10
INTERLINK ELECTRONICS	828146	NONE	CF–10
INTERMETRICS IN	702736	CF–06	CF–09
INTERNATIONAL ASSETS HOLDING CORP	913760	NONE	CF–10
INTERNATIONAL FRANCHISE SYSTEMS INC	923142	NONE	CF–10
INTERNATIONAL METALS ACQUISITION CORP	907116	NONE	CF–10
INTERNATIONAL MOVIE GROUP INC /DE/	835640	NONE	CF–10
INTERNATIONAL PIZZA CORP	910111	NONE	CF–10
INTERNATIONAL POWER MACHINES CORP	318775	CF–06	REMOVE
INTERNATIONAL TRAINING & EDUCATION CORP	925376	NONE	CF–10
INTERNATIONAL VITAMIN CORP	916614	NONE	CF–10
INTERPOOL INC	898777	NONE	CF–10
INTERSCIENCE COMPUTER CORP /CA/	907686	NONE	CF–10
INTERSTATE NATIONAL DEALER SERVICES INC	918184	NONE	CF–10
INTERTAN INC	803227	NONE	CF–10
INTERVEST BANCSHARES CORP	927807	NONE	CF–10
INTIME SYSTEMS INTERNATIONAL INC	934539	NONE	CF–10
INTRAMED LABORATORIES INC /CA/	884509	CF–10	REMOVE
INTRAV INC	942317	NONE	CF–10
INTUIT INC	896878	NONE	CF–10
INVESTMENT TECHNOLOGY GROUP INC	920424	NONE	CF–10
INVESTORS INSURANCE GROUP INC	043340	CF–06	CF–08

CHANGES FROM CORPORATION FINANCE EDGAR PHASE-IN LIST AS PUBLISHED IN SECURITIES ACT RELEASE NO. 7122—Continued

[December 19, 1994]

Name	CIK No.	Former group	New group
INVESTORS TRUST INC	052441	CF–05	CF–09
IVEY PROPERTIES INC	315882	CF–08	CF–10
IONIC FUEL TECHNOLOGY INC	925006	NONE	CF–10
IOWA BANCORP INC	921184	NONE	CF–10
IOWA SOUTHERN UTILITIES CO	052508	CF–04	REMOVE
IPC INFORMATION SYSTEMS INC	923071	NONE	CF–04
IPI INC	921753	NONE	CF–10
IRG TECHNOLOGIES INC	899283	NONE	CF–10
ISB FINANCIAL CORP/LA	933141	NONE	CF–10
ISOLYSER CO INC /GA/	929299	NONE	CF–10
ISRAEL TECH ACQUISITION CORP	918275	NONE	CF–10
ITHACA BANCORP INC	846656	CF–10	REMOVE
ITI TECHNOLOGIES INC	930542	NONE	CF–10
ITT EDUCATIONAL SERVICES INC	922475	NONE	CF–10
ITT FLOORPLAN RECEIVABLES LP	914063	NONE	CF–10
IVEX HOLDINGS CORP	900367	NONE	CF–10
IVI PUBLISHING INC	910391	NONE	CF–10
JABIL CIRCUIT INC	898293	NONE	CF–10
JACKSON HEWITT INC	840346	NONE	CF–10
JACKSON HOLDING CORP	925527	NONE	CF–10
JACOBS JAY INC	812127	CF–05	CF–08
JACQUES MILLER REALTY PARTNERS LP	703710	CF–07	REMOVE
JACQUES MILLER REALTY PARTNERS LP IV	784040	CF–06	REMOVE
J A INDUSTRIES INC	919723	NONE	CF–10
JAKES PIZZA INTERNATIONAL INC	904148	NONE	CF–10
JALATE LTD INC	914026	NONE	CF–10
JAMES RIVER BANKSHARES INC	935037	NONE	CF–10
JASON NORTHCO PROPERTIES LP II	746031	CF–07	REMOVE
JAVA CENTRALE INC /CA/	920528	NONE	CF–10
JDN REALTY CORP	916836	NONE	CF–10
JEFFERSON BANCORP INC /LA/	921581	NONE	CF–10
JEFFERSON SMURFIT CORP	727742	CF–02	CF–02
Change to JSCE INC	727742	CF–02	CF–02
JETFLEET III	930832	NONE	CF–10
JOHNSTOWN AMERICA INDUSTRIES INC	906114	NONE	CF–10
JOHNSTOWN CONSOLIDATED INCOME PARTNERS	787621	CF–06	CF–08
JOHNSTOWN CONSOLIDATED INCOME PARTNERS 2	812431	CF–07	CF–08
JONES INTERACTIVE MULTIMEDIA TRUST	935809	NONE	CF–10
JONES PROGRAMMING PARTNERS 3 LTD	934390	NONE	CF–10
JORGENSEN EARLE M HOLDING CO INC	931687	NONE	CF–10
JOS A BANK CLOTHIERS INC	814675	NONE	CF–10
JOSHUA J LTD	925604	NONE	CF–10
JOTAN INC	921381	NONE	CF–10
JPS AUTOMOTIVE PRODUCTS CORP	919233	NONE	CF–10
JP FOODSERVICE INC	928395	NONE	CF–10
JUNO ACQUISITIONS INC	927040	NONE	CF–10
JUPITER NATIONAL INC	043620	NONE	CF–10
JUST FOR FEET INC	918111	NONE	CF–10
JUST LIKE HOME INC	934380	NONE	CF–10
KAHLER MANAGEMENT CORP	929536	NONE	CF–08
KAHLER REALTY CORP	928697	CF–10	CF–08
KANEB PIPE LINE PARTNERS LP	853890	CF–05	CF–04
KARCHER CARL ENTERPRISES INC	353718	CF–04	REMOVE
KASLER HOLDING CO	906469	NONE	CF–10
KATZ MEDIA GROUP INC	934494	NONE	CF–10
KBK CAPITAL CORP	921559	NONE	CF–10
KEARNY STREET REAL ESTATE CO LP	901080	NONE	CF–10
KELLER FINANCIAL SERVICES OF CENTRAL FLORIDA INC /FL/	915776	NONE	CF–10
KELLER FINANCIAL SERVICES OF CLEARWATER INC	895779	NONE	CF–10
KELLER FINANCIAL SERVICES OF FLORIDA INC	886021	NONE	CF–10
KELLER FINANCIAL SERVICES OF MID FLORIDA INC	922363	NONE	CF–10
KELLER FINANCIAL SERVICES OF NORTH FLORIDA INC	923170	NONE	CF–10
KELLER FINANCIAL SERVICES OF PINELLAS INC	906604	NONE	CF–10
KELLER FINANCIAL SERVICES OF WEST FLORIDA INC	927974	NONE	CF–10
KELLEY OIL CORP	746627	CF–06	REMOVE
KELLEY OIL & GAS CORP	930529	NONE	CF–10
KELLEY PARTNERS 1991 DEVELOPMENT DRILLING PROGRAM	876859	CF–10	REMOVE
KELLEY PARTNERS 1994 DEVELOPMENT DRILLING PROGRAM	915915	NONE	CF–10
KENDALL INTERNATIONAL INC	851961	CF–10	REMOVE

CHANGES FROM CORPORATION FINANCE EDGAR PHASE-IN LIST AS PUBLISHED IN SECURITIES ACT RELEASE NO. 7122—Continued

[December 19, 1994]

Name	CIK No.	Former group	New group
KENETECH CORP	807708	NONE	CF–10
KENMAR PERFORMANCE PARTNERS LP /NY/	922575	NONE	CF–10
KENTUCKY ELECTRIC STEEL INC /DE/	910394	NONE	CF–10
KENTUCKY FIRST BANCORP INC	943891	NONE	CF–10
KEPTEL INC	819840	CF–07	REMOVE
KEYSTONE CUSTODIAN FUNDS INC	907244	NONE	CF–10
KEYSTONE INVESTMENTS INC	907243	NONE	CF–10
KEY TECHNOLOGY INC	906193	NONE	CF–10
KFX INC	912365	NONE	CF–10
KIRLIN HOLDING CORP	930797	NONE	CF–10
KIRSCHNER MEDICAL CORP	785022	CF–06	REMOVE
KITTY HAWK INC	932110	NONE	CF–10
KLS ENVIRO RESOURCES INC	894988	NONE	CF–10
KMS INDUSTRIES INC	056356	CF–06	CF–09
KM SYSTEMS INC	730991	CF–06	CF–10
KNICKERBOCKER CAPITAL CORPORATION	818806	NONE	CF–10
KNICKERBOCKER L L CO INC	932136	NONE	CF–10
KNICKERBOCKER VILLAGE INC	056396	CF–07	CF–09
KNIGHT NATURAL GAS INC	940516	NONE	CF–10
KNIGHT TRANSPORTATION INC	929452	NONE	CF–10
KNOGO CORP	056439	CF–05	REMOVE
KNOGO NORTH AMERICA INC	933161	NONE	CF–10
KNOWLEDGEWARE INC	854992	CF–05	REMOVE
Change to STERLING SOFTWARE SOUTHERN INC	854992	CF–05	REMOVE
KOALA CAPITAL CORP	894539	NONE	CF–10
KOALA CORP /CO/	913285	NONE	CF–10
KOGER PROPERTIES INC /FL/	355357	CF–03	REMOVE
KOPPERS INDUSTRIES INC	916075	NONE	CF–10
KP GRUBB & ELLIS REALTY INCOME FUND LP	806186	CF–07	CF–09
KP MILLER REALTY GROWTH FUND I LP	700834	CF–06	CF–09
KRELITZ INDUSTRIES INC	056808	CF–06	REMOVE
KRUPP INSTITUTIONAL MORTGAGE FUND LTD PARTNERSHIP	757549	CF–06	CF–04
K&S VENTURES INC	928373	NONE	CF–10
KTI INC	931581	NONE	CF–10
KURZWEIL APPLIED INTELLIGENCE INC /DE/	769191	NONE	CF–10
LABORATORY SPECIALISTS OF AMERICA INC	925052	NONE	CF–10
LACROSSE FOOTWEAR INC	919443	NONE	CF–10
LADY LUCK GAMING FINANCE CORP	921178	NONE	CF–10
LAFAYETTE INDUSTRIES INC	918377	NONE	CF–10
LA JOLLA PHARMACEUTICAL CO	920465	NONE	CF–10
LAKEVIEW FINANCIAL CORP /NJ/	921692	NONE	CF–10
LAMAR ADVERTISING CO	899045	NONE	CF–10
LAMBERT COMMUNICATIONS INC	913755	NONE	CF–10
LANCER INDUSTRIES INC /DE/	722069	CF–09	REMOVE
LANDAIR SERVICES INC	912728	NONE	CF–10
LANDMARK BANCORP	705403	CF–08	CF–10
LANDRYS SEAFOOD RESTAURANTS INC	908652	NONE	CF–10
LA PETITE HOLDINGS CORP	901116	NONE	CF–10
LA QUINTA MOTOR INNS LTD PARTNERSHIP	799169	CF–04	REMOVE
LARK TECHNOLOGIES INC	942134	NONE	CF–10
LASERTECHNICS INC	710597	CF–07	CF–09
LAS VEGAS COMMUNICATIONS CORP	933031	NONE	CF–10
LAS VEGAS MAJOR LEAGUE SPORTS INC	918764	NONE	CF–10
LAZER TRON CORP	906730	NONE	CF–10
LCI INTERNATIONAL INC /VA/	899760	NONE	CF–10
LCS BANCORP INC	929989	NONE	CF–10
LDB CORP /TX/	740745	CF–05	REMOVE
LEADER FINANCIAL CORP	901829	NONE	CF–10
LEADING EDGE EARTH PRODUCTS INC	911212	NONE	CF–10
LEAK X ENVIRONMENTAL CORP	842697	CF–08	CF–10
LEASEWAY TRANSPORTATION CORP	313153	NONE	CF–10
LEATHER FACTORY INC	909724	NONE	CF–10
LEGGOONS INC	911934	NONE	CF–10
LEHMAN STRUCTURED ASSETS INC	898738	NONE	CF–10
LESLIE BUILDING PRODUCTS INC	922984	NONE	CF–10
LEVEL ONE COMMUNICATIONS INC /CA/	908985	NONE	CF–10
LEVIATHAN GAS PIPELINE PARTNERS L P	895040	NONE	CF–10
LEVITZ FURNITURE INC	902279	NONE	CF–10
LEXINGTON CORPORATE PROPERTIES INC	910108	NONE	CF–10

CHANGES FROM CORPORATION FINANCE EDGAR PHASE-IN LIST AS PUBLISHED IN SECURITIES ACT RELEASE NO. 7122—Continued

[December 19, 1994]

Name	CIK No.	Former group	New group
LIBBEY INC	902274	NONE	CF–10
LIBERTY GROWTH PROPERTIES LTD PARTNERSHIP	775527	NONE	CF–10
LIBERTY HIGH INCOME PLUS LTD PARTNERSHIP	813248	NONE	CF–10
LIBERTY HOUSING PARTNERS LTD PARTNERSHIP	744766	NONE	CF–10
LIBERTY INCOME PROPERTIES LTD PARTNERSHIP	783901	NONE	CF–10
LIBERTY MEDIA CORPORATION	869614	CF–10	REMOVE
LIBERTY PROPERTY LIMITED PARTNERSHIP	921113	NONE	CF–10
LIBERTY PROPERTY TRUST	921112	NONE	CF–10
LIBERTY REAL ESTATE LTD PARTNERSHIP	701545	NONE	CF–10
LIBERTY REAL ESTATE LTD PARTNERSHIP II	711248	NONE	CF–10
LIBERTY REAL ESTATE LTD PARTNERSHIP III	737169	NONE	CF–10
LIBERTY TECHNOLOGIES INC	897730	NONE	CF–10
LIDA INC	822372	NONE	CF–10
LIFE BANCORP INC	926039	NONE	CF–10
LIFECELL CORP	849448	NONE	CF–10
LIFERATE SYSTEMS INC	937251	NONE	CF–10
LIFESTAR CORP	923137	NONE	CF–10
LIFETIME PRODUCTS INC	039503	CF–06	REMOVE
LIGHT SAVERS U S A INC	911434	NONE	CF–10
LIN TELEVISION CORP	931058	NONE	CF–10
LINCOLN FINANCIAL BANCORP INC	921214	NONE	CF–10
LINCOLN FOODSERVICE PRODUCTS INC	791726	CF–06	REMOVE
LINCOLN LOGS LTD	717422	CF–07	CF–08
LINCOLN SNACKS CO	914642	NONE	CF–10
LINDAS FLAME ROASTED CHICKEN INC	920210	NONE	CF–10
LOAN AMERICA FINANCIAL CORP	759578	CF–09	REMOVE
LOCKHEED MARTIN CORP	936468	NONE	CF–05
LODGENET ENTERTAINMENT CORP	911002	NONE	CF–10
LOEWENSTEIN FURNITURE GROUP INC	905723	CF–10	REMOVE
LOGANSPORT FINANCIAL CORP	939928	NONE	CF–10
LOIS/USA INC	930004	NONE	CF–10
LONE MOUNTAIN MINING CORP	943379	NONE	CF–10
LONE STAR CASINO CORP	897545	NONE	CF–10
LONGPORT INC	919043	NONE	CF–10
LORONIX INFORMATION SYSTEMS INC	925538	NONE	CF–10
LOTTERY ENTERPRISES INC	896195	NONE	CF–10
LOUIS DREYFUS NATURAL GAS CORP	912264	NONE	CF–10
LOUISIANA CASINO CRUISES INC	916758	NONE	CF–10
LSB FINANCIAL CORP	930405	NONE	CF–10
LUCILLE FARMS INC	908179	NONE	CF–10
LUCOR INC /FL/	914791	NONE	CF–10
LUNDGREN BROS CONSTRUCTION INC	898148	NONE	CF–10
LUND INTERNATIONAL HOLDINGS INC	820526	CF–07	CF–09
LXR BIOTECHNOLOGY INC	899504	NONE	CF–10
LYMAN LUMBER CO /MN	889605	NONE	CF–10
LYNX THERAPEUTICS INC	913275	NONE	CF–10
M&M FINANCIAL CORP /SC/	919162	NONE	CF–10
MACE SECURITY INTERNATIONAL INC	912607	NONE	CF–10
MACERICH CO	912242	NONE	CF–10
MACHEEZMO MOUSE RESTAURANTS INC	928065	NONE	CF–10
MACROMEDIA INC	913949	NONE	CF–10
MADDEN STEVEN LTD	913241	NONE	CF–10
MADISON GROUP ASSOCIATES INC /DE/	016926	CF–07	CF–10
MADISON HOLDINGS INC	934847	NONE	CF–10
MADISON SPORTS & ENTERTAINMENT GROUP INC	907238	NONE	CF–10
MAGNA LAB INC	895464	NONE	CF–10
MAIL WELL CORP	920944	NONE	CF–10
MALAN REALTY INVESTORS INC	914735	NONE	CF–10
MALRITE GUARANTEED BROADCAST PARTNERS LP	803018	CF–10	REMOVE
MANATEE AMERICAN FINANCIAL CORP	911355	NONE	CF–10
MANHATTAN BAGEL CO INC	914565	NONE	CF–10
MANUFACTURED HOME COMMUNITIES INC	895417	NONE	CF–10
MAPINFO CORP	916238	NONE	CF–10
MARBLEDGE GROUP INC	907161	NONE	CF–10
MARCUS CABLE CO LP	910629	NONE	CF–10
MARINER HEALTH GROUP INC	900304	NONE	CF–10
MARK CENTERS TRUST	899629	NONE	CF–10
MARKER INTERNATIONAL	925172	NONE	CF–10
MARQUETTE ELECTRONICS INC	062675	NONE	CF–10

CHANGES FROM CORPORATION FINANCE EDGAR PHASE-IN LIST AS PUBLISHED IN SECURITIES ACT RELEASE NO. 7122—Continued

[December 19, 1994]

Name	CIK No.	Former group	New group
MARRIOTT INTERNATIONAL INC	905036	NONE	CF–10
MARS ACQUISITIONS INC	936001	NONE	CF–10
MARSHALLTOWN FINANCIAL CORP	916395	NONE	CF–10
MARTIN COLOR-FI INC	898311	NONE	CF–10
MARTIN INDUSTRIES INC /DE/	942143	NONE	CF–10
MARTIN MARIETTA MATERIALS INC	916076	NONE	CF–10
MARTIN MARIETTA TECHNOLOGIES INC	062857	CF–02	REMOVE
MARVEL HOLDINGS INC	904083	NONE	CF–10
MARVEL III HOLDINGS INC	921145	NONE	CF–10
MARVEL PARENT HOLDINGS INC	909169	NONE	CF–10
MASTER GLAZIERS KARATE INTERNATIONAL INC	906249	NONE	CF–10
MATHSOFT INC	895095	NONE	CF–10
MATTSON TECHNOLOGY INC	928421	NONE	CF–10
MAXIM GROUP INC	910468	NONE	CF–10
MAXIS INC	943583	NONE	CF–10
MAXWELL SHOE CO INC	918578	NONE	CF–10
MBLA FINANCIAL CORP	897999	NONE	CF–10
MCARTHUR GLEN REALTY CORP	909283	NONE	CF–10
MCB FINANCIAL CORP	902789	NONE	CF–10
MCCAW CELLULAR COMMUNICATIONS INC	818687	CF–02	REMOVE
MCCORMICK COMMODITY FUND I LP	354995	CF–06	REMOVE
MCCORMICK COMMODITY FUND II LP	843819	CF–09	REMOVE
MCCRORY PARENT CORP	055211	CF–09	REMOVE
MCDERMOTT J RAY SA	934590	CF–10	CF–07
MCMORAN OIL & GAS CO /DE/	921941	NONE	CF–10
MCQUIDDY HOLDINGS INC	943089	NONE	CF–10
MCRAE INDUSTRIES INC /DE/	729284	CF–06	CF–05
MDL INFORMATION SYSTEMS INC	895330	NONE	CF–10
MEADOW VALLEY CORP	934749	NONE	CF–10
MECKLERMEDIA CORP	916759	NONE	CF–10
MED-DESIGN CORP	943736	NONE	CF–10
MEDCATH INC	931782	NONE	CF–10
MEDIA ARTS GROUP INC	924645	NONE	CF–10
MEDICAL AMBULATORY CARE INC	924775	NONE	CF–10
MEDICALCONTROL INC	897546	NONE	CF–10
MEDICAL DEFENSE HOLDING CO	934384	NONE	CF–10
MEDICAL MANAGEMENT INC	911691	NONE	CF–10
MEDICAL POLYMERS TECHNOLOGIES INC	898770	NONE	CF–10
MEDIQ PRN LIFE SUPPORT SERVICES INC	887420	CF–10	REMOVE
MEDISENSE INC /MA/	922872	NONE	CF–10
MEDITE CORP	934610	CF–10	CF–04
MEDPARTNERS INC	906568	NONE	CF–10
MEDPLUS INC /OH/	922723	NONE	CF–10
MEDSTAT SYSTEMS INC	726732	CF–08	REMOVE
Change to MEDSTAT GROUP INC	726732	CF–08	REMOVE
MEGAHERTZ HOLDING CORP	797164	CF–08	REMOVE
MENDOCINO BREWING CO INC	919134	NONE	CF–10
MEPC CAPITAL CORP	819343	CF–03	REMOVE
MERCANTILE BANK OF ILLINOIS NATIONAL ASSOCIATION	937939	NONE	CF–10
MERIDIAN FINANCIAL CORP	917214	NONE	CF–10
MERIDIAN POINT REALTY TRUST 82	315138	CF–08	REMOVE
MERIDIAN POINT REALTY TRUST 83	703702	CF–08	CF–09
MERIDIAN POINT REALTY TRUST IV CO	759819	CF–08	CF–09
MERIDIAN POINT REALTY TRUST VI CO	786050	CF–08	CF–09
MERIDIAN POINT REALTY TRUST VII CO	774653	CF–08	CF–09
MERIDIAN SPORTS INC	926474	NONE	CF–10
MERIT HOLDING CORP	930807	NONE	CF–10
MERIT SECURITIES CORP	929426	NONE	CF–10
MERIT SOFTWARE INC	914380	NONE	CF–10
MERIX CORP	921365	NONE	CF–10
METAMORPHIC CORP	899173	NONE	CF–10
METROLOGIC INSTRUMENTS INC	815910	NONE	CF–10
METRO ONE DIRECT INFORMATION SERVICES INC	920990	NONE	CF–10
METROCALL INC	906525	NONE	CF–10
METROTRANS CORP	920464	NONE	CF–10
MEWBOURNE ENERGY 95–96 DRILLING PROGRAMS	942308	NONE	CF–10
MEYERSON M H & CO INC /NJ/	913781	NONE	CF–10
MFRI INC	914122	NONE	CF–10
MFS COMMUNICATIONS CO INC	898623	NONE	CF–10

CHANGES FROM CORPORATION FINANCE EDGAR PHASE-IN LIST AS PUBLISHED IN SECURITIES ACT RELEASE NO. 7122—Continued

[December 19, 1994]

Name	CIK No.	Former group	New group
MICOM COMMUNICATIONS CORP	920611	NONE	CF–10
MICREL INC	932111	NONE	CF–10
MICRION CORP /MA/	919646	NONE	CF–10
MICROCHIP TECHNOLOGY INC	827054	NONE	CF–10
MICRO COMPONENT TECHNOLOGY INC	911149	NONE	CF–10
MICROELECTRONIC PACKAGING INC /CA/	916232	NONE	CF–10
MICRO INTEGRATION CORP /DE/	920863	NONE	CF–10
MICROTEC RESEARCH INC /DE/	932203	NONE	CF–10
MICROTERRA INC	830991	CF–07	CF–09
MICROTEST INC	891920	NONE	CF–10
MICROS TO MAINFRAMES INC	906282	NONE	CF–10
MID AMERICA APARTMENT COMMUNITIES INC	912595	NONE	CF–10
MIDAMERICAN ENERGY CO	928576	NONE	CF–10
MID ATLANTIC BANKCORP	759727	CF–09	REMOVE
MID CENTRAL FINANCIAL CORP	916790	NONE	CF–10
MIDCOM COMMUNICATIONS INC	943357	NONE	CF–10
MIDDLE BAY OIL CO INC	903267	NONE	CF–10
MIDGARD ENERGY CO	934591	NONE	CF–10
MIDLAND RESOURCES INC /TX/	868424	NONE	CF–10
MID SOUTH PHYSICIAN ALLIANCE INC	943308	NONE	CF–10
MID STATE TRUST II	828978	CF–09	REMOVE
MID STATE TRUST IV	936157	NONE	CF–10
MIKASA INC	920758	NONE	CF–10
MIKOHN GAMING CORP	912241	NONE	CF–10
MILLBURN WORLD RESOURCE TRUST	943487	NONE	CF–10
MILLER INDUSTRIES INC /TN/	924822	NONE	CF–10
MILLS CORP	914713	NONE	CF–10
MILTON FEDERAL FINANCIAL CORP	925722	NONE	CF–10
MINERAL KING BANCORP INC	842179	CF–09	REMOVE
MINISTOR PERIPHERALS INTERNATIONAL LTD	922871	NONE	CF–10
MINNESOTA EDUCATIONAL COMPUTING CORP	917390	NONE	CF–10
MISSION ENERGY CO	930835	NONE	CF–10
MISSISSIPPI VIEW HOLDING CO	933404	NONE	CF–10
MISTER JAY FASHIONS INTERNATIONAL INC	895092	NONE	CF–10
MITCHAM INDUSTRIES INC	926423	NONE	CF–10
MITY LITE INC	921030	NONE	CF–10
MK GOLD CO	913586	NONE	CF–10
MK RAIL CORP	919563	NONE	CF–10
MLF BANCORP INC	920616	NONE	CF–10
ML GLOBAL HORIZONS LP	904918	NONE	CF–10
MLH INCOME REALTY PARTNERSHIP	317150	CF–09	CF–10
MLH INCOME REALTY PARTNERSHIP II	701285	CF–09	CF–10
MLH INCOME REALTY PARTNERSHIP III	710132	CF–08	CF–10
MLH INCOME REALTY PARTNERSHIP IV	718417	CF–08	CF–10
MLH INCOME REALTY PARTNERSHIP V	755643	CF–08	CF–10
MLH INCOME REALTY PARTNERSHIP VI	771586	CF–08	CF–10
ML PRINCIPAL PROTECTION PLUS LP	917259	NONE	CF–10
ML REAL ESTATE RECOVERY FUND LP	825036	CF–09	REMOVE
MMCA AUTO RECEIVABLES INC	910224	NONE	CF–10
MMI COMPANIES INC	767308	NONE	CF–10
M MORTGAGE 1993–B	942286	NONE	CF–10
M MORTGAGE INC 1993–D	942399	NONE	CF–10
MNX INC	795425	CF–05	CF–05
Change to MARK VII INC	795425	CF–05	CF–05
MOBILE MINI INC	911109	NONE	CF–10
MOBILEMEDIA COMMUNICATIONS INC	912192	NONE	CF–10
MOBILEMEDIA CORP	912091	NONE	CF–10
MOBILE NATIONAL CORP	783739	CF–08	CF–08
Change to SOUTH ALABAMA BANCORPORATION INC /DE/	783739	CF–08	CF–08
MODEL IMPERIAL INC	921550	NONE	CF–10
MODERN MEDICAL MODALITIES CORP	902635	NONE	CF–10
MODERN TECHNOLOGY CORP	711422	CF–08	CF–10
MOLINE REAL ESTATE INC	909125	NONE	CF–10
MOLTEN METAL TECHNOLOGY INC /DE/	895517	NONE	CF–10
MONACO COACH CORP /DE/	910619	NONE	CF–10
MONDAVI ROBERT CORP	902276	NONE	CF–10
MONEY MARKET AUTO LOAN TRUST 1990–1	864920	CF–10	CF–07
MONOCACY BANCSHARES INC	908962	NONE	CF–10
MONOCLONAL MEDICAL INC	841112	CF–09	REMOVE

CHANGES FROM CORPORATION FINANCE EDGAR PHASE-IN LIST AS PUBLISHED IN SECURITIES ACT RELEASE NO. 7122—Continued

[December 19, 1994]

Name	CIK No.	Former group	New group
MONROC INC	919016	NONE	CF–10
MONTANA NATURALS INTERNATIONAL INC	819182	CF–08	REMOVE
MONTEDISON SPA /ITALY/	814287	NONE	CF–07
MONTEREY BAY BANCORP INC	930429	NONE	CF–10
MONTEREY PASTA CO	913032	NONE	CF–10
MORAN TRANSPORTATION CO	928188	NONE	CF–10
MORGAN FOOD CORP	881767	NONE	CF–10
MORGAN GROUP INC	906609	NONE	CF–10
MORGAN J P STRUCTURED FINANCE CORP	920466	NONE	CF–10
MORGAN JP COMMERCIAL MORTGAGE FINANCE CORP	937955	NONE	CF–10
MORNINGSTAR FOODS INC	832768	CF–03	CF–03
Change to MORNINGSTAR GROUP INC	832768	CF–03	CF–03
MOSLER INC	792851	NONE	CF–10
MOTHERS WORK INC	896985	NONE	CF–10
MOTORCAR PARTS & ACCESSORIES INC	918251	NONE	CF–10
MOUNTAIN PARKS FINANCIAL CORP	901375	NONE	CF–10
MOUNTASIA ENTERTAINMENT INTERNATIONAL INC	912027	NONE	CF–10
MOUNTBATTEN INC	922597	NONE	CF–10
MOVIE GALLERY INC	925178	NONE	CF–10
MOVIEFONE INC	919867	NONE	CF–10
MRI OF NORTHERN NEW JERSEY LP	810143	CF–08	CF–10
MSB FINANCIAL INC	930541	NONE	CF–10
MSI INCOME FUND 104 LP	906935	NONE	CF–10
MSR EXPLORATION LTD	719187	NONE	CF–10
MTI TECHNOLOGY CORP	901696	NONE	CF–10
MULTI BENEFIT REALTY FUND 87–1	802200	CF–06	CF–08
MULTI MARKET RADIO INC	900302	NONE	CF–10
MULTI-MEDIA TUTORIAL SERVICES INC	935496	NONE	CF–10
MULTIVEST REAL ESTATE FUND LTD SERIES VI	068842	CF–06	REMOVE
MUSTANG SOFTWARE INC	940986	NONE	CF–10
MUTUAL BAN CO INC /MO/	929589	NONE	CF–10
MUTUAL BENEFIT COMMERCIAL PROPERTIES INCOME PARTNERSHIP LP	766828	CF–09	CF–10
MUTUAL BENEFIT INCOME PARTNERS LP I	830350	CF–09	CF–10
MUTUAL BENEFIT MORTGAGE INVESTORS III LP	786420	CF–09	CF–10
MUTUAL BENEFIT MORTGAGE INVESTORS 1985	760994	CF–09	CF–10
MUTUAL BENEFIT TRAMMELL CROW RESIDENTIAL OPPORTUNITY FUND	779317	CF–09	CF–10
MUTUAL RISK MANAGEMENT LTD	826918	NONE	CF–10
MVE HOLDINGS INC	930404	NONE	CF–10
MVSI INC	937603	NONE	CF–10
N–VISION INC	940518	NONE	CF–10
NABISCO HOLDINGS CORP	932130	NONE	CF–10
NACO INDUSTRIES INC	931585	NONE	CF–10
NACOLAH HOLDING CORP	913667	NONE	CF–10
NASHVILLE COUNTRY CLUB INC	913201	NONE	CF–10
NATIONAL CITY BANCORPORATION	069968	NONE	CF–10
NATIONAL DIAGNOSTICS INC	925894	NONE	CF–10
NATIONAL ENERGY GROUP INC	870756	NONE	CF–07
NATIONAL ENVIRONMENTAL SERVICE CO	922868	NONE	CF–10
NATIONAL GAMING CORP	929929	NONE	CF–10
NATIONAL GOLF PROPERTIES INC	905897	NONE	CF–10
NATIONAL GYPSUM CO /DE/	910071	NONE	CF–10
NATIONAL HEALTH LABORATORIES INC	832427	CF–03	REMOVE
NATIONAL HEALTH & SAFETY CORP	901899	NONE	CF–10
NATIONAL HOUSING TRUST LP	818803	CF–06	CF–09
NATIONAL INDUSTRIAL SECURITY CORP	104401	CF–08	CF–09
NATIONAL INSTRUMENTS CORP /DE/	935494	NONE	CF–10
NATIONAL MEDICAL FINANCIAL SERVICES CORP	934548	NONE	CF–10
NATIONAL PROPERTY ANALYSTS MASTER LIMITED PARTNERSHIP	926843	NONE	CF–10
NATIONAL RECORD MART INC /DE/	904535	NONE	CF–10
NATIONAL SPECIALTY NETWORKS INC	895521	NONE	CF–10
NATIONAL TELEPHONE COMMUNICATIONS INC	862883	CF–10	REMOVE
NATIONAL WIRELESS HOLDINGS INC	915016	NONE	CF–10
NATIONSBANK OF DELAWARE NA	912838	NONE	CF–10
NATIONSMART CORP	896502	NONE	CF–10
NATIONWIDE ACQUISITION CORP	943754	NONE	CF–10
NATTEM USA INC	729443	NONE	CF–10
NATURADE INC	797167	NONE	CF–10
NATURAL ALTERNATIVES INTERNATIONAL INC	787253	CF–07	CF–09
NATURAL MICROSYSTEMS CORP	915866	NONE	CF–10

CHANGES FROM CORPORATION FINANCE EDGAR PHASE-IN LIST AS PUBLISHED IN SECURITIES ACT RELEASE NO. 7122—Continued

[December 19, 1994]

Name	CIK No.	Former group	New group
NDL PRODUCTS INC /DE/	814930	CF–07	REMOVE
NEIMAN MARCUS FUNDING CORP	934844	NONE	CF–10
NEOPHARM INC	942788	NONE	CF–10
NEOPATH INC	851729	NONE	CF–10
NEOSTAR RETAIL GROUP INC	932790	NONE	CF–08
NETCOM ON LINE COMMUNICATIONS SERVICES INC	909624	NONE	CF–10
NETMANAGE INC	909793	NONE	CF–10
NETVANTAGE INC	934620	NONE	CF–10
NETWORK CONNECTION INC	932088	NONE	CF–10
NETWORK EXPRESS INC	896281	NONE	CF–10
NETWORK FINANCIAL SERVICES INC	820771	CF–09	CF–09
Change to WESTMARK GROUP HOLDINGS INC	820771	CF–09	CF–09
NETWORK PERIPHERALS INC	922521	NONE	CF–10
NEUROBIOLOGICAL TECHNOLOGIES INC /CA/	918112	NONE	CF–10
NEURO NAVIGATIONAL CORP	896726	NONE	CF–10
NEVADA ENERGY COMPANY INC	712803	NONE	CF–10
NEW CENTRAL ILLINOIS FINANCIAL CO INC	941622	NONE	CF–10
NEW DANA ACQUISITION CORP	933750	NONE	CF–10
NEW DOSKOCIL INC	938348	NONE	CF–06
NEW ENVIROQ CORP	937256	NONE	CF–10
NEW GMH INC	932202	NONE	CF–10
NEW ISRAEL ACQUISITION CORP	936387	NONE	CF–10
NEW LFC INC	936372	NONE	CF–10
NEW PROSPERITY BANKING CORP	934856	NONE	CF–10
NEW SOUTH FEDERAL SAVINGS BANK	923663	NONE	CF–10
NEW WEST EYEWORKS INC	914538	NONE	CF–10
NEW WORLD COMMUNICATION GROUP INC	916083	NONE	CF–10
NEW YORK LIFE OIL & GAS NET PROFITS PRODUCING PROP III G L P	895201	NONE	CF–10
NEW YORK LIFE OIL & GAS NET PROFITS PRODUCING PROP III H L P	895204	NONE	CF–10
NEW YORK LIFE OIL & GAS OPERATING PRODUCING PROP III G L P	895203	NONE	CF–10
NEW YORK LIFE OIL & GAS OPERATING PRODUCING PROP III H L P	895202	NONE	CF–10
NEWCARE HEALTH CORP	923020	NONE	CF–10
NEWFIELD EXPLORATION CO /DE/	912750	NONE	CF–10
NEXGEN INC	909183	NONE	CF–10
NEXSTAR PHARMACEUTICALS INC	915359	NONE	CF–10
NFS FINANCIAL CORP	794103	CF–07	CF–09
NICHOLS INSTITUTE /DE/	765410	CF–09	REMOVE
NICKELODEON THEATER CO INC	931085	NONE	CF–10
NN BALL & ROLLER INC	918541	NONE	CF–10
NNRC INC	927522	NONE	CF–10
NOEL GROUP INC	829269	NONE	CF–10
NOONEY REAL PROPERTY INVESTORS TWO LP	312155	CF–09	CF–06
NOONEY REAL PROPERTY INVESTORS THREE LP	350113	CF–06	REMOVE
NORTH AMERICAN ADVANCED MATERIALS CORP	919169	NONE	CF–10
NORTH AMERICAN TRUST INC	773654	CF–06	CF–09
NORTH BAY BANCORP	754440	CF–06	CF–09
NORTHERN STATES FINANCIAL CORP /DE/	744485	NONE	CF–10
NORTH JERSEY ENERGY ASSOCIATES	934666	NONE	CF–10
NORTHCORP REALTY ADVISORS INC	915338	NONE	CF–10
NORTHEAST ENERGY ASSOCIATES	934667	NONE	CF–10
NORTHEAST INDIANA BANCORP INC	942898	NONE	CF–10
NORTHERN BORDER PARTNERS LP	909281	NONE	CF–10
NORTHERN DANCER CORP	820408	NONE	CF–10
NORTHSTAR HEALTH SERVICES INC	896880	NONE	CF–10
NORTHWEST AIRLINES CORP	917678	NONE	CF–10
NORTHWEST AIRLINES INC /MN	919897	NONE	CF–10
NORTHWEST EQUITY CORP	916527	NONE	CF–10
NORTHWEST INDIANA BANCORP	919864	NONE	CF–10
NORTHWESTERN FINANCIAL CORP	912611	NONE	CF–10
NORWEST MORTGAGE CONVENTIONAL 1 INC	731162	CF–07	CF–10
NORWEST MORTGAGE INSURED 1 INC	731767	CF–07	CF–10
NORWEST MORTGAGE INSURED 2 INC	740768	CF–08	CF–10
NORWOOD PROMOTIONAL PRODUCTS INC	902793	NONE	CF–10
NOVA CAPITAL INC	840404	CF–09	CF–09
Change to VISUAL EQUITIES INC	840404	CF–09	CF–09
NSC SERVICE GROUP INC	810111	CF–09	CF–09
Change to FIBERCORP INTERNATIONAL INC	810111	CF–09	CF–09
NS&L BANCORP INC	939929	NONE	CF–10
NSD BANCORP INC	898624	NONE	CF–10

CHANGES FROM CORPORATION FINANCE EDGAR PHASE-IN LIST AS PUBLISHED IN SECURITIES ACT RELEASE NO. 7122—Continued

[December 19, 1994]

Name	CIK No.	Former group	New group
NU KOTE HOLDING INC /DE	812423	NONE	CF–10
NUMBER NINE VISUAL TECHNOLOGY CORP	936448	NONE	CF–10
NUMED SURGICAL INC	921878	NONE	CF–10
NUTRITION FOR LIFE INTERNATIONAL INC	913614	NONE	CF–10
NVF CO	073515	CF–05	CF–09
N–VIRO RECOVERY INC	895565	CF–10	CF–10
Change to SYNAGRO TECHNOLOGIES INC	895565	CF–10	CF–10
NVR INC	906163	NONE	CF–10
NWCG HOLDINGS CORP	927805	NONE	CF–10
NWPS CAPITAL FINANCING I	946925	NONE	CF–07
NW VENTURE CORP	929752	NONE	CF–10
NYNEX CABLECOMMS GROUP INC	939916	NONE	CF–10
NYTEST ENVIRONMENTAL INC	766823	CF–07	CF–09
OAKWOOD MORTGAGE INVESTORS INC	929541	NONE	CF–10
OASIS RESIDENTIAL INC	910846	NONE	CF–10
OCCUSYSTEMS INC	924639	NONE	CF–10
ODETICS INC	350868	CF–05	CF–06
COUNSEL ENTERPRISES INC	912146	NONE	CF–10
OFFICE PRODUCTS NETWORK OF NORTH AMERICA INC	943087	NONE	CF–10
OFFICEMAX INC /OH/	929428	NONE	CF–10
OGDEN MCDONALD & CO	928375	NONE	CF–10
OGDEN PROJECTS INC	851945	CF–02	REMOVE
OHIO STATE BANCSHARES INC	919644	NONE	CF–10
OKLAHOMA SAVINGS INC	900626	CF–10	REMOVE
OLD AMERICA STORES INC	897506	NONE	CF–10
OLDE WINDSOR BANCORP INC	752324	CF–08	CF–08
Change to NEW ENGLAND COMMUNITY BANCORP	752324	CF–08	CF–08
OLD LYME HOLDING CORP	907575	NONE	CF–10
OLIVER TRANSPORTATION INC	900339	NONE	CF–10
OLYMPIC ENTERTAINMENT GROUP INC /NV/	934646	NONE	CF–10
OLYMPIC RECEIVABLES FIN CORP OLYMPIC AUTOMOBILE RE TR 1994–B	930558	NONE	CF–10
OLYMPIC RECEIVABLES FINANCE CORP	896982	NONE	CF–10
OLYMPIC STEEL INC	917470	NONE	CF–10
OMNI INSURANCE GROUP INC	906786	NONE	CF–10
OMNI MULTIMEDIA GROUP INC	933586	NONE	CF–10
OMNITEC INC	838872	CF–07	REMOVE
ONCORMED INC	922821	NONE	CF–10
ONECOMM CORP	906421	NONE	CF–10
ONSITE ENERGY CORP	909171	NONE	CF–10
ONYX ACCEPTANCE FINANCIAL CORP	927764	NONE	CF–10
OPAL INC	934385	NONE	CF–10
OPEN ENVIRONMENT CORP	940033	NONE	CF–10
OPPENHEIMER LANDMARK PROPERTIES LIQUIDATING TRUST	205741	CF–07	CF–10
OPPORTUNITY MANAGEMENT CO INC	912395	NONE	CF–10
OPTEX BIOMEDICAL INC /DE/	920374	NONE	CF–10
OPTICAL DATA SYSTEMS INC	736012	NONE	CF–10
OPTICAL SECURITY GROUP INC	843961	CF–08	CF–09
OPTI INC	899297	NONE	CF–10
OPTIONS CLEARING CORP	074751	NONE	CF–10
OPTO MECHANIK INC	031688	CF–06	CF–10
OPT SCIENCES CORP	074688	CF–08	CF–10
ORANGE BANCORP	702302	CF–08	CF–10
ORANGE COUNTY BREWING CO	927913	NONE	CF–10
ORAVAX INC	900122	NONE	CF–10
ORBIT SEMICONDUCTOR INC	930599	NONE	CF–10
ORBIT TECHNOLOGIES INC /DE/	937814	NONE	CF–10
ORPHAN MEDICAL INC	929548	NONE	CF–10
ORTEL CORP/DE/	928878	NONE	CF–10
ORTHODONTIC CENTERS OF AMERICA INC /DE/	931702	NONE	CF–10
ORTHOMET INC	765353	CF–06	REMOVE
ORTHOPEDIC TECHNOLOGY INC	896840	NONE	CF–10
ORYX TECHNOLOGY CORP	915355	NONE	CF–10
OSCC HOME EQUITY LOAN TRUST 1993–1	895146	NONE	CF–10
OSI SPECIALTIES HOLDING CO	922505	NONE	CF–10
OSI SPECIALTIES INC	909284	NONE	CF–10
OSMONICS INC	075049	CF–05	CF–04
OSTEX INTERNATIONAL INC /WA/	932631	NONE	CF–10
OSTRICH RESEARCH & TECHNOLOGIES CO INC	933506	NONE	CF–10
O'SULLIVAN INDUSTRIES HOLDINGS INC	915354	NONE	CF–10

CHANGES FROM CORPORATION FINANCE EDGAR PHASE-IN LIST AS PUBLISHED IN SECURITIES ACT RELEASE NO. 7122—Continued

[December 19, 1994]

Name	CIK No.	Former group	New group
OTTAWA FINANCIAL CORP	920604	NONE	CF–10
OVERHEAD DOOR INC	918857	NONE	CF–10
OWEN HEALTHCARE INC	919242	NONE	CF–10
OWOSSO CORP	921046	NONE	CF–10
OXFORD CAPITAL CORP	818475	NONE	CF–10
OXFORD RESOURCES CORP	911570	NONE	CF–10
OXIGENE INC	908259	NONE	CF–10
PACE HEALTH MANAGEMENT SYSTEMS INC	943324	NONE	CF–10
PACIFIC GREYSTONE CORP	920760	NONE	CF–10
PACIFIC GULF PROPERTIES INC	912597	NONE	CF–10
PACIFICORP FINANCIAL SERVICES INC	072965	CF–08	CF–10
PACIFIC REHABILITATION & SPORTS MEDICINE INC	910109	NONE	CF–10
PACIFIC RIM ENTERTAINMENT INC	898802	NONE	CF–10
PACIFIC SNAX CORP	923211	NONE	CF–10
PACIFIC SUNWEAR OF CALIFORNIA INC	874841	NONE	CF–10
PACKAGE MACHINERY CO	075675	CF–08	CF–10
PAGEMART INC	922227	NONE	CF–10
PAGING PARTNERS CORP	920854	NONE	CF–10
PAINEWEBBER COMMODITY LP II	352911	CF–08	REMOVE
PAINEWEBBER INSURED MORTGAGE PARTNERS 1–A	846557	CF–10	REMOVE
PAINEWEBBER MORTGAGE ACCEPTANCE CORP V	917248	NONE	CF–10
PAINEWEBBER MUNICIPAL ASSETS CORP	928361	NONE	CF–10
PAINEWEBBER MUNICIPAL STRUCTURED ASSETS CORP	931412	NONE	CF–10
PAIRGAIN TECHNOLOGIES INC /CA/	910032	NONE	CF–10
PALACE CASINOS INC	914626	NONE	CF–10
PALM BEACH TAN INC	914003	NONE	CF–10
PALM HARBOR HOMES INC /FL/	923473	NONE	CF–10
PALMER WIRELESS INC	919044	NONE	CF–10
PANAMSAT CORP	931134	NONE	CF–10
PANAMSAT LP	906283	NONE	CF–10
PANAX PHARMACEUTICAL CO LTD	929547	NONE	CF–10
PANDA PROJECT INC	917736	NONE	CF–10
PANTRY INC	915862	NONE	CF–10
PARAGON GROUP INC	921744	NONE	CF–10
PARAGON TRADE BRANDS INC	889429	NONE	CF–10
PARALLAN COMPUTER INC	864568	NONE	CF–10
PARCPLACE SYSTEMS INC	916354	NONE	CF–10
PARFUMS PARQUET INC	933749	NONE	CF–10
PARIS BUSINESS FORMS INC	789660	CF–06	CF–08
PARKERVISION INC	914139	NONE	CF–10
PARTNER RE HOLDINGS LTD	911421	NONE	CF–10
PATHFINDER CORP	757073	NONE	CF–10
PATHMARK STORES INC	095585	NONE	CF–10
PAXSON COMMUNICATIONS CORP	923877	CF–10	CF–07
P-COM INC	935493	NONE	CF–10
PC SERVICE SOURCE INC	919999	NONE	CF–10
PDC 1993–E LIMITED PARTNERSHIP	921111	NONE	CF–10
PDC 1994–1995 DRILLING PROGRAM	913779	NONE	CF–10
PDG REMEDIATION INC	927761	NONE	CF–10
PDK LABS INC	855352	NONE	CF–10
PDS FINANCIAL CORP	921438	NONE	CF–10
PDT INC /DE/	933745	NONE	CF–10
PEARCE SYSTEMS INTERNATIONAL INC	898901	NONE	CF–10
PEMEX EXPORT FUNDING CORP	933092	NONE	CF–10
PEMI BANCORP INC	768868	CF–08	CF–09
PENDA CORP	921745	NONE	CF–10
PENFED BANCORP INC	933158	NONE	CF–10
PENGUIN REFRIGERATION INC	901639	NONE	CF–10
PENN AMERICA GROUP INC	910110	NONE	CF–10
PENNFED FINANCIAL SERVICES INC	920945	NONE	CF–10
PENNICHUCK CORP	788885	NONE	CF–10
PENN NATIONAL GAMING INC	921738	NONE	CF–10
PENN OCTANE CORP	893813	NONE	CF–10
PENSKE TRUCK LEASING CO LP	921086	NONE	CF–10
PEOPLES BANK	906111	NONE	CF–10
PEOPLES BANK CORP OF INDIANAPOLIS	796322	NONE	CF–10
PEOPLES CHOICE TV CORP	903275	NONE	CF–10
PEOPLES FINANCIAL CORP	770460	NONE	CF–10
PEOPLES FINANCIAL CORP INC /PA/	936948	NONE	CF–10

CHANGES FROM CORPORATION FINANCE EDGAR PHASE-IN LIST AS PUBLISHED IN SECURITIES ACT RELEASE NO. 7122—Continued

[December 19, 1994]

Name	CIK No.	Former group	New group
PEOPLES SAVINGS FINANCIAL CORP /PA/	912861	NONE	CF–10
PEORIA REAL ESTATE INC	909123	NONE	CF–10
PEREGRINE FUTURES FUND L P	875263	CF–10	REMOVE
PERFECTDATA CORP	719662	CF–08	CF–10
PERFORMANCE FOOD GROUP CO	908254	NONE	CF–10
PERFORMANCE SYSTEMS INTERNATIONAL INC /NY/	940716	NONE	CF–10
PERIPHONICS CORP	937598	NONE	CF–10
PERRY COUNTY FINANCIAL CORP	931074	NONE	CF–10
PERSEPTIVE TECHNOLOGIES II CORP	914842	NONE	CF–10
PERSONNEL MANAGEMENT INC	916606	NONE	CF–10
PETCO ANIMAL SUPPLIES INC	888455	NONE	CF–10
PET FOOD WAREHOUSE INC	909752	NONE	CF–10
PET METRO INC	919148	NONE	CF–10
PET PRACTICE INC	931612	NONE	CF–10
PET PRODUCTS INC	881915	CF–10	REMOVE
PETROCORP INC	911359	NONE	CF–10
PETSTUFF INC	907147	NONE	CF–10
PHAMIS INC /WA/	932280	NONE	CF–10
PHARMACEUTICAL RESOURCES INC	878088	NONE	CF–04
PHC INC /MA/	915127	NONE	CF–10
PHILLIPS R H INC	925712	NONE	CF–10
PHOENIX GOLD INTERNATIONAL INC	943032	NONE	CF–10
PHOENIX LEASING AMERICAN BUSINESS FUND LP	898628	NONE	CF–10
PHOENIX LEASING INCOME FUND 1982–1	355945	CF–09	REMOVE
PHOTONICS CORP	912844	NONE	CF–10
PHYSICIAN CORPORATION OF AMERICA /DE/	812929	NONE	CF–10
PHYSICIAN RELIANCE NETWORK INC	930610	NONE	CF–10
PHYSICIAN SALES & SERVICE INC /FL/	920527	NONE	CF–10
PHYSICIANS CLINICAL LABORATORY INC	890685	NONE	CF–10
PICNIC POINT DEVELOPMENT CO LTD	277318	CF–08	REMOVE
PICO HOLDINGS INC	943893	NONE	CF–10
PIERCING PAGODA INC	925544	NONE	CF–10
PILLOWTEX CORP	896265	NONE	CF–10
PILOT TRANSPORT INC /NV/	943317	NONE	CF–10
PINNACLE FINANCIAL CORP	910678	NONE	CF–10
PIONEER BANCORPORATION	909953	NONE	CF–10
PITTENCRIEFF COMMUNICATIONS INC	903869	NONE	CF–10
PLAID CLOTHING GROUP INC	906769	NONE	CF–10
PLAINS REFRIGERANT RECLAIM CORP	909214	NONE	CF–10
PLANAR SYSTEMS INC /OR/	914251	NONE	CF–10
PLASTIGONE TECHNOLOGIES INC	835494	CF–08	CF–09
PLAY CO TOYS	927643	NONE	CF–10
PLAZA HOME MORTGAGE CORP /DE/	884500	CF–10	REMOVE
PLM EQUIPMENT GROWTH FUND	788813	CF–05	CF–04
PLM TRANSPORTATION EQUIPMENT PARTNERS IXD 1986 INCOME FUND	778794	CF–08	CF–07
PMC COMMERCIAL TRUST /TX	908311	NONE	CF–10
PM HOLDINGS CORP	909987	NONE	CF–10
PMI GROUP INC	935724	NONE	CF–10
PM MANAGEMENT SYSTEMS INC	910415	NONE	CF–10
PMT SERVICES INC /TN/	923410	NONE	CF–10
POCONO HOTELS CORP	079274	CF–07	CF–08
POINDEXTER J B & CO INC	918962	NONE	CF–10
POINTE FINANCIAL CORP	917331	NONE	CF–10
POLAR EXPRESS CORP	932508	NONE	CF–10
POLARIS INDUSTRIES INC /MN	931015	NONE	CF–04
POLAR MOLECULAR CORP /UT/	810613	CF–08	REMOVE
POLISH TELEPHONES & MICROWAVE CORP	925928	NONE	CF–10
POLLO TROPICAL INC	911601	NONE	CF–10
POLYMER GROUP INC	927417	NONE	CF–10
PORTLAND BREWING CO /OR/	943658	NONE	CF–10
PORTSMOUTH CORP /FL/	934768	NONE	CF–10
PORTSMOUTH SQUARE INC	079661	CF–08	CF–10
POSITIVE RESPONSE TELEVISION INC	921044	NONE	CF–10
POST PROPERTIES INC	903127	NONE	CF–10
POTOMAC BANCSHARES INC	925173	NONE	CF–10
PRECISION SYSTEMS INC	886074	NONE	CF–10
PREFERRED ENTERTAINMENT INC	906606	NONE	CF–10
PREISS BYRON MULTIMEDIA CO INC	919005	NONE	CF–10
PREMISYS COMMUNICATIONS INC	938733	NONE	CF–10

CHANGES FROM CORPORATION FINANCE EDGAR PHASE-IN LIST AS PUBLISHED IN SECURITIES ACT RELEASE NO. 7122—Continued

[December 19, 1994]

Name	CIK No.	Former group	New group
PRESIDIO CAPITAL CORP	943358	NONE	CF–10
PRESTIGE FINANCIAL CORP	899163	NONE	CF–10
PRI AUTOMATION INC	927362	NONE	CF–10
PRICE CO	356461	CF–01	REMOVE
PRICELLULAR CORP	932089	NONE	CF–10
PRICELLULAR WIRELESS CORP	935303	NONE	CF–10
PRIMADONNA RESORTS INC	901118	NONE	CF–10
PRIMECO INC	934387	CF–10	CF–07
PRIME MANAGEMENT GROUP INC	926234	NONE	CF–10
PRIME RESIDENTIAL INC	921946	NONE	CF–10
PRIME RETAIL INC	911708	NONE	CF–10
PRINCETON NATIONAL BANCORP INC	707855	NONE	CF–10
PRINTRONIX INC	311505	CF–05	CF–04
PRISMASYSTEMS CORP	925603	NONE	CF–10
PROBAC INTERNATIONAL CORP	800401	CF–08	CF–08
Change to TRIDENT ENVIRONMENTAL SYSTEMS	800401	CF–08	CF–08
PRODUCTION SYSTEMS ACQUISITION CORP	911787	NONE	CF–10
PROFESSIONAL BENEFITS INSURANCE CO	911690	NONE	CF–10
PROFESSIONAL SPORTS CARE MANAGEMENT INC NY	927122	NONE	CF–10
PROGRAMMING & SYSTEMS INC	080630	CF–06	REMOVE
PROJECT SOFTWARE & DEVELOPMENT INC	920354	NONE	CF–10
PROLOGIC MANAGEMENT SYSTEMS INC	938320	NONE	CF–10
PROMETHEUS INCOME PARTNERS	803026	CF–06	CF–09
PROMUS HOTEL CORP	944647	NONE	CF–06
PROPHET 21 INC	917823	NONE	CF–10
PROTECTION ONE INC	916230	NONE	CF–10
PROTOSOURCE CORP	932772	NONE	CF–10
PROXIM INC /DE/	914027	NONE	CF–10
PROXYMED INC /FT LAUDERDALE/	906337	NONE	CF–10
PRT FUNDING CORP	912897	NONE	CF–10
PRUDENTIAL BACHE FUTURES GROWTH FUND LP	823347	CF–09	REMOVE
PRUDENTIAL HOME MOR SEC CO INC MOR PA THRO CERT SER 1993–36	914133	NONE	CF–10
PRUDENTIAL HOME MOR SEC CO INC MOR PA THRO CERT SER 1993–43	914149	NONE	CF–10
PRUDENTIAL HOME MOR SEC CO INC MOR PA THRO CERT SER 1993–44	914644	NONE	CF–10
PRUDENTIAL HOME MOR SEC CO INC MOR PA THRO CERT SER 1993–45	914646	NONE	CF–10
PRUDENTIAL HOME MOR SEC CO INC MOR PA THRO CERT SER 1993–48	916139	NONE	CF–10
PRUDENTIAL HOME MOR SEC CO INC MOR PA THRO CERT SER 1993–61	916147	NONE	CF–10
PRUDENTIAL HOME MOR SEC INC MOR PA THRO CERT SER 1993–35	912041	NONE	CF–10
PRUDENTIAL SECURITIES AGGRESSIVE GROWTH FUND LP	899174	NONE	CF–10
PRUDENTIAL SECURITIES CMO TRUST	874242	CF–10	REMOVE
PS CAROLINAS BALANCED FUND LTD	724536	CF–07	REMOVE
PSF FINANCE LP	934546	NONE	CF–10
PSI RESOURCES INC	829966	CF–02	REMOVE
PST VANS INC	933589	NONE	CF–10
PUEBLO XTRA INTERNATIONAL INC	906307	NONE	CF–10
PURE TECH NEWCO INC	928451	NONE	CF–10
PURUS INC	912156	NONE	CF–10
PUTUMAYO INC	934854	NONE	CF–10
PVF CAPITAL CORP	928592	NONE	CF–10
Q STEAKS INC	912287	NONE	CF–10
QCF BANCORP INC	933508	NONE	CF–10
QHI GROUP HOLDINGS INC	939921	NONE	CF–10
QMC TECHNOLOGIES INC	809800	CF–07	CF–09
Q MED INC	729213	CF–07	CF–08
QUAD CITY HOLDINGS INC	906465	NONE	CF–10
QUAD SYSTEMS CORP /DE/	899823	NONE	CF–10
QUALCOMM INC /DE/	804328	NONE	CF–10
QUALITY DINING INC	917126	NONE	CF–10
QUALITY SEMICONDUCTOR INC	869886	NONE	CF–10
QUANTUM COMMUNICATIONS GROUP INC	943443	NONE	CF–10
QUANTUM FINANCIAL HOLDINGS INC	941810	NONE	CF–10
QUICKRESPONSE SERVICES INC	906551	NONE	CF–10
QUIDEL CORP /DE/	353569	CF–07	CF–08
QUINTESSENCE INC	939923	NONE	CF–10
QUINTILES TRANSNATIONAL CORP	919623	NONE	CF–10
QUIZNOS FRANCHISE CORP	915803	NONE	CF–10
QUME CORP	812544	CF–05	CF–10
Change to DTC DATA TECHNOLOGY CORP	812544	CF–05	CF–10
QVC NETWORK INC	797565	CF–03	REMOVE

CHANGES FROM CORPORATION FINANCE EDGAR PHASE-IN LIST AS PUBLISHED IN SECURITIES ACT RELEASE NO. 7122—Continued

[December 19, 1994]

Name	CIK No.	Former group	New group
RADIANT TECHNOLOGY CORP	310235	CF–07	CF–10
RADIATION DISPOSAL SYSTEMS INC	758256	CF–08	CF–10
RAILTEX INC	877326	NONE	CF–10
RAINFOREST CAFE INC	924919	NONE	CF–10
RALCORP HOLDINGS INC	918021	NONE	CF–10
RAM–Z ENTERPRISES INC	937136	NONE	CF–10
RAMSAY MANAGED CARE INC	932275	NONE	CF–10
RANCON DEVELOPMENT FUND VII LP	861456	CF–10	REMOVE
RATTLESNAKE HOLDING CO INC	935499	NONE	CF–10
RAUCH INDUSTRIES INC	715817	CF–06	CF–09
RAWLINGS SPORTING GOODS CO INC	921915	NONE	CF–10
R B RUBBER PRODUCTS INC	942615	NONE	CF–10
RC ARBYS CORP	904892	NONE	CF–10
RCL CAPITAL CORP	904541	NONE	CF–10
REALAMERICA CO/NEW	716266	CF–08	CF–10
REAL GOODS TRADING CORP	912953	NONE	CF–10
RECEIVABLES PARTNERS LP	896643	NONE	CF–10
RECKSON ASSOCIATES REALTY CORP	930548	NONE	CF–10
RECONDITIONED SYSTEMS INC	891915	NONE	CF–10
RED HOT CONCEPTS INC	932623	NONE	CF–10
RED LION HOTELS INC	941557	NONE	CF–10
RED ROOF INNS INC	920941	NONE	CF–10
REDWOOD EQUIPMENT LEASING INCOME FUND LP	857615	NONE	CF–10
REDWOOD FINANCIAL INC /MN/	942895	NONE	CF–10
REDWOOD MORTGAGE INVESTORS VI	811592	CF–07	CF–08
REDWOOD MORTGAGE INVESTORS VIII	889123	NONE	CF–10
REGAL CINEMAS INC	905035	NONE	CF–10
REGAN HOLDING CORP	870069	CF–07	CF–10
REGENCY BANCORP	927718	NONE	CF–10
REGENCY REALTY CORP	910606	NONE	CF–10
REGI U S INC	922330	NONE	CF–10
REGIONAL ACCEPTANCE CORP	901077	NONE	CF–10
RELIABLE FINANCIAL CORP	882072	CF–10	REMOVE
RELIANCE FINANCIAL INC	934737	NONE	CF–10
RELIFE INC /DE/	875491	CF–10	REMOVE
REMEDY CORP	936653	NONE	CF–10
RENAISSANCE COSMETICS INC /DE/	933747	NONE	CF–10
RENAISSANCE GOLF PRODUCTS INC	912592	NONE	CF–10
RENAISSANCE SOLUTIONS INC	937948	NONE	CF–10
RENCO METALS INC	911566	NONE	CF–10
RENTERS CHOICE INC	933036	NONE	CF–10
RENT WAY INC	893046	NONE	CF–10
REPAP WISCONSIN INC	913669	NONE	CF–10
REPLIGEN CLINICAL PARTNERS LP	885434	NONE	CF–10
REPTRON ELECTRONICS INC	918765	NONE	CF–10
REPUBLIC BANCORP INC /KY/	921557	NONE	CF–10
REPUBLIC ENGINEERED STEELS INC	913883	NONE	CF–10
RESIDENTIAL ASSET SECURITIES CORP	932858	NONE	CF–04
RESMED INC	943819	NONE	CF–10
RESOLUTION TRUST CORP COMM MORT PASS THRU CERT SER 1993–C1	900701	NONE	CF–10
RESTRUCTURING ACQUISITION CORP	907333	NONE	CF–10
RESURGENCE PROPERTIES INC	929223	NONE	CF–10
RETIREMENT CARE ASSOCIATES INC /CO/	798540	NONE	CF–10
REXALL SUNDOWN INC	901620	NONE	CF–10
R F MANAGEMENT CORP	934011	NONE	CF–10
RF MONOLITHICS INC /DE/	922204	NONE	CF–10
RGB COMPUTER & VIDEO INC	902056	NONE	CF–10
R H MACY & CO INC	794367	CF–10	CF–06
Change to FEDERATED DEPARTMENT STORES INC /DE/	794367	CF–10	CF–06
RIC 26 LTD	855660	CF–05	REMOVE
RICHMAN GORDMAN 1/2 PRICE STORES INC.	924120	NONE	CF–10
RICHWOOD INDUSTRIES INC	916986	NONE	CF–10
RICKEL HOME CENTERS INC	929036	NONE	CF–10
RICKS CABARET INTERNATIONAL INC	935419	NONE	CF–10
RIDE SNOWBOARD CO	917734	NONE	CF–10
RIO MAR ASSOCIATES L P S E	918652	NONE	CF–10
RIVER OAKS FURNITURE INC	908309	NONE	CF–10
RIVIANA FOODS INC /DE/	934650	NONE	CF–10
RIVIERA HOLDINGS CORP	899647	NONE	CF–10

CHANGES FROM CORPORATION FINANCE EDGAR PHASE-IN LIST AS PUBLISHED IN SECURITIES ACT RELEASE NO. 7122—Continued

[December 19, 1994]

Name	CIK No.	Former group	New group
RKS FINANCIAL GROUP INC	816330	CF–06	CF–07
Change to JB OXFORD HOLDINGS INC	816330	CF–06	CF–07
ROBEC INC	854462	CF–05	CF–09
ROBERDS INC	912952	NONE	CF–10
ROC COMMUNITIES INC	906325	NONE	CF–10
ROCHESTER TELEPHONE CORP /NEW/	936105	NONE	CF–10
ROCK BOTTOM RESTAURANTS INC	924896	NONE	CF–10
ROCKLAND ELECTRIC CO	084613	CF–03	REMOVE
ROCKY MOUNTAIN FINANCIAL ENTERPRISES INC	927131	NONE	CF–10
ROCKY SHOES & BOOTS INC	895456	NONE	CF–10
ROMAC INTERNATIONAL INC	930420	NONE	CF–10
ROSEWOOD CARE CENTERS CAPITAL FUNDING CORP	909110	NONE	CF–10
ROSEWOOD CARE CENTERS INC OF ALSTON	909117	NONE	CF–10
ROSEWOOD CARE CENTERS INC OF EAST PEORIA	909115	NONE	CF–10
ROSEWOOD CARE CENTERS INC OF GALESBURG	909114	NONE	CF–10
ROSEWOOD CARE CENTERS INC OF MOLINE	909118	NONE	CF–10
ROSEWOOD CARE CENTERS INC OF PEORIA	909116	NONE	CF–10
ROSEWOOD CARE CENTERS INC OF SWANSEA	909113	NONE	CF–10
ROSS MARTIN CO INC	943092	NONE	CF–10
ROTARY POWER INTERNATIONAL INC	914539	NONE	CF–10
ROTOR TOOL CO	085357	CF–05	REMOVE
ROTTLUND CO INC	891329	NONE	CF–10
ROYAL CANADIAN FOODS CORP	911318	NONE	CF–10
ROYAL CAPITAL CORP	828956	CF–08	CF–09
Change to NUOASIS GAMING INC	828956	CF–08	CF–09
ROYAL GRIP INC	910568	NONE	CF–10
RS FINANCIAL CORP	840252	CF–09	CF–10
RTW INC /MN/	915781	NONE	CF–10
RURAL METRO CORP /DE/	906326	NONE	CF–10
RUSSEL METALS INC	903657	NONE	CF–07
RUST INTERNATIONAL INC	901172	NONE	CF–10
RYKA INC	828750	CF–07	CF–09
S3 INC	850519	NONE	CF–10
SABER SOFTWARE CORP	862564	NONE	CF–10
SABRELINER CORP	910649	NONE	CF–10
SAFESKIN CORP	911636	NONE	CF–10
SAFETY 1ST INC	898306	NONE	CF–10
SAFETY COMPONENTS INTERNATIONAL INC	918964	NONE	CF–10
SAGE TECHNOLOGIES INC	876346	CF–10	CF–10
Change to AMERIDATA TECHNOLOGIES INC	876346	CF–10	CF–10
SAINT ANDREWS GOLF CORP	930245	NONE	CF–10
SALOMON PHIBRO OIL TRUST	929180	NONE	CF–10
SALVATORI OPHTHALMICS INC	823187	CF–07	CF–07
Change to AMERICAN CONSOLIDATED LABORATORIES INC	823187	CF–07	CF–07
SANGSTAT MEDICAL CORP	913610	NONE	CF–10
SANGUINE CORP	926287	NONE	CF–10
SANIFILL INC	834263	NONE	CF–10
SANITAS INC	086727	CF–07	CF–10
SANMARK STARDUST INC	093631	CF–05	CF–05
Change to MOVIE STAR INC	093631	CF–05	CF–05
SAN MATEO COUNTY BANCORP	775473	CF–08	CF–08
Change to MID PENINSULA BANCORP	775473	CF–08	CF–08
SANMINA CORP/DE	897723	NONE	CF–10
SANTA CRUZ OPERATION INC	851560	NONE	CF–10
SANTA FE FINANCIAL CORP	086759	CF–07	CF–10
SANTA FE PACIFIC GOLD CORP	921754	NONE	CF–10
SARATOGA BEVERAGE GROUP INC	904362	NONE	CF–10
SARNIA CORP	923021	NONE	CF–10
SATURN ACQUISITIONS INC	931150	NONE	CF–10
SAUL CENTERS INC	907254	NONE	CF–10
SAVOY PICTURES ENTERTAINMENT INC	897079	NONE	CF–10
SBC TECHNOLOGIES INC /DE/	812955	CF–06	REMOVE
SCANSOURCE INC	918965	NONE	CF–10
SCHMITT INDUSTRIES INC	922612	NONE	CF–10
SCHNITZER STEEL INDUSTRIES INC	912603	NONE	CF–10
SCHULLER INTERNATIONAL GROUP INC	930818	NONE	CF–10
SCHWABACHER FREY INC	943093	NONE	CF–10
SCIENCE ACCESSORIES CORP /DE/	803498	CF–07	REMOVE
SCIENTIFIC SOFTWARE INTERCOMP INC	087822	CF–06	CF–09

CHANGES FROM CORPORATION FINANCE EDGAR PHASE-IN LIST AS PUBLISHED IN SECURITIES ACT RELEASE NO. 7122—Continued

[December 19, 1994]

Name	CIK No.	Former group	New group
SCOTSMAN HOLDINGS INC	923144	NONE	CF–10
SCOTT MILLS INC	920375	NONE	CF–10
SCRIPT SYSTEMS INC	750485	CF–10	REMOVE
SDL INC	934741	NONE	CF–10
SDO PARENT CO /CA	940170	NONE	CF–06
SEABRITE FOODS INC	932135	NONE	CF–10
SEA GALLEY STORES INC	275985	CF–08	CF–09
SEAGO GROUP INC	063516	CF–07	REMOVE
SEARCH EXPLORATION INC	853630	NONE	CF–10
SEARS CREDIT ACCOUNT MASTER TRUST II	923569	NONE	CF–10
SEARS MORT SEC CORP MORT PASS THRU CERT SERIES 1992–20	894388	NONE	CF–10
SEATTLE BREWING CO	924952	NONE	CF–10
SECTOR STRATEGY FUND VI LP	904364	NONE	CF–10
SECURITIZED ASSET SALES INC	895035	NONE	CF–10
SECURITY CAPITAL CORP /WI/	912243	NONE	CF–10
SECURITY CAPITAL INDUSTRIAL TRUST	899881	NONE	CF–10
SECURITY CONNECTICUT CORP	913601	NONE	CF–10
SECURITY DYNAMICS TECHNOLOGIES INC /DE/	932064	NONE	CF–10
SECURITY FEDERAL BANCORP INC	929931	NONE	CF–10
SECA SPECIALTY PACKAGING CORP	912034	NONE	CF–10
SEILER POLLUTION CONTROL SYSTEMS INC	718827	NONE	CF–10
SEL-LEB MARKETING INC	934853	NONE	CF–10
SELECT BEVERAGES INC	797279	NONE	CF–10
SELECT MEDIA COMMUNICATIONS INC	925648	NONE	CF–10
SELKIRK COGEN FUNDING CORP	929518	NONE	CF–10
SELKIRK COGEN PARTNERS LP	929540	NONE	CF–10
SELMER CO INC	918904	NONE	CF–10
SELMER INDUSTRIES INC	911583	NONE	CF–10
SEMITOOL INC	934550	NONE	CF–10
SENIOR TOUR PLAYERS DEVELOPMENT INC	927471	NONE	CF–10
SENSOR CONTROL CORP	806168	CF–07	CF–07
Change to SAFETYTEK CORP	806168	CF–07	CF–07
SENTINEL FINANCIAL CORP	912959	NONE	CF–10
SEVEN FIELDS DEVELOPMENT CO	931405	NONE	CF–10
SEVEN FIELDS DEVELOPMENT PA INC	931429	NONE	CF–10
SFC FINANCIAL CORP /CO/	930317	NONE	CF–10
SFS BANCORP INC	942135	NONE	CF–10
SFX BROADCASTING INC	908612	NONE	CF–10
SGV BANCORP INC	940511	NONE	CF–10
SHARED TECHNOLOGIES CELLULAR INC	933583	NONE	CF–10
SHAW GROUP INC	914024	NONE	CF–10
SHEFFIELD STEEL CORP	910719	NONE	CF–10
SHILOH INDUSTRIES INC	904979	NONE	CF–10
SHIPHOLDING INTERNATIONAL INC	943356	NONE	CF–10
SHOE CARNIVAL INC	895447	NONE	CF–10
SHRP INC	911080	NONE	CF–10
SHURGARD INCOME PROPERTIES II	353812	CF–07	REMOVE
SHURGARD MINI STORAGE LP I	313297	CF–07	REMOVE
SIEKERT & BAUM INC	943099	NONE	CF–10
SIERRA HOME SERVICE COMPANIES INC	910709	NONE	CF–10
SIERRA PACIFIC POWER CO	090144	CF–09	CF–10
SIERRA PACIFIC RESOURCES	741508	CF–09	CF–10
SIGMA ALPHA ENTERTAINMENT GROUP LTD	941814	NONE	CF–10
SIGMATRON INTERNATIONAL INC	915358	NONE	CF–10
SIGNAL TECHNOLOGY CORP	901119	NONE	CF–10
SILICON VALLEY RESEARCH INC	708367	CF–07	CF–10
SILVER KING COMMUNICATIONS INC	891103	NONE	CF–10
SILVER SLIPPER INC	919701	NONE	CF–10
SIMETCO INC	073967	CF–06	REMOVE
Change to OHIO FERRO ALLOYS CORP /OH/	073967	CF–06	REMOVE
SIMMONS OUTDOOR CORP	907585	NONE	CF–10
SIMON PROPERTY GROUP INC	912564	NONE	CF–10
SIMPSON HOUSING CORP	926235	NONE	CF–10
SIMPSON MANUFACTURING CO INC /CA/	920371	NONE	CF–10
SIMS COMMUNICATIONS INC	907127	NONE	CF–10
SINCLAIR BROADCAST GROUP INC	912752	NONE	CF–10
SINGING MACHINE CO INC	923601	NONE	CF–10
SINTER METALS INC	927970	NONE	CF–10
SIRENA APPAREL GROUP INC	925543	NONE	CF–10

CHANGES FROM CORPORATION FINANCE EDGAR PHASE-IN LIST AS PUBLISHED IN SECURITIES ACT RELEASE NO. 7122—Continued

[December 19, 1994]

Name	CIK No.	Former group	New group
SITEL CORP	943820	NONE	CF–10
SITHE ENERGIES INC	901376	NONE	CF–10
SITHE INDEPENDENCE FUNDING CORP	899281	NONE	CF–10
SJS BANCORP INC	930836	NONE	CF–10
SKYLANDS PARK MANAGEMENT INC	904075	NONE	CF–10
SKYLINE MULTIMEDIA ENTERTAINMENT INC	916271	NONE	CF–10
SKYSAT COMMUNICATIONS NETWORK CORP	919374	NONE	CF–10
SLB MIDWEST FUTURES FUND LP	924875	NONE	CF–10
SLED DOGS CO	918573	NONE	CF–10
SLUDGE MANAGEMENT INC	874144	CF–10	REMOVE
SMC CORP	932129	NONE	CF–10
S&M CO	217058	CF–07	REMOVE
SMITH BARNEY SHEARSON HOLDINGS INC /DE/	911562	NONE	CF–10
SMITH BARNEY SHEARSON INTERNATIONAL ADVISORS CURRENCY FD LP	912547	NONE	CF–10
SMITH CHARLES E RESIDENTIAL REALTY INC	919004	NONE	CF–10
SMITH CHARLES E RESIDENTIAL REALTY LP	906785	NONE	CF–10
SMITH MADRONE VINEYARDS & WINERY	921822	NONE	CF–10
SMITH MIDLAND CORP	924719	NONE	CF–10
SMITHWAY MOTOR XPRESS CORP	941914	NONE	CF–10
SMITTYS SUPER VALU INC	927773	NONE	CF–10
SMITTYS SUPERMARKETS INC	927774	NONE	CF–10
S/M REAL ESTATE FUND IV LTD	319303	CF–09	REMOVE
SMR NATURAL GAS INCOME FUND 1995	926901	NONE	CF–10
SNB BANCSHARES INC	925464	NONE	CF–10
SOBIESKI BANCORP INC	934860	NONE	CF–10
SODAK GAMING INC	903856	NONE	CF–10
SOFTDESK INC	916397	NONE	CF–10
SOFTWARE ETC STORES INC	883999	CF–10	REMOVE
SOFTWARE PROFESSIONALS INC	919175	NONE	CF–10
SOIL TECHNOLOGIES CORP /IA/	924404	NONE	CF–10
SOLA INTERNATIONAL INC	912088	NONE	CF–10
SOLARATTIC INC	927654	NONE	CF–10
SOLARCELL CORP	091649	CF–09	CF–09
Change to 4 FRONT SOFTWARE INTERNATIONAL INC /CO/	091649	CF–09	CF–09
SOLAR-MATES INC	940183	NONE	CF–10
SOLIGEN TECHNOLOGIES INC	916460	NONE	CF–10
SOLOMON PAGE GROUP LTD	926259	NONE	CF–10
SONIC ENVIRONMENTAL SYSTEMS INC	900393	NONE	CF–10
SONIC SOLUTIONS /CA/	916235	NONE	CF–10
SOURCE MEDIA INC	900029	NONE	CF–10
SOUTH CAROLINA COMMUNITY BANCSHARES INC	920615	NONE	CF–10
SOUTH DAKOTA STATE MEDICAL HOLDING CO INC	919176	NONE	CF–10
SOUTHEASTERN BANKING CORP	353386	CF–05	CF–08
SOUTHEAST REALTY CORP	935897	NONE	CF–10
SOUTHERN ENERGY HOMES INC	896397	NONE	CF–10
SOUTHERN HEALTH MANAGEMENT CORP /VA/	869813	CF–10	REMOVE
SOUTHERN PACIFIC RAIL CORP	904691	NONE	CF–10
SOUTHFIRST BANCSHARES INC	925963	NONE	CF–10
SOUTHSIDE FINANCIAL GROUP INC	922286	NONE	CF–10
SOUTH STANDARD MINING CO	091950	CF–08	CF–10
SOUTHWEST BANCORP INC	914374	NONE	CF–10
SOUTHWEST ROYALTIES INCOME FUND XII LP	922889	NONE	CF–10
SPANISH BROADCASTING SYSTEM INC	927720	NONE	CF–10
SPECIALTY EQUIPMENT COMPANIES INC	814013	NONE	CF–10
SPECIALTY TELECONSTRUCTORS INC	925269	NONE	CF–10
SPECTRANETICS CORP	789132	NONE	CF–10
SPECTRIAN CORP /CA/	925054	NONE	CF–10
SPECTRUM INFORMATION TECHNOLOGIES INC	812551	CF–07	CF–08
SPEEDWAY MOTORSPORTS INC	934648	NONE	CF–10
SPIEGEL CREDIT CORP III	931781	NONE	CF–10
SPIEKER PROPERTIES INC	911361	NONE	CF–10
SPI PHARMACEUTICALS INC	723046	CF–04	REMOVE
SPIRIT OF AMERICA NATIONAL BANK	917312	NONE	CF–10
SPORTS AUTHORITY INC /DE/	929470	NONE	CF–10
SPORTS CLUB CO INC	924373	NONE	CF–10
SPORTS & RECREATION INC	890093	NONE	CF–10
SPORTS SCIENCES INC	915766	NONE	CF–10
SPRINGHILL LAKE INVESTORS LTD PARTNERSHIP	763399	NONE	CF–10
SP VENTURES INC	927653	CF–04	CF–04

CHANGES FROM CORPORATION FINANCE EDGAR PHASE-IN LIST AS PUBLISHED IN SECURITIES ACT RELEASE NO. 7122—Continued

[December 19, 1994]

Name	CIK No.	Former group	New group
Change to MCKESSON CORP	927653	CF–04	CF–04
STANDARD FINANCIAL INC	920603	NONE	CF–10
STANDARD FUNDING CORP	919007	NONE	CF–10
STANLY CAPITAL CORP	898171	NONE	CF–10
STANT CORP	906523	NONE	CF–10
STAR CARD ENTERPRISES INC	935801	NONE	CF–10
STARCRAFT AUTOMOTIVE CORP	906473	NONE	CF–10
STAR MARKETS CO INC	933160	NONE	CF–10
STARBASE CORP	911577	NONE	CF–10
STARLOG FRANCHISE CORP	907435	NONE	CF–10
STAR MARKETS CO INC	933160	NONE	CF–10
STARSIGHT TELECAST INC	906612	NONE	CF–10
STATE BANCSHARES INC /PA/	904101	NONE	CF–10
STARTER CORP	897507	NONE	CF–10
STATER BROS HOLDINGS INC	882829	NONE	CF–10
STAT HEALTHCARE INC	932424	NONE	CF–10
STATEWIDE BANCORP	700722	CF–07	CF–10
STATORDYNE CORP ET AL	899684	NONE	CF–10
STB SYSTEMS INC	934596	NONE	CF–10
STECK VAUGHN PUBLISHING CORP	904081	NONE	CF–10
STERILE CONCEPTS HOLDINGS INC	925966	NONE	CF–10
STERLING BANCSHARES CORP	810962	CF–05	REMOVE
ST FRANCOIS COUNTY FINANCIAL CORP	912501	NONE	CF–10
STILLWATER MINING CO /DE/	931948	NONE	CF–10
ST JOHN KNITS INC	896100	NONE	CF–10
ST LANDRY FINANCIAL CORP	933981	NONE	CF–10
STONE ENERGY CORP	904080	NONE	CF–10
STORAGE COMPUTER CORP	933452	NONE	CF–10
STORAGE TRUST REALTY	928735	NONE	CF–10
STORAGE USA INC	912116	NONE	CF–10
STORMEDIA INC	942787	NONE	CF–10
ST PAUL CAPITAL LLC	943639	NONE	CF–06
STRATASYS INC	915735	NONE	CF–10
STRATEGIC DISTRIBUTION INC	073822	CF–08	CF–09
STRATOSPHERE CORP	897743	NONE	CF–10
STRATTEC SECURITY CORP	933034	NONE	CF–10
STROUDS INC	927760	NONE	CF–10
STRUTHERS INDUSTRIES INC	094945	CF–08	CF–10
STUDIO PLUS OF AMERICA INC	934599	NONE	CF–10
STYLES ON VIDEO INC	897074	NONE	CF–10
SUAVE SHOE CORP	095052	CF–05	CF–10
SUBURBAN BANKSHARES INC /FL	793080	CF–09	REMOVE
SUGEN INC	908121	NONE	CF–10
SUMMA METALS CORP /NV/	927578	NONE	CF–10
SUMMIT BANCORP INC	879096	CF–10	REMOVE
SUMMIT COMMUNICATIONS GROUP INC	898304	NONE	CF–10
SUMMIT HEALTH LTD	725555	CF–04	REMOVE
SUMMIT PETROLEUM CORP	353196	NONE	CF–10
SUN COMMUNITIES INC	912593	NONE	CF–10
SUNBELT COMPANIES INC	911623	NONE	CF–10
SUNDANCE HOMES INC	900616	NONE	CF–10
SUNGROWTH PROPERTY INVESTORS LTD	727165	CF–07	REMOVE
SUN HEALTHCARE GROUP INC	904978	NONE	CF–10
SUNNYLAND HOLDINGS CORP	923860	NONE	CF–10
SUNRISE BANCORP INC	701709	CF–08	CF–10
SUPERMAC TECHNOLOGY INC	885592	CF–10	REMOVE
SUPERMAIL INTERNATIONAL INC	832508	CF–08	CF–09
SUPER VISION INTERNATIONAL INC	917523	NONE	CF–10
SUPERCART INTERNATIONAL INC /CN/	928762	NONE	CF–10
SUPERCONDUCTOR TECHNOLOGIES INC	895665	NONE	CF–10
SUPERIOR BANK FSB	897845	NONE	CF–10
SUPERTEL HOSPITALITY INC	919640	NONE	CF–10
SUPREME INTERNATIONAL CORP	900349	NONE	CF–10
SURE SHOT INTERNATIONAL INC /FL/	923291	NONE	CF–10
SURGICAL CARE AFFILIATES INC	722692	CF–05	CF–04
SUSSEX VENTURES LTD	876320	CF–10	CF–10
Change to AGRIBIOTECH INC	876320	CF–10	CF–10
SWANSEA REAL ESTATE INC	909120	NONE	CF–10
SWEETWATER INC	914271	NONE	CF–10

CHANGES FROM CORPORATION FINANCE EDGAR PHASE-IN LIST AS PUBLISHED IN SECURITIES ACT RELEASE NO. 7122—Continued

[December 19, 1994]

Name	CIK No.	Former group	New group
SWIFT ENERGY INCOME PARTNERS 1986–A LTD	799064	NONE	CF–08
SWVA BANCSHARES INC	925656	NONE	CF–10
SYBASE INC	768262	NONE	CF–10
SYLVAN LEARNING SYSTEMS INC	912766	NONE	CF–10
SYMBOLLON CORP	912086	NONE	CF–10
SYNCRONYS SOFTCORP	798077	NONE	CF–10
SYNTELLECT INC	758830	NONE	CF–10
SYNTEX CORP	096000	CF–02	REMOVE
SYNTHETIC INDUSTRIES LP	901175	NONE	CF–10
SYSCON ENTERPRISES INC	923024	NONE	CF–10
SYSTEM INDUSTRIES INC	317781	CF–05	CF–07
Change to ANCHOR PACIFIC UNDERWRITERS	317781	CF–05	CF–07
TAITRON COMPONENTS INC	942126	NONE	CF–10
TALBOTS INC	912263	NONE	CF–10
TAPE SPECIALTY INC	353821	CF–08	REMOVE
TARGETED GENETICS CORP /WA/	921114	NONE	CF–10
TATHAM OFFSHORE INC	913358	NONE	CF–10
TAUBMAN REALTY GROUP LTD PARTNERSHIP	917473	NONE	CF–10
TAYCO DEVELOPMENTS INC	894952	NONE	CF–10
TAYLOR INVESTMENT CORP /MN/	934373	NONE	CF–10
TCC MANAGED FUTURES TRUST	931580	NONE	CF–10
TDINDUSTRIES INC	716757	CF–06	REMOVE
TEAM RENTAL GROUP INC	922471	NONE	CF–10
TECHE HOLDING CO	934538	NONE	CF–10
TECHNICAL CHEMICALS & PRODUCTS INC	924921	NONE	CF–10
TECHNOLOGY FUNDING PARTNERS I	744964	CF–07	CF–06
TECHNOLOGY FUNDING PARTNERS II	772001	CF–07	CF–06
TECHNOLOGY FUNDING SECURED INVESTORS III	844217	CF–09	CF–06
TECH SQUARED INC	939077	NONE	CF–10
TECNOL MEDICAL PRODUCTS INC	876968	NONE	CF–10
TEL COM WIRELESS CABLE TV CORP	929061	NONE	CF–10
TELEBANC FINANCIAL CORP	920986	NONE	CF–10
TELECOMMUNICATIONS INCOME FUND X LP	904005	NONE	CF–10
TELE MATIC CORP	929757	NONE	CF–10
TELE-MEDIA BROADCASTING CO	930297	NONE	CF–10
TELETOUCH COMMUNICATIONS INC	928659	NONE	CF–10
TELEWEST COMMUNICATIONS PLC	922574	NONE	CF–10
TELEWORLD ENTERPRISES LTD	798543	NONE	CF–10
TELMARK INC /NY/	914028	NONE	CF–10
TELTREND INC	943822	NONE	CF–10
TELULAR CORP	915324	NONE	CF–10
TENERE GROUP INC	922887	NONE	CF–10
TENET INFORMATION SERVICES INC	845696	CF–07	CF–09
TERMIFLEX CORP	726431	CF–07	REMOVE
TESSCO TECHNOLOGIES INC	927355	NONE	CF–10
TETRA TECH INC	831641	NONE	CF–10
TEXARKANA FIRST FINANCIAL CORP	943355	NONE	CF–10
TEXAS BOTTLING GROUP INC	912499	NONE	CF–10
TEXAS STAR RESOURCES CORP	908177	NONE	CF–10
TEXASGULF INC /DE/	936286	NONE	CF–10
TEXAS VANGUARD OIL CO	315261	CF–08	CF–09
TEXCON ENERGY CORP	312827	CF–06	CF–10
TEXTAINER EQUIPMENT INCOME FUND V LP	915194	NONE	CF–10
TFC ENTERPRISES INC	913958	NONE	CF–10
TGV SOFTWARE INC	935495	NONE	CF–10
THERAGENICS CORP	796762	CF–07	CF–07
Change to THERAGENICS CORP	795551	CF–07	CF–07
THERAPEUTIC DISCOVERY CORP	899753	NONE	CF–10
THERATX INC /CA/	922980	NONE	CF–10
THERMO REMEDIATION INC	913771	NONE	CF–10
THERMOLASE CORP	901416	NONE	CF–10
THOMAS GROUP INC	900017	NONE	CF–10
THOMASVILLE INDUSTRIES INC	940032	NONE	CF–10
THOMPSON PBE INC	929035	NONE	CF–10
THRIFTY PAYLESS INC	916794	NONE	CF–10
THRUSTMASTER INC	932290	NONE	CF–10
TIMELINE INC	909736	NONE	CF–10
TIMES MIRROR CO	098349	CF–02	REMOVE
TIMES MIRROR CO /NEW/	925260	NONE	CF–05

CHANGES FROM CORPORATION FINANCE EDGAR PHASE-IN LIST AS PUBLISHED IN SECURITIES ACT RELEASE NO. 7122—Continued

[December 19, 1994]

Name	CIK No.	Former group	New group
TIME WARNER ENTERTAINMENT CO LP	893657	NONE	CF–10
TITAN HOLDINGS INC	904975	NONE	CF–10
TITAN TECHNOLOGIES INC	932144	NONE	CF–10
TITAN WHEEL INTERNATIONAL INC	899751	NONE	CF–10
TIVOLI INDUSTRIES INC	924835	NONE	CF–10
TIVOLI SYSTEMS INC	900120	NONE	CF–10
T J CINNAMONS INC	915661	NONE	CF–10
TLC BEATRICE INTERNATIONAL HOLDINGS INC	835589	NONE	CF–10
TOP SOURCE INC	800055	CF–07	CF–07
Change to TOP SOURCE TECHNOLOGIES INC	800055	CF–07	CF–07
TORCH ENERGY ROYALTY TRUST	912030	NONE	CF–10
TOTAL CONTAINMENT INC	913666	NONE	CF–10
TOTAL RESEARCH CORP	803058	CF–07	CF–08
TOWER AUTOMOTIVE INC	925548	NONE	CF–10
TOWER TECH INC	913034	NONE	CF–10
TOWN & COUNTRY TRUST	906110	NONE	CF–10
TOY BIZ INC	933730	NONE	CF–10
TPEX EXPLORATION INC	312842	CF–08	CF–08
Change to KRESTREL ENERGY INC	312842	CF–08	CF–08
TRACTOR SUPPLY CO /DE/	916365	NONE	CF–10
TRAMWAY BUILDING CORP	940325	NONE	CF–10
TRANSCOLOR CORP	832444	CF–09	REMOVE
TRANS ENERGY INC	919721	NONE	CF–10
TRANSNATIONAL INDUSTRIES INC	796228	CF–06	CF–10
TRANSNATIONAL RE CORP	911628	NONE	CF–10
TRANS OCEAN CONTAINER CORP	917691	NONE	CF–10
TRANS PACIFIC GROUP INC	922659	NONE	CF–10
TRANSTECTOR SYSTEMS INC	746630	CF–07	REMOVE
TRANS WORLD GAMING CORP	914577	NONE	CF–10
TRANS WORLD INSURANCE CO	932095	NONE	CF–10
TRANSWORLD TELECOMMUNICATIONS INC	830381	NONE	CF–10
TRANSACTION NETWORK SERVICES INC	920231	NONE	CF–10
TRANSACTION SYSTEMS ARCHITECTS INC	935036	NONE	CF–10
TRANSAMERICAN REFINING CORP	927762	NONE	CF–10
TRANSMEDIA EUROPE INC	906908	NONE	CF–10
TRANSNATIONAL RE CORP	911628	NONE	CF–10
TRANSTAR HOLDINGS LP	916533	NONE	CF–10
TRANSTEXAS GAS CORP	904977	NONE	CF–10
TRANSTEXAS TRANSMISSION CORP	908852	NONE	CF–10
TREASURE HOUSE NORTH L P	936353	NONE	CF–10
TREND LINES INC	922978	NONE	CF–10
TRI LITE INC /PA/	910350	NONE	CF–10
TRIAD GUARANTY INC	911631	NONE	CF–10
TRIANGLE CORP	099703	CF–05	CF–05
Change to AUDITS & SURVEYS WORLDWIDE INC	099703	CF–05	CF–05
TRICO PRODUCTS CORP	099724	CF–04	REMOVE
TRIGEN ENERGY CORP	925655	NONE	CF–10
TRINET CORPORATE REALTY TRUST INC	899162	NONE	CF–10
TRINITECH SYSTEMS INC	099047	NONE	CF–10
TRINITY SIX INC	907069	NONE	CF–10
TRIPLE S PLASTICS INC	918642	NONE	CF–10
TRIPOS INC	920691	NONE	CF–10
TRISM INC /DE/	914480	NONE	CF–10
TRIUMPHE LEASING IX LP	916364	NONE	CF–10
TROY HILL BANCORP INC	921363	NONE	CF–10
TRUCK COMPONENTS INC	923151	NONE	CF–10
TRUMP HOTELS & CASINO RESORTS HOLDINGS LP	943322	NONE	CF–10
TRUMP HOTELS & CASINO RESORTS INC	943320	NONE	CF–10
TSB FINANCIAL INC	920107	NONE	CF–10
TSX CORP	896560	NONE	CF–10
TUCKER PROPERTIES CORP	908257	NONE	CF–10
TUFCO TECHNOLOGIES INC	895329	NONE	CF–10
TURBOCHEF INC	916545	NONE	CF–10
TWIN CITY BANCORP INC	930373	NONE	CF–10
TYLAN GENERAL INC	894776	NONE	CF–10
TYREX OIL CO	317889	CF–08	CF–10
UAC SECURITIZATION CORP	935301	NONE	CF–10
UCAR GLOBAL ENTERPRISES INC	940404	NONE	CF–10
UCAR INTERNATIONAL INC	931148	NONE	CF–10

CHANGES FROM CORPORATION FINANCE EDGAR PHASE-IN LIST AS PUBLISHED IN SECURITIES ACT RELEASE NO. 7122—Continued

[December 19, 1994]

Name	CIK No.	Former group	New group
UCFC ACCEPTANCE CORP	901488	NONE	CF–10
UFP TECHNOLOGIES INC	914156	NONE	CF–10
ULTIMATE ELECTRONICS INC	911626	NONE	CF–10
ULTRADATA SYSTEMS INC	931947	NONE	CF–10
ULTRATECH STEPPER INC	909791	NONE	CF–10
UMC ELECTRONICS CO	100619	CF–08	CF–10
UNAPIX ENTERTAINMENT INC	902787	NONE	CF–10
UNCLE BS BAKERY INC	911886	NONE	CF–10
UNIMARK GROUP INC	922712	NONE	CF–10
UNION ACCEPTANCE CORP	927790	NONE	CF–10
UNION BANKSHARES LTD	895688	NONE	CF–10
UNION FINANCIAL BANCSHARES INC	926164	NONE	CF–10
UNION INSURANCE CO OF PROVIDENCE	914746	NONE	CF–10
UNION PLAZA HOTEL & CASINO INC	087918	CF–05	CF–08
UNION SWITCH & SIGNAL INC	912464	NONE	CF–10
UNIPHASE CORP /CA/	912093	NONE	CF–10
UNIROYAL INVESTORS MANAGEMENT CO	890096	CF–10	CF–10
Change to UNIROYAL TECHNOLOGY CORP	890096	CF–10	CF–10
UNISOURCE ENERGY CORP	941138	NONE	CF–10
UNISTAR GAMING CORP	940327	NONE	CF–10
UNITECH INDUSTRIES INC	921620	NONE	CF–10
UNITED AIR SPECIALISTS INC /OH/	932985	NONE	CF–10
UNITED FINANCIAL BANKING COMPANIES INC	714286	CF–06	CF–09
UNITED GROCERS CLEARING HOUSE INC	932734	NONE	CF–10
UNITED HERITAGE CORP	354567	CF–07	CF–10
UNITED MARKET SERVICES CO	919861	NONE	CF–10
UNITED MORTGAGE SECURITIES CORP	910033	NONE	CF–10
UNITED NATIONAL BANCORPORATION	355453	CF–08	REMOVE
UNITED PAYPHONE SERVICES INC	923150	NONE	CF–10
UNITED RESTAURANTS INC	909483	NONE	CF–10
UNITED STATES LEATHER INC /WI/	906613	NONE	CF–10
UNITED STATES PAGING CORP	813239	NONE	CF–10
UNITED VANGARD HOMES INC /DE/	021221	NONE	CF–10
UNITED VIDEO SATELLITE GROUP INC	913061	NONE	CF–10
UNITED WASTE SYSTEMS INC	879688	NONE	CF–10
UNIVERSAL AUTOMOTIVE INDUSTRIES INC /DE/	931457	NONE	CF–10
UNIVERSAL OUTDOOR HOLDINGS INC	928063	NONE	CF–10
UNIVERSAL OUTDOOR INC	916079	NONE	CF–10
UNIVERSAL STAINLESS & ALLOY PRODUCTS INC	931584	NONE	CF–10
UNIVERSITY REAL ESTATE FUND 10 LTD	356311	CF–08	CF–09
UNIVERSITY REAL ESTATE FUND 12 LTD	713010	CF–08	CF–09
UNIVERSITY REAL ESTATE PARTNERSHIP V	311173	CF–08	CF–09
UNIVISION TELEVISION GROUP INC	898804	NONE	CF–10
UNSL FINANCIAL CORP	846807	CF–09	REMOVE
UPWARD TECHNOLOGY CORP	062600	CF–08	CF–10
URBAN OUTFITTERS INC	912615	NONE	CF–10
URBAN SHOPPING CENTERS INC	907077	NONE	CF–10
UROMED CORP	917821	NONE	CF–10
US 1 INDUSTRIES INC	351498	NONE	CF–10
USAIR INC /NEW/	714560	CF–02	CF–02
Change to USAIR INC	714560	CF–02	CF–02
U S ALCOHOL TESTING OF AMERICA INC	853017	NONE	CF–10
USANA INC	896264	NONE	CF–10
US AUTOMOBILE ACCEPTANCE 1995–I INC	936652	NONE	CF–10
U S AUTOMOBILE ACCEPTANCE CORP	910107	NONE	CF–10
US BRIDGE OF NEW YORK INC	937931	NONE	CF–10
US CHINA INDUSTRIAL EXCHANGE INC	922717	NONE	CF–10
US DELIVERY SYSTEMS INC	920755	NONE	CF–10
U S DIAGNOSTIC LABS INC	911012	NONE	CF–10
U S DRUG TESTING INC	910523	NONE	CF–10
US ELECTRICAR INC	922237	NONE	CF–10
US EXIM TRUST PDVSA	920470	NONE	CF–10
US FLYWHEEL SYSTEMS INC	928958	NONE	CF–10
US INTELCO HOLDINGS INC	929139	NONE	CF–10
USLICO CORP	750234	CF–03	REMOVE
U S MEDICAL PRODUCTS INC	919168	NONE	CF–10
US OFFICE PRODUCTS CO	934852	NONE	CF–10
US ORDER INC	943652	NONE	CF–10
U S ROBOTICS CORP/DE/	933353	NONE	CF–10

CHANGES FROM CORPORATION FINANCE EDGAR PHASE-IN LIST AS PUBLISHED IN SECURITIES ACT RELEASE NO. 7122—Continued

[December 19, 1994]

Name	CIK No.	Former group	New group
U S THRIFT OPPORTUNITY PARTNERS LP	831660	CF–09	REMOVE
US TRADE FUNDING CORP	927567	NONE	CF–10
U S WIRELESS DATA INC	895716	NONE	CF–10
US XPRESS ENTERPRISES INC	923571	NONE	CF–10
USA COMMUNICATIONS INC /DE/	929056	NONE	CF–10
USA ENTERTAINMENT CENTER INC	896429	NONE	CF–10
USA MOBILE COMMUNICATIONS HOLDINGS INC	929544	NONE	CF–10
USA MOBILE COMMUNICATIONS HOLDINGS INC ET AL	915390	NONE	CF–10
USA MOBILE COMMUNICATIONS INC II	916122	NONE	CF–10
USANA INC	896264	NONE	CF–10
USDATA CORP	943895	NONE	CF–10
USTEL INC	919274	NONE	CF–10
UTI ENERGY CORP	912899	NONE	CF–10
VAALCO ENERGY INC /DE/	894627	NONE	CF–10
VALLEY FINANCIAL CORP /VA/	921590	NONE	CF–10
VALRICO BANCORP INC	942789	NONE	CF–10
VALUE SOFTWARE CORP	928493	NONE	CF–10
VALUJET AIRLINES INC	914277	NONE	CF–10
VANDERBILT MORTGAGE & FINANCE INC	816512	NONE	CF–10
VANDERBILT SQUARE CORP	764773	NONE	CF–10
VARCO INTERNATIONAL INC	102993	CF–05	CF–04
VARI L CO INC	917173	NONE	CF–10
VARIFLEX INC	921366	NONE	CF–10
VASTAR RESOURCES INC	918252	NONE	CF–10
VECTOR ENERGY CORP /TX/	931180	NONE	CF–10
VECTOR ENVIRONMENTAL TECHNOLOGIES INC	918997	NONE	CF–10
VECTRA BANKING CORP	862695	NONE	CF–10
VEECO INSTRUMENTS INC	103145	NONE	CF–10
VENDELL HEALTHCARE INC	896646	NONE	CF–10
VENTRITEX INC	793354	NONE	CF–10
VENTURE ENTERPRISES INC	778165	CF–09	CF–09
Change to HANOVER GOLD COMPANY INC	778165	CF–09	CF–09
VENTURIAN CORP	745756	CF–06	CF–08
VERDIX CORP	722056	CF–06	CF–09
Change to RATIONAL SOFTWARE CORP	722056	CF–06	CF–09
VERITAS MUSIC ENTERTAINMENT INC	940672	NONE	CF–10
VERITAS SOFTWARE CORP	867666	NONE	CF–10
VERMONT TEDDY BEAR CO INC	912960	NONE	CF–10
VESTA INSURANCE GROUP INC	911576	NONE	CF–10
VETCO INC/NY	931753	NONE	CF–10
VETERINARY CENTERS OF AMERICA INC	817366	NONE	CF–10
VIASOFT INC /DE/	935418	NONE	CF–10
VICON INDUSTRIES INC /NY/	310056	CF–05	CF–06
VIDAMED INC	929900	NONE	CF–10
VIDEONICS INC	932113	NONE	CF–10
VIDEO PROFESSOR INDUSTRIES INC	851965	CF–10	REMOVE
VIDEOTELECOM CORP /DE/	884144	CF–10	CF–10
Change to VTEL CORP	884144	CF–10	CF–10
VIDEO UPDATE INC	920042	NONE	CF–10
VIDEOSERVER INC	943894	NONE	CF–10
VIKING RECYCLING INC	915651	NONE	CF–10
VILLAGE BANKSHARES INC	858754	NONE	CF–10
VIRATEK INC	351237	CF–04	REMOVE
VISION MARKETING GROUP INC	920757	NONE	CF–10
VISTA 2000 INC	916802	NONE	CF–10
VISTA BANCORP INC	831979	NONE	CF–10
VITAMIN SPECIALTIES CORP	910329	NONE	CF–10
VOLUNTEER STATE BANCSHARES INC	709417	CF–08	REMOVE
VOXEL /CA/	927472	NONE	CF–10
VU VIDEOS INC	917697	NONE	CF–10
WACKENHUT CORRECTIONS CORP	923796	NONE	CF–10
WALDEN RESIDENTIAL PROPERTIES INC	913280	NONE	CF–10
WALKER INTERNATIONAL INDUSTRIES INC	104224	CF–07	CF–09
WALL DATA INC	722607	NONE	CF–10
WALTER INDUSTRIES INC /NEW/	837173	NONE	CF–10
WANDEL & GOLTERMANN TECHNOLOGIES INC	918381	NONE	CF–10
WARREN S D CO /PA/	935704	NONE	CF–10
WASHINGTON COMMERCIAL BANCORP	817643	CF–08	REMOVE
WASHINGTON CORP	314625	CF–09	CF–10

CHANGES FROM CORPORATION FINANCE EDGAR PHASE-IN LIST AS PUBLISHED IN SECURITIES ACT RELEASE NO. 7122—Continued

[December 19, 1994]

Name	CIK No.	Former group	New group
WASHINGTON FEDERAL INC	936528	NONE	CF–10
WASHINGTON HOMES INC	104834	NONE	CF–10
WATERS CORP	930809	NONE	CF–10
WATSON PHARMACEUTICALS INC	884629	NONE	CF–10
WAVE SYSTEMS CORP	919013	NONE	CF–10
WAVE TECHNOLOGIES INTERNATIONAL INC	925869	NONE	CF–10
WAVEFRONT TECHNOLOGIES INC /CA/	921301	NONE	CF–10
WCI STEEL INC	897745	NONE	CF–10
WEBCO INDUSTRIES INC	916314	NONE	CF–10
WEEKS CORP	925558	NONE	CF–10
WEGENER CORP	715073	CF–06	CF–07
WEINGARTEN PROPERTIES TRUST	913584	NONE	CF–10
WEITZER HOMEBUILDERS INC	926613	NONE	CF–10
WELBILT CORP	105494	CF–10	REMOVE
WELCOME HOME INC	922817	NONE	CF–10
WELLCARE MANAGEMENT GROUP INC	900630	NONE	CF–10
WELLFLEET COMMUNICATIONS INC	876516	CF–10	CF–10
Change to BAY NETWORKS INC	876516	CF–10	CF–10
WELLINGTON PROPERTIES TRUST	928953	NONE	CF–10
WELLS FINANCIAL CORP	934739	NONE	CF–10
WELLS REAL ESTATE FUND VI L P	895334	NONE	CF–10
WELLS REAL ESTATE FUND VII L P	895347	NONE	CF–10
WELLS REAL ESTATE FUND VIII LP	929920	NONE	CF–10
WEST MARINE INC	912833	NONE	CF–10
WEST TOWN BANCORP INC	926867	NONE	CF–10
WESTCOTT FINANCIAL CORP	922257	NONE	CF–10
WESTERN ATLAS INC	913340	NONE	CF–10
WESTERN COUNTRY CLUBS INC	916298	NONE	CF–10
WESTERN NATIONAL CORP	913202	NONE	CF–10
WESTERN OHIO FINANCIAL CORP	920769	NONE	CF–10
WESTERN POWER & EQUIPMENT CORP	939729	NONE	CF–10
WESTINGHOUSE AIR BRAKE CO /DE/	943452	NONE	CF–10
WESTSIDE BANK & TRUST CO	922244	NONE	CF–10
WESTVIEW HEALTH CARE ASSOCIATES LP	930315	NONE	CF–10
WFS BANCORP INC	919888	NONE	CF–10
WHAT A WORLD INC /DE/	931073	NONE	CF–10
WHEELING PITTSBURGH CORP /DE/	941738	NONE	CF–10
WHITE RIVER CORP	913338	NONE	CF–10
WICKES LUMBER CO /DE/	910620	NONE	CF–10
WILD WINGS INC	939728	NONE	CF–10
WILLIAMS COAL SEAM GAS ROYALTY TRUST	895007	NONE	CF–10
WILLIAMS INDUSTRIES INC	107294	CF–05	CF–10
WILLIAMS J B HOLDINGS INC	929651	NONE	CF–10
WILSHIRE TECHNOLOGIES INC	891762	NONE	CF–10
WINSLOEW FURNITURE INC	931814	NONE	CF–10
WINSTON FURNITURE COMPANY INC	818015	CF–10	REMOVE
WINSTON HOTELS INC	920605	NONE	CF–10
WIRELESS CABLE OF ATLANTA INC	904355	NONE	CF–10
WISCONSIN REAL ESTATE INVESTMENT TRUST	107835	CF–05	CF–09
WISCONSIN SOUTHERN GAS CO INC	107841	CF–06	REMOVE
WITTER DEAN DISCOVER & CO	895421	NONE	CF–10
WITTER DEAN DIVERSIFIED FUTURES FUND LTD PART /DE/	941912	NONE	CF–10
WITTER DEAN PRINCIPAL GUARANTEED FUND II	841754	NONE	CF–10
WITTER DEAN PRINCIPAL PLUS FUND LP	854915	NONE	CF–10
WITTER DEAN SPECTRUM STRATEGIC LP	925263	NONE	CF–10
WITTER DEAN WORLD CURRENCY FUND L P	895239	NONE	CF–10
WIZ TECHNOLOGY INC	914282	NONE	CF–10
WNC CALIFORNIA HOUSING TAX CREDITS IV LP SERIES 4	921052	NONE	CF–10
WNC HOUSING TAX CREDIT FUND IV LP	907253	NONE	CF–10
WNC HOUSING TAX CREDIT FUND V LP SERIES 3	943904	NONE	CF–10
WNC HOUSING TAX CREDIT FUND V LP SERIES 5	943907	NONE	CF–10
WNC HOUSING TAX CREDIT FUND V LP SERIES 6	943908	NONE	CF–10
WNC HOUSING TAX CREDIT FUND V LP SERIES 7	943909	NONE	CF–10
WNC HOUSING TAX CREDIT FUND V LP SERIES 8	943934	NONE	CF–10
WOMACK APARTMENT INVESTORS I LTD PART	921159	NONE	CF–10
WONDERWARE CORP	906519	NONE	CF–10
WOODROAST SYSTEMS INC	919273	NONE	CF–10
WORLD OMNI 1994 B AUTOMOBILE LEASE SECURITIZATION TRUST	931355	NONE	CF–10
WORLD OMNI 1994–A AUTOMOBILE LEASE SECURITIZATION TRUST	920344	NONE	CF–10

CHANGES FROM CORPORATION FINANCE EDGAR PHASE-IN LIST AS PUBLISHED IN SECURITIES ACT RELEASE NO. 7122—Continued

[December 19, 1994]

Name	CIK No.	Former group	New group
WORLD OMNI DEALER FUNDING INC	929543	NONE	CF–10
WORLD OMNI LEASE SECURITIZATION L P	920343	NONE	CF–10
WORLD TRADITIONAL TAEKWONDO UNION INC	940031	NONE	CF–10
WPC OPERATING PARTNERSHIP LP	931783	NONE	CF–10
WPS REC CO WESTPOINT STE RE MA TR FL RT TR RE PA CE S 1994–1	930224	NONE	CF–10
WPS RECEIVABLES CORP	921045	NONE	CF–10
WRIGHT MEDICAL TECHNOLOGY INC	912560	NONE	CF–10
XCELLENET INC /GA/	919746	NONE	CF–10
XECHEM INTERNATIONAL INC	919611	NONE	CF–10
Y&A GROUP INC	813359	CF–07	REMOVE
YAMAHA MOTOR RECEIVABLES CORP	916095	NONE	CF–10
YARDVILLE NATIONAL BANCORP	787849	NONE	CF–10
YOUNG BROADCASTING INC /DE/	929144	NONE	CF–10
YOUNKERS CREDIT CORP	937604	NONE	CF–10
ZARING HOMES INC	899750	NONE	CF–10
ZEIGLER COAL HOLDING CO	925942	NONE	CF–10
ZENITH LABORATORIES INC	109259	CF–05	REMOVE
ZONAGEN INC	897075	NONE	CF–10
ZOOM TELEPHONICS INC	822708	NONE	CF–10
ZURICH REINSURANCE CENTRE HOLDINGS INC	898612	NONE	CF–10
ZYTEC CORP /MN/	912092	NONE	CF–10
TOTAL: 2754			

Dated: September 13, 1995.

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 95–23141 Filed 9–18–95; 8:45 am]

BILLING CODE 8010–01–P

[Release No. 34–36222; Filed No. SR–NYSE–95–25]

Self-Regulatory Organizations; New York Stock Exchange, Inc.; Order Granting Approval to Proposed Rule Change Relating to Amendments to Rules 600 (Arbitration), 619 (General Provision Governing Subpoenas, Production of Documents, etc.), 629 (Schedule of Fees), and 637 (Failure to Honor Award)

September 13, 1995.

On June 26, 1995, the New York Stock Exchange, Inc. (''NYSE'' 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'')[1] and Rule 19b–4 thereunder,[2] a proposed rule change to adopt certain arbitration procedures.

The proposed rule change was published for comment in the Federal Register on July 26, 1995.[3] No comments were received on the proposal.

As described more fully below, the Exchange has proposed amendments to its arbitration procedures that were developed primarily by the Securities Industry Conference on Arbitration.[4]

The Commission has reviewed carefully the NYSE's proposed rule changes and concludes that the proposed changes are consistent with the requirements of the Act and the rules and regulations thereunder applicable to a national securities exchange, and, in particular, with the requirements of Section 6(b).[5] The Exchange proposes to amend NYSE Rules 600 (Arbitration), 619 (General Provision Governing Subpoenas, Production of Documents, etc.) 629 (Schedule of Fees), and 637 (Failure to Honor Award).[6]

NYSE Rule 600(d)(iii) currently bars members, allied members, member organizations, and associated persons from seeking to enforce an agreement to arbitrate against a customer where the customer has initiated in court a putative class action or is a member of a putative or certified class with respect to any claims encompassed by the class action. The rule, however, omits specific reference to claims filed by members, allied members, member organizations, and associated persons against other members, allied members, member organizations, and associated persons. This proposed amendment clarifies that all class actions, including claims involving members, allied members, member organizations, and associated persons, are ineligible for submission to the Exchange's arbitration facility.

The Commission finds that the proposed amendment to NYSE Rule 600(d)(iii) is consistent with the Section 6(b)(5)[7] requirements that the rules of an exchange be designed to promote just and equitable principles of trade, prevent unfair discrimination between customers, issuers, brokers, or dealers, and, in general, protect investors and the public. Over the years, the courts have developed procedures and expertise for managing class action litigation and duplicating the often complex procedural safeguards necessary for these lawsuits is unnecessary. In addition, access to the courts for class action litigation should be preserved for claims filed by

---

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] Securities Exchange Act Release No. 36001 (July 20, 1995), 60 FR 38389.

[4] NYSE Rule 600(d)(iii) corresponds to Securities Industry Conference on Arbitration Uniform Code of Arbitration (''SICA UCA'') Section 1(d)(iii) (as amended Jan. 20, 1994); NYSE Rule 619(c) corresponds to SICA UCA Section 20(c) (as amended Jan. 7, 1993 and Oct. 21, 1994); NYSE Rule 629(e) corresponds to SICA UCA Section 30(e) (as amended Oct. 21, 1994).

[5] 15 U.S.C. 78f(b).

[6] The Commission notes that it has approved some of the proposals contained in this filing previously for another self-regulatory organization. See Securities Exchange Act Release Nos. 35525 (Mar. 23, 1995), 60 FR 16219 (increasing the NASD's prehearing document exchange deadline from 10 days to 20 days before the arbitration hearing); 35167 (Dec. 28, 1994), 60 FR 1816 (unifying the NASD's nonrefundable filing fee for industry parties at $500); 33939 (Apr. 20, 1994), 59 FR 22032 (excluding all class action claims from NASD arbitration.

[7] 15 U.S.C. 78f(b)(5).

members, allied members, member organizations, and associated persons against other members, allied members, member organizations, and associated persons, as well as for claims involving investors. Hence, this rule change should provide a sound procedure for the management of class action disputes, should promote the efficient resolution of these types of class action disputes, and should prevent wasteful litigation over the possible applicability of agreements to arbitrate between members, allied members, member organizations, and associated persons, notwithstanding the exclusion of class action claims from NYSE arbitration.

NYSE Rule 619(c) currently requires all parties to serve on each other copies of documents in their possession that they intend to present at the hearing and to identify witnesses they intend to present at the hearing not less than ten calendar days prior to the first scheduled hearing date. The Exchange is proposing to amend this rule to allow parties to: (1) Provide a list of documents that have been produced previously to the other side, instead of providing the actual documents; (2) require the list identifying witnesses to include the address and business affiliation of the witnesses listed; and (3) require prehearing exchanges of documents and the list of documents previously produced to occur twenty days in advance of the hearing, instead of ten days as is presently required.

The Commission finds that the proposed amendments to NYSE Rule 619(c) are consistent with Section 6(b)(5) because they are designed to promote just and equitable principles of trade, prevent unfair discrimination between customers, issuers, brokers, or dealers, and, in general, protect investors and the public,.[8] The proposed amendments should increase the efficiency of the arbitration process because they: (1) Eliminate duplicative prehearing document exchanges; (2) should assist parties in the process of preparing and organizing their cases by providing them with advance notice regarding the background of witnesses and the location of nonparty witnesses; (3) should reduce the number of instances of surprise; and (4) should provide the parties with a more reasonable time frame in which to address last minute discovery requests.

NYSE Rule 629(e) presently provides that the nonrefundable filing fee for a dispute that does not specify a money claim shall be $250, while NYSE Rule 629(i) charges industry parties a $500 nonrefundable filing fee when the dispute does state a money claim. The proposed amendment to NYSE Rule 629(e) would unify the nonrefundable filing fee for all industry claims at $500.

The commission finds that this proposed amendment is consistent with Section 6(b)(4)[9] because it provides for the equitable allocation of reasonable fees among its members and other persons using its facilities. A uniform filing fee would remove any temptation for an industry party to purposely omit the monetary amount of their claim in order to reduce the nonrefundable filing fee from $500 to $250.[10]

Currently, NYSE Rule 637 subjects any member, allied member, registered representative, or member organization who fails to honor an award of arbitrators appointed by the Exchange to disciplinary proceedings in accordance with the Exchange's constitution and rules. The proposed amendment to NYSE Rule 637 would expand the coverage of this rule to include arbitration awards issued at another self-regulatory organization or by the American Arbitration Association. As amended, the penalties authorized under this rule would include disciplinary proceedings at the Exchange or the imposition of a fine by way of a summary proceeding.

The Commission finds that this proposed amendment is consistent with the section 6(b)(6)[11] requirement that the rules of an exchange provide for appropriate disciplinary action for violating the provisions of the Act, the rules and regulations thereunder, or the rules of the Exchange. This proposal would establish the enforceability of arbitration awards issued by other self-regulatory organizations and by the American Arbitration Association and, in turn, should increase the effectiveness of the arbitration process.

It therefore is ordered, pursuant to Section 19(b)(2) of the Act,[12] that the proposed rule change (SR–NYSE–95–25) is approved.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[13]

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 95–23164 Filed 9–18–95; 8:45 am]

BILLING CODE 8010–01–M

[8] 15 U.S.C. 78f(b)(5).

[9] 15 U.S.C. 78f(b)(4).

[10] See Securities Exchange Act Release No. 35167 (Dec. 28, 1994), 60 FR 1816 (approving File No. SR–NASD–94–75 and publishing the NASD's determination that there have been situations in which industry parties have purposely not disclosed the monetary amount of their claim in order to reduce the nonrefundable filing fee from $500 to $250).

[11] 15 U.S.C. 78f(b)(6).

[12] 15 U.S.C. 78s(b)(2).

[13] 17 CFR 200.30–3(a)(12).

[File No. 1–12212]

Issuer Delisting; Notice of Application to Withdraw From Listing and Registration; (CVD Financial Corporation, Common Stock, $.01 Par Value, Variable Rate Bonds Due 2008)

September 13, 1995.

CVD Financial Corporation (''Company'') has filed an application with the Securities and Exchange Commission (''Commission''), pursuant to Section 12(d) of the Securities Exchange Act of 1934 (''Act'') and Rule 12d2–2 (d) promulgated thereunder, to withdraw the above specified securities (''Securities'') from listing and registration on the American Stock Exchange, Inc. (''Amex'' or ''Exchange'').

The reasons alleged in the application for withdrawing the Securities from listing and registration include the following:

According to the Company, it received a letter dated May 26, 1995, from the Exchange stating that it was considering delisting the Securities. The Exchange believed the Company's financial condition was substantially impaired, and it had failed to comply with the Exchange's listing agreement by not holding an annual meeting of shareholders since being listed in August 1993. After the Company submitted its response to the Exchange by a letter dated June 28, 1995 and met with Amex officials on July 6, 1995, the Exchange sent a letter to the Company dated July 13, 1995, stating that the Exchange had decided to delist the Securities. Although the Company initially elected to appeal the Exchange's decision to delist the Securities to the Exchange's Board of Governors, the Company has decided to settle matters by voluntarily removing the Securities from listing on the Exchange. It is now the Company's position, in view of the impasse between the Exchange and the Company and the large expenditures of money and management time that would be required before a final resolution of the matters at issue could be obtained, that it is in the best interest of both the Company and its shareholders that matters be settled by voluntarily delisting the Securities from the Exchange.

The Exchange also has agreed that it would be in the best interest of the

Exchange and the investing public to resolve this issue between the Company and the Exchange in this manner.

Any interested person may, on or before October 4, 1995, submit by letter to the Secretary of the Securities and Exchange Commission, 450 Fifth Street, N.W., Washington, D.C. 20549, facts bearing upon whether the application has been made in accordance with the rules of the Amex and what terms, if any, should be imposed by the Commission for the protection of investors. The Commission, based on the information submitted to it, will issue an order granting the application after the date mentioned above, unless the Commission determines to order a hearing on the matter.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.

Jonathan G. Katz,

Secretary.

[FR Doc. 95–23165 Filed 9–18–95; 8:45 am]

BILLING CODE 8010–01–M

[Rel. No. IC–21349; File No. 812–9388]

Integrity Life Insurance Company, et al.

September 12, 1995.

AGENCY: The Securities and Exchange Commission (the ''Commission'').

ACTION: Notice of Application for an Order under the Investment Company Act of 1940 (''1940 Act'').

APPLICANTS: Integrity Life Insurance Company (''Integrity''), Separate Account I of Integrity Life Insurance Company (''Account I''), Separate Account II of Integrity Life Insurance Company (''Account II,'' and collectively with Account I, the ''Separate Accounts'') and Integrity Financial Services, Inc. (''Services'').

RELEVANT 1940 ACT SECTIONS: Exemptions requested under Section 6(c) from Sections 26(a)(2)(C) and 27(c)(2) of the 1940 Act.

SUMMARY OF THE APPLICATION: Applicants seek an order under Section 6(c) of the 1940 Act granting exemptions from Sections 26(a)(2)(C) and 27(c)(2) to the extent necessary to permit the deduction of a mortality and expense risk charge from the assets of the Separate Accounts or other Separate Accounts (''Other Accounts'') established by Integrity to support certain flexible premium variable annuity policies (''Contracts'') as well as other variable annuity contracts that are substantially similar in all material respects to the Contracts (''Future Contracts''). In addition, Applicants propose that Services replace Integrity as principal underwriter for the Contracts, and that the order extend the same exemptions granted to Services, and to any other broker-dealer that may in the future serve a principal underwriter for the Contracts or Future Contracts, the same exemptions currently granted to Integrity.

FILING DATES: The application was filed on December 22, 1994, and was amended on August 2, 1995 and September 8, 1995.

HEARING OR NOTIFICATION OF HEARING: An order granting the application will be issued unless the Commission orders a hearing. Interested persons may request a hearing by writing to the SEC's Secretary and serving Applicants with a copy of the request, personally or by mail. Hearing requests should be received by the SEC by 5:30 p.m., on October 10, 1995, and should be accompanied by proof of service on Applicants in the form of an affidavit or, for lawyers, a certificate of service. Hearing requests should state the nature of the requestor's interest, the reason for the request, and the issues contested. Persons may request notification of a hearing by writing to the Secretary of the SEC.

ADDRESSES: Secretary, Securities and Exchange Commission, 450 Fifth Street, N.W., Washington, D.C. 20549. Applicants, Kevin L. Howard, Esq., Integrity Life Insurance Company, 239 S. Fifth Street, 12th Floor, Louisville, Kentucky, 40202.

FOR FURTHER INFORMATION CONTACT: Pamela K. Ellis, Senior Counsel, or Wendy Finck Friedlander, Deputy Chief, at (202) 942–0670, Office of Insurance Products, Division of Investment Management.

SUPPLEMENTARY INFORMATION: Following is a summary of the application; the complete application is available for a fee from the SEC's Public Reference Branch.

Applicant's Representations

1. Integrity, a stock life insurance company, is organized in Ohio and licensed to sell life insurance and annuities in forty-four states and the District of Columbia. In addition, Integrity is licensed to sell variable contracts in forty-three states and the District of Columbia. Integrity is an indirect wholly-owned subsidiary of ARM Financial Group, Inc. (''ARM Financial''). Integrity is currently the principal underwriter of the Contracts and is registered as a broker-dealer under the Securities Exchange Act of 1934 and is a member of the National Association of Securities Dealers, Inc. (''NASD'').

2. Account I and Account II are separate accounts established by Integrity to fund the Contracts. Both Separate Accounts are registered under the 1940 as unit investment trusts. Interests in the Contracts are registered as securities under the 1933 Act.

3. Account I has ten investment divisions (''Divisions''), each of which invests in one of the ten corresponding portfolios of the Variable Insurance Products Fund and the Variable Insurance Products Fund II, which are both part of the Fidelity Investments (R) group of companies (collectively, ''Trusts''). Account II has ten Divisions, each of which invests in a corresponding portfolio of The Legends Fund, Inc. (''Legends Fund,'' and collectively with the Trusts, ''Funds''). The Funds are diversified, open-end management investment companies registered under the 1940 Act.

4. Services, a wholly-owned subsidiary of ARM Financial, is registered with the Commission under the Securities Exchange Act of 1934 as a broker-dealer and is a member of the NASD. Applicants now seek to substitute Services for Integrity as the principal underwriter for the Contracts.[1]

5. Integrity, the Separate Accounts, and Services will enter into an agreement under which Services will become principal underwriter for the Contracts. Integrity and Services propose to enter into selling agreements with broker-dealers for the distribution of the Contracts.

6. The Contracts are flexible premiums variable annuity contracts. Contract owners (''Participants'') may allocate premium payments to one or more of the Separate Accounts' Divisions, or to one or more of Integrity's guaranteed periods, or both. Amounts allocated to guarantee periods accumulate on a fixed basis, except as adjusted for any applicable value adjustment.

7. A death benefit is available under the Contracts if a Participant dies prior to his or her retirement date. The amount of the death benefit is equal to the greatest of (1) the Participant's annuity value, (2) the minimum death benefit, which equals total contributions less the sum of the market value

[1] The Commission has previously granted relief permitting Integrity to deduct mortality and expense risk charges from the assets of the Separate Accounts in connection with the sales of the Contracts. See, Integrity Life Insurance Company, Investment Company Act Release No. 19120 (Nov. 24, 1992) and The Equitable Life Assurance Society of the United States, Investment Company Act Release No. 15406 (Nov. 7, 1986) (''Existing Orders''). Applicants are not requesting that the order sought herein amend or supersede the Existing Orders.

adjusted withdrawals, and (3) the Participant's highest annuity value at the beginning of any participation year, plus subsequent contributions and minus subsequent withdrawals (''Enhanced Death Benefit'').

8. Retirement benefits under the Contracts may take the form of a lump sum payment or an annuity. The retirement benefits are calculated as of the retirement date selected by the Participant. If no annuity payment option is elected by the retirement date, Integrity will deem the retirement date to have been extended.

9. Certain charges and fees are assessed under the Contracts. Until annuity payments begin, Participants may transfer their Contract values among Divisions of the relevant Separate Account and the relevant guarantee periods, except that transfers to any guarantee period must be to a newly elected guarantee period at the current guaranteed interest rate. No fee currently is imposed for a Participant's first twelve transfers per participation year. Integrity reserves the right to impose a fee of up to $25 for each transfer in excess of twelve per participation year. The transfer fee will be paid to Integrity to compensate it for the anticipated actual administrative expenses relating to transfers and is guaranteed not to increase during the life of the Contracts. In addition, Applicants reserve the right to impose a transfer fee in connection with Future Contracts of up to $25 on transfers beginning with the first transfer of Contract values in any participation year. No charges will be assessed for transfers made under Integrity's dollar cost averaging program.

10. A contingent deferred sales charge (''CDSC'') may be imposed on certain withdrawals. The amount of the CDSC decreases annually from 7% to 0% over 7 participation years. No CDSC will be applied to partial withdrawals made during any participation year that do not exceed the specified amount. In addition, Integrity may waive the CDSC in certain circumstances.

11. If a Participant's Contract value is less than $50,000 on the last day of any participation year prior to the Participant's retirement date, Integrity charges an annual administrative charge of $30. In addition, all Contracts are subject to a daily charge equal, on an annual basis, to .15% of the net asset value of the relevant Separate Account to cover policy administration expenses. These daily and annual fees are guaranteed for the life of the Contracts and will not exceed the cost of services to be provided over the life of the Contract.

12. Integrity imposes charges as compensation for bearing certain mortality and expense risks under the Contracts. The amount of the mortality and expense risk charges under the Contracts is equal, on an annual basis, to 1.20% (of which .35% is attributable to mortality risks and .85% to expense risks) of the daily net asset value of the relevant Separate Account. For the Future Contracts, the annual mortality and expense risk charge will not exceed an effective annual rate of 1.20% of the net asset value of any Separate Account, or of Other Accounts, attributable to such contracts.

13. Integrity assumes the mortality risk that the life expectancy of the annuitant will be greater than that assumed in the guaranteed annuity purchase rates, thus requiring Integrity to pay out more in annuity income than it had planned. Integrity assumes an additional mortality risks because of its contractual obligation to provide a minimum death benefit and an Enhanced Death Benefit prior to the annuity date. Thus, Integrity assumes the risk that it may not be able to cover its distribution expenses and that the owner may die at a time when the amount of the death benefit payable exceeds the then net surrender value of the Contracts. The expense risk assumed by Integrity is that the administration charge will be sufficient to cover the actual cost of administering the Contracts.

Applicants' Legal Analysis

1. Section 6(c) of the 1940 Act authorizes the Commission, by order upon application, to conditionally or unconditionally grant an exemption from any provision, rule or regulation of the 1940 to the extent that the exemption is necessary or appropriate in the public interest and consistent with the protection of investors and the purposes fairly intended by the policy and provisions of the 1940 Act.

2. Sections 26(a)(2)(C) and 27(c)(2) of the 1940, in relevant part, prohibit a registered unit investment trust, its depositor or principal underwriter, from selling periodic payment plan certificates unless the proceeds of all payments, other than sales loads, are deposited with a qualified bank and held under arrangements which prohibit any payment to the depositor or principal underwriter except a reasonable fee, as the Commission may prescribe, for performing bookkeeping and other administrative duties normally performed by the bank itself.

3. Applicants request an order under Section 6(c) exempting them from Sections 26(a)(2)(C) and 27(c)(2) of the 1940 Act to the extent necessary to permit the deduction of the mortality and expense risk charge from the assets of the Separate Accounts or Other Accounts that issue the Contracts or Future Contracts. Applicants also propose that Services replace Integrity as principal underwriter for the Contracts, and that the order extend the same exemptions granted to Services, and to any other broker-dealer that may in the future serve a principal underwriter for the Contracts or Future Contracts, the same exemptions currently granted to Integrity. Any such principal underwriter will be wholly-owned, directly or indirectly, by ARM Financial.

4. Applicants submit that their request for an order is appropriate in the public interest. Such an order would promote competitiveness in the variable annuity contract market by eliminating the need for Integrity to file redundant exemptive applications, thereby reducing Integrity's administrative expenses and maximizing the efficient use of Integrity's resources. The delay and expense involved in having repeatedly to seek exemptive relief would impair Integrity's ability effectively to take advantage of business opportunities as these opportunities arise. Applicants further submit that the requested relief is consistent with the purposes of the 1940 Act and the protection of investors for the same reasons. If Integrity were required repeatedly to seek exemptive relief with respect to the same issues addressed in this Application, investors would not receive any benefit or additional protection thereby. Thus, Applicants believe that the requested exemptions are appropriate in the public interest and consistent with the protection of investors and the purposes fairly intended by the policy and provisions of the 1940 Act.

5. Applicants represent that they have reviewed publicly-available information regarding the aggregate level of the mortality and expense risk charges under variable annuity contracts comparable to the Contracts currently being offered in the insurance industry taking into consideration such factors as current charge levels, the manner in which charges are imposed, the presence of charge-level or annuity-rate guarantees and the markets in which the Contracts will be offered. Based upon the foregoing, Applicants further represent that the mortality and expense risk charges under the Contracts are within the range of industry practice for comparable contracts. Applicants will maintain and make available to the Commission, upon request, a

memorandum outlining the methodology underlying this representation. Similarly, prior to making available any Future Contracts through the Separate Accounts or Other Accounts, Applicants will represent that the mortality and expense risk charges under any such contracts will be within the range of industry practice for comparable contracts. Applicants will maintain and make available to the Commission, upon request, a memorandum outlining the methodology underlying such representation.

6. Applicants do not believe that the contingent withdrawal charges under the Contracts will necessarily cover the expected costs of distributing the Contracts. Any ''shortfall'' will be made up from Integrity's general account assets which will include amounts derived from mortality and expense risk charges. Integrity has concluded that there is a reasonable likelihood that the distribution financing arrangement being used in connection with the Contracts will benefit the Separate Accounts and the Contract owners. Integrity will keep and make available to the Commission, upon request, a memorandum setting forth the basis for this representation. Similarly, Integrity will maintain and make available to the Commission, upon request, a memorandum setting forth the basis for the same representation with respect to Future Contracts offered by the Separate Accounts or by Other Accounts established by Integrity.

7. Applicants represent that the Separate Accounts and Other Accounts will invest only in a management investment company which has undertaken, in the event such company adopts a plan under Rule 12b–1 under the 1940 Act to finance distribution expenses, to have a board of directors (or trustees), a majority of whom are not ''interested persons'' of the management investment company within the meaning of Section 2(a)(19) of the 1940 Act, formulate and approve any plan under Rule 12b–1 to finance distribution expenses.

Conclusion

Applicants assert that, for the reasons and upon the facts set forth above, the requested exemptions from sections 26(a)(2)(C) and 27(c)(2) of the 1940 Act to deduct the mortality and expense risk charge from the assets of the Separate Accounts or Other Accounts that issue the Contracts and/or the Future Contracts, and in connection with Contracts or Future Contracts for which broker-dealers other than Services will serve as principal underwriter, meet the applicable statutory standards in Section 6(c) of the 1940 Act. Applicants assert that the exemptions requested are necessary and appropriate in the public interest and consistent with the protection of investors and the policies and provisions of the 1940 Act.

For the Commission, by the Division of Investment Management, pursuant to delegated authority.

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 95–23143 Filed 9–18–95; 8:45 am]

BILLING CODE 8010–01–M

[Rel. No. IC–21350– 812–9680]

Northstar Advantage Multi-Sector Bond Fund, et al.; Notice of Application

September 13, 1995.

AGENCY: Securities and Exchange Commission (''SEC'').

ACTION: Notice of application for exemption under the Investment Company Act of 1940 (the ''Act'').

APPLICANTS: Northstar Advantage Multi-Sector Bond Fund (the ''Acquired Fund''), a series of Northstar Advantage Trust (the ''Trust''), Northstar Advantage Strategic Income Fund (the ''Acquiring Fund''), NWNL Northstar Distributors, Inc. (the ''Distributor''), Northstar Investment Management Corporation (the ''Adviser''), ReliaStar Financial Corp. (''ReliaStar''), Northwestern National Life Insurance Company, and Northern Life Insurance Company.

RELEVANT ACT SECTIONS: Order requested under section 17(b) granting an exemption from section 17(a) and under rule 17d–1 permitting certain joint transactions under section 17(d) and rule 17d–1.

SUMMARY OF APPLICATION: Applicants seek an order to permit the Acquiring Fund to acquire all of the assets of the Acquired Fund. Because of certain affiliations, the two funds may not rely on rule 17a–8 under the Act.

FILING DATES: The application was filed on July 19, 1995, and amended on September 1, 1995.

HEARING OR NOTIFICATION OF HEARING: An order granting the application will be issued unless the SEC orders a hearing. Interested persons may request a hearing by writing to the SEC's Secretary and serving applicants with a copy of the request, personally or by mail. Hearing requests should be received by the SEC by 5:30 p.m. on October 4, 1995, and should be accompanied by proof of service on the applicants, in the form of an affidavit or, for lawyers, a certificate of service. Hearing requests should state the nature of the writer's interest, the reason for the request, and the issues contested. Persons who wish to be notified of a hearing may request notification by writing to the SEC's Secretary.

ADDRESSES: Secretary, SEC, 450 Fifth Street, N.W., Washington, D.C. 20549. Applicants: The Acquired Fund, the Acquiring Fund, the Distributor, and Adviser, Two Pickwick Plaza, Greenwich, Connecticut 08630; ReliaStar and Northwestern National Life Insurance Company, 20 Washington Avenue South, Minneapolis, Minnesota 55401; and Northern Life Insurance Company, 1110 Third Avenue, Seattle, Washington 98101.

FOR FURTHER INFORMATION CONTACT: James J. Dwyer, Staff Attorney, at (202) 942–0581, or Alison E. Baur, Branch Chief, at (202) 942–0564 (Office of Investment Company Regulation, Division of Investment Management).

SUPPLEMENTARY INFORMATION: The following is a summary of the application. The complete application may be obtained for a fee at the SEC's Public Reference Branch.

Applicants' Representations

1. The Trust and the Acquiring Fund are Massachusetts business trusts that are registered under the Act as open-end management investment companies. The Trust offers its shares in three series, one of which is the Acquired Fund. The Acquiring Fund and the Acquired Fund (each a ''Fund'') offer their shares in three classes. For the Acquired Fund, Class A shares are sold with a maximum front-end sales load of 4.75% and a rule 12b-1 fee of .30% annually of average net assets; Class B shares are sold with a maximum contingent deferred sales load (a ''CDSL'') of 5% and a 1% rule 12b-1 fee; Class C shares are sold with a 1% CDSL if redeemed within one year of purchase and a 1% rule 12b-1 fee. The three classes and expense structure for each class of the Acquiring Fund will be similar to the existing expense structure of the Acquired Fund, except that the Acquiring Fund has a lower advisory fee and is not subject to any administrative services fee.

2. On June 2, 1995, as a result of a transfer to the Adviser of the advisory business of Advest, Inc. and its affiliates, the Adviser and the Distributor became, respectively, the investment adviser and principal underwriter of the Trust and the Acquiring Fund. The Adviser and the Distributor are wholly-owned by NWNL

Northstar, Inc., which in turn is majority-owned by ReliaStar. Northwestern National Life Insurance Company and Northern Life Insurance Company (collectively, the ''Life Insurance Companies'') are wholly-owned by ReliaStar. The Life Insurance Companies collectively own approximately 40% of the outstanding voting securities of the Acquired Fund.

3. The Acquiring Fund proposes to acquire all of the assets of the Acquired Fund in exchange for shares of the Acquiring Fund pursuant to an agreement and plan of reorganization (the ''Reorganization Agreement''). The Adviser submitted the proposal to the trustees of the Acquired Fund based on, among other things, the Funds' very similar investment objectives, policies, and techniques, and the burdens of marketing two virtually identical Funds. Under the Reorganization Agreement, the number of shares of each class of the Acquiring Fund to be issued to the Acquired Fund will be determined on the basis of each party's relative net asset value per its respective classes of shares computed as of 4:00 p.m. (New York time) on the Closing Date, as set forth in the Reorganization Agreement. The Acquired Fund then will liquidate and distribute such shares of the Acquiring Fund pro rata to its shareholders.

4. The trustees of each Fund, in approving the terms of the proposed reorganization, made an inquiry into a number of matters and considered the following factors, among others: The relative expense ratios of the Funds; the terms and conditions of the reorganization and whether the reorganization would result in dilution of shareholder interests; the compatibility of the Funds' investment objectives, policies and restrictions, as well as varying service features available to shareholders of each Fund; the benefits anticipated to inure to the shareholders of both Funds as a result of the combination; and the tax consequences of the reorganization. In addition, the board of trustees of the Acquired Fund determined that the proposed reorganization would likely provide certain benefits to shareholders. In making such determination, the trustees considered, among other things, that the reorganization would promote more efficient operations and eliminate the duplication inherent in marketing two Funds with similar investment objectives.

5. The proposed reorganization was unanimously approved by the boards of trustees of each Fund, including a majority of the trustees who are not interested persons, on April 26, 1995, and June 2, 1995, respectively. In approving the proposed reorganization, each board found that participation in the reorganization is in the best interests of the relevant Fund and that the interests of existing Fund shareholders will not be diluted as a result of the reorganization. The reorganization is subject to approval by the holders of a majority of the outstanding shares of the Acquired Fund expected at a meeting to be held on or about September 28, 1995. Such approval will be solicited pursuant to a prospectus/proxy statement that the Acquiring Fund filed with the SEC on August 17, 1995. No material change affecting the application will be made to the agreement and plan of reorganization without prior approval of the SEC.

6. The Acquiring Fund will bear all expenses related to the registration of its shares to be issued in the reorganization. The Acquired Fund will bear all expenses related to the solicitation of its shareholders in seeking approval of the reorganization. The Adviser will bear all expenses related to obtaining the requested order.

Applicants' Legal Analysis

1. Section 17(a) in relevant part prohibits an affiliated person or principal underwriter of a registered investment company, or affiliated person of such affiliated person or principal underwriter, acting as principal, from selling to or purchasing from such registered company, any security or other property. Section 2(a)(3) defines ''affiliated person'' in relevant part to include persons under common control, and, under section 2(a)(9), it is presumed that an entity that owns 25% or more of the outstanding voting securities of another entity controls such other entity.

2. Rule 17a–8 under the Act exempts from section 17(a) mergers, consolidations, or purchases or sales of substantially all the assets involving registered investment companies that may be affiliated persons solely by reason of having a common investment adviser, common directors/trustees and/or common officers, provided that certain conditions are satisfied. In this case, ReliaStar controls the Acquired Fund by virtue of its wholly-owned subsidiaries, the Life Insurance Companies, owning more than 25% of the shares of the Acquired Fund. Thus, the Funds may be affiliated persons of each other for reasons other than the fact that the Funds have a common adviser.

3. Section 17(b) provides that the SEC may exempt a transaction from section 17(a) if evidence establishes that the terms of the proposed transaction, including the consideration to be paid, are reasonable and fair and do not involve overreaching on the part of any person concerned, and that the proposed transaction is consistent with the policies of the registered investment companies concerned and with the general purposes of the Act.

4. Applicants believe that the terms of the proposed reorganization satisfy the standards set forth in section 17(b). Applicants indicate that section 17(a) is designed to protect investors from transactions in which a party thereto has both the ability and the pecuniary interest to influence the actions of the investment company. Applicants assert that any pecuniary interest ReliaStar has in the Acquired Fund is aligned with the best interests of the Acquired Fund's other shareholders. In addition, because ReliaStar's interests in the Funds is insignificant when compared to its aggregate overall net worth, applicants believe that it is reasonable to conclude that ReliaStar has no pecuniary incentive to influence the actions of the Funds.

5. Applicant submit that many of the elements of the type of combination specifically contemplated by rule 17a–8 exist with respect to the proposed reorganization. The boards of the Funds have reviewed the terms of the reorganization as set forth in the Reorganization Agreement, including the consideration to be paid or received, and have found that participation in the reorganization is in the best interests of each Fund and that the interests of the existing shareholders of each Fund will not be diluted as a result of the reorganization. The investment objectives of the Funds, moreover, are essentially the same. Accordingly, applicants argue that the proposed reorganization will be consistent with the policies of each Fund.

6. Section 17(d) and rule 17d–1 prohibit an affiliated person or principal underwriter of an investment company, or an affiliated person of such affiliated person or principal underwriter, acting as principal, from participating in or effecting any transaction in connection with any joint enterprise or joint arrangement in which the investment company participates. Applicants believe that the proposed merger could be deemed to be a ''joint enterprise or other joint arrangement'' within the meaning of rule 17d–1.

7. Applicants believe that the terms of the proposed transaction are consistent with the provisions, policies, and purposes of the Act, and not on a basis less advantageous than that of other participants. Applicants further note

that the proposed merger is consistent with the investment policies of the Funds.

For the SEC, by the Division of Investment Management, under delegated authority.

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 95–23167 Filed 9–18–95; 8:45 am]

BILLING CODE 8010–01–M

[Rel. No. IC–21348; File No. 812–9622]

SAFECO Life Insurance Company, et al.

September 12, 1995.

AGENCY: Securities and Exchange Commission (''SEC'' or ''Commission'').

ACTION: Notice of application for an order under the Investment Company Act of 1940 (the ''1940 Act'').

APPLICANTS: SAFECO Life Insurance Company (''SAFECO''), First SAFECO National Life Insurance Company of New York (''First SAFECO''), SAFECO Separate Account C (''Account C''), SAFECO Resource Variable Account B (the ''Resource Account''), SAFECO Securities, Inc. (''SAFECO Securities''), and PNMR Securities, Inc. (''PNMR'').

RELEVANT 1940 ACT SECTIONS: Order requested under Section 6(C) for exemptions from Sections 26(a)(2)(C) and 27(c)(2) of the 1940 Act.

SUMMARY OF APPLICATION: Applicants seek an order to permit the deduction of a mortality and expense risk charge from the assets of Account C, the Resource Account, or any separate account established by SAFECO or First SAFECO in connection with certain variable annuity contracts (''Contracts''). The exemptions also would apply to any other registered broker-dealer, which is or will be controlling, controlled by, or under common control with SAFECO, and which may serve in the future as principal underwriter for variable annuity contracts that are similar in all material respects to the Contracts and that are offered in the future by SAFECO or First SAFECO (''Future Contracts'').

FILING DATE: The application was filed on May 31, 1995, and amended and restated on September 6, 1995.

HEARING OR NOTIFICATION OF HEARING: An order granting the application will be issued unless the Commission orders a hearing. Interested persons may request a hearing by writing to the Secretary of the SEC and serving Applicants with a copy of the request, personally or by mail. Hearing requests must be received by the SEC by 5:30 p.m. on October 10, 1995, and should be accompanied by proof of service on Applicants in the form of an affidavit or, for lawyers, a certificate of service. Hearing requests should state the nature of the writer's interest, the reasons for the request, and the issues contested. Persons may request notification of a hearing by writing to the Secretary of the SEC.

ADDRESSES: Secretary, SEC, 450 Fifth Street, NW., Washington, DC 20549. Applicants, P.O. Box 34690, Seattle, Washington 98124–1690, Attn: William E. Crawford, Esq.

FOR FURTHER INFORMATION CONTACT: Joseph G. Mari, Senior Special Counsel, or Wendy Friedlander, Deputy Chief, Office of Insurance Products, Division of Investment Management, at (202) 942–0670.

SUPPLEMENTARY INFORMATION: Following is a summary of the application. The complete application is available for a fee from the Public Reference Branch of the Commission.

Applicants' Representations

1. SAFECO is a stock life insurance company organized under the laws of Washington and is the depositor of Account C and the Resource Account. First SAFECO, a wholly-owned subsidiary of SAFECO, is a stock life insurance company organized under the laws of New York.

2. Account C and the Resource Account, organized by SAFECO under Washington law as insurance company separate accounts to fund certain variable annuity contracts, are registered under the 1940 Act as unit investment trusts. Account C currently funds certain individual variable annuity contracts (''Current C Contracts''), and will fund certain additional forms of variable annuity contracts currently being registered and to be offered by SAFECO through Account C (the ''Account C Contracts''). The Resource Account currently funds certain individual and group variable annuity contracts (''Current Resource Contracts'') and, in the future, may fund certain additional forms of variable annuity contracts offered by SAFECO. The Current C Contracts and the Current Resource Contracts collectively are referred to as the ''Current Contracts''; the Current Contracts and Account C Contracts constitute the ''Contracts.''

3. SAFECO or First SAFECO may establish one or more separate accounts in the future (''Other Accounts'') (Other Accounts, Account C, and Resource Account are referred to collectively as the ''Separate Accounts'') to support certain variable annuity contracts that are materially similar to the Contracts and are offered through any other broker-dealer that (i) may serve in the future as principal underwriter in respect of certain variable annuity contracts offered by SAFECO or First SAFECO, (ii) is registered under the Securities Exchange Act of 1934 as a broker-dealer and which is or will be a member of the National Association of Securities Dealers, Inc. (the ''NASD''), and (iii) is controlling, controlled by, or under common control with SAFECO (''Other Principal Underwriters'').

4. The Separate Accounts are comprised of sub-accounts each of which invests in the corresponding portfolio or series of a management investment company registered under the 1940 Act. SAFECO and First SAFECO may create new sub-account(s) of the Separate Accounts.

5. SAFECO Securities, a registered broker-dealer and a member of the NASD, is the principal underwriter of the Current C Contracts and will be the principal underwriter of the Account C Contracts. SAFECO Securities also is the principal underwriter for the Current Resource Contracts, for which PNMR, a registered broker-dealer and a member of the NASD, previously had been the principal underwriter. SAFECO Securities or PNMR may act as principal underwriter for any Contracts issued in the future by SAFECO or First SAFECO.

6. Applicants intend to offer the Account C Contracts to the public for individuals who qualify for federal income tax advantages available under Section 408 of the Internal Revenue Code of 1986, as amended (''qualified Account C Contracts''), and for individuals desiring such benefits who do not qualify for such tax advantages (''non-qualified Account C Contracts''). Account C Contracts will be offered on a flexible payment basis. Owners may allocate purchase payments to SAFECO's general account under the fixed account portion of the Account C Contracts, or to one of several sub-accounts of Account C.

7. Applicants state that the minimum initial purchase payment for an Account C Contract is $2,000 for a qualified Account C Contract and $5,000 for a non-qualified Account C Contract. The minimum additional purchase payment is $250, except for additional purchase payments made through a systematic investing program, in which case the minimum payment is $100.

8. Regarding the Current C Contracts and the Current Resource Contracts, Applicants only seek relief to assess mortality and expense risk charges from the assets of the Separate Accounts in connection with the offering of variable annuity contracts that are materially similar to those contracts. SAFECO, the

Resource Account and SAFECO Securities were granted exemptive relief under Section 6(c) of the 1940 Act from the provisions of Sections 26(a)(2)(C) and 27(c)(2) of the 1940 Act permitting the assessment of a mortality and expense risk charge (the ''Resource Application'') to the extent set forth therein.[1] Applicants represent that no material facts contained in the Resource Application have changed since the issuance of the Resource Order and incorporate that application herein by reference. SAFECO, Account C and PNMR were granted exemptive relief under Section 6(c) oft he 1940 Act from the provisions of Sections 26(a)(2)(C) and 27(c)(2) of the 1940 Act permitting the deduction of a mortality and expense risk charge (the ''Account C Application'') to the extent set forth therein.[2] Applicants represent that no material facts contained in the Account C Application have changed since the issuance of the Account C Order and incorporate that application herein by reference.

9. Certain charges and fees are assessed under the Contracts. A Contract owner will be able to make up to twelve transfers each Contract year at no charge. Each additional transfer will be subject to a charge of $10, which, according to Applicants, will not exceed the average costs associated with administering the Contracts.

10. Contract owners will be permitted to make one withdrawal of Contract Value (the amount that the Contract provides for investment at any time), subject to the other limitations and charges under the Contracts, without the assessment of an excess withdrawal charge. A maximum charge of $25 is assessed for each withdrawal in excess of one withdrawal per Contract year.

11. For non-qualified Account C Contracts, SAFECO intends to deduct, as a charge against Contract Value, an amount equal to and for premium taxes. For qualified Account C Contracts, SAFECO intends to pay premium taxes, although SAFECO reserves the right to deduct, as a charge against Contract Value, an amount equal to and for premium taxes. For non-qualified Current Contracts, SAFECO deducts, as a charge against Contract Value, an amount equal to and for premium taxes. For qualified Current Contracts, SAFECO has reserved the right to deduct, as a charge against Contract Value, an amount equal to and for premium taxes. Premium taxes generally range up to 3.5%.

12. No front-end sales charge is imposed when purchase payments are applied under the Account C Contracts. However, a contingent deferred sales charge (''CDSC'') is assessed if the Account C Contract is surrendered or partial withdrawals exceeding certain amounts are taken during the six-year period from the issue date of the Account C Contract. Each Contract year, an Account C Contract owner generally may withdraw a total of 10% of the Contract Value as of the date of the withdrawal, without payment of the CDSC. The percentage imposed at the time of surrender or partial withdrawal depends on when the Account C Contract is surrendered or partial withdrawals are taken. The maximum CDSC is 7% of the amount withdrawn during the first Contract year. The percentage scales downward by one percent each year. In no event will the CDSC under the Account C Contracts be greater than 9% of purchase payments.

13. Applicants submit that proceeds from the CDSC may not cover the expected cost of distributing the Contracts and that any shortfall will be recovered from SAFECO's or First SAFECO's general assets, which may include revenue from the mortality and expense risk charge deducted from the Separate Accounts.

14. The administrative charges to be assessed with respect to the Account C Contracts will be (i) an annual administration maintenance charge, currently $30 per Contract year, and (ii) an asset-related administration charge at an annual rate of approximately .15%, which rate may not be increased for the duration of the Account C Contracts. The annual administration maintenance charge is imposed only on Account C Contracts with a Contract Value less than $100,000. SAFECO states that it may change the annual administration maintenance charge over the period that the Account C Contracts are in force, but in no event will the annual administration maintenance charge exceed $40 per Contract year.

15. SAFECO represents that it does not expect that the total revenues from the administrative charges will be greater than the total expected cost of administering the Contracts, on average, excluding costs that are properly categorized as distribution expenses, over the period that the Contracts are in force. Applicants represent that they rely on and are in compliance with the requirements of Rule 26a–1 in connection with charges under the Contracts.

16. Applicants propose to deduct a daily charge for mortality and expense risks from the assets of the Separate Accounts. With respect to the Account C Contracts, SAFECO will assess the Separate Accounts with a daily charge for mortality and expense risks at an aggregate annual rate of 1.25%. Approximately .90% of the annual charge is allocated to the mortality risks and .35% is allocated to the expense risks.

17. SAFECO will assume a mortality risk by its contractual obligation to pay a death benefit to the beneficiary if the owner, as defined in the Account C Contract (''Account C Contract Owner''), dies prior to the Annuity Date. Applicants assert that the Account C Contracts provide a guaranteed death benefit that is the greater of: (a) the Contract Value at the time of notification of death and election of a settlement option, but not later than six months following the date of death; or (b) the previous minimum guaranteed death benefit. Applicants represent that the minimum guaranteed death benefit is reset at the end of each sixth Contract Year (the ''Six Year Contract Anniversary''), as described below. At each Six Year Contract Anniversary the last minimum guaranteed death benefit value on record is compared to the then current Contract Value. The greater of the two values becomes the new minimum guaranteed death benefit value. At the first Six year Contract Anniversary the last minimum guaranteed death benefit value of record is the sum of all payments less any withdrawals during the first six Contract Years; that value will be compared to Contract Value. The minimum guaranteed death benefit value is fixed as of the last Six Year Contract Anniversary preceding the Account C Contract Owner's 76th birthday. If an Account C Contract Owner makes withdrawals during the period between Six Year Contract Anniversaries, the minimum guaranteed death benefit value is reset to equal the sum of: (a) The previous minimum guaranteed death benefit value; multiplied by (b) the Contract Value after the withdrawal; divided by (c) the Contract Value before the withdrawal. Similarly, if an Account C Contract Owner makes purchase payments during the period between Six Year Contract Anniversaries, the previous minimum guaranteed death benefit is adjusted to reflect the amount of the purchase payments.

18. Applicants also represent that SAFECO assumes a similar mortality risk under the Current Contracts. The

[1] Safeco Life Insurance Company, Investment Company Act Release Nos. 15396 (Nov. 5, 1986) (notice) and 15459 (Dec. 5, 1986) (''Resource Order'').

[2] Safeco Life Insurance Company, Investment Company Act Release Nos. 20043 (Jan. 28, 1994) (notice) and 20097 (Feb. 25, 1994) (the ''Account C Order'').

Current Contracts provide a guaranteed death benefit that is the greater of: (1) Net purchase payments plus any deposits less any withdrawals (including any applicable charges) at the time of death; or (2) the Contract Value determined as of the ''Valuation Period'' (as defined in the Current Contract), next following the date both proof of death and an election of a single sum payment or of a form of annuity payment is received by SAFECO.

19. SAFECO also represents that it assumes a mortality risk by its contractual obligation to continue to make annuity payments for the life of the annuitant under annuity options involving life contingencies. This assures each annuitant that neither the annuitant's own longevity nor an improvement in life expectancy generally will have an adverse effect on the annuity payments received under an Account C Contract. This relieves the annuitant from the risk of outliving the amounts accumulated for retirement. At the same time, SAFECO represents that it assumes the risk that annuitants as a group will live a longer time than SAFECO's annuity tables predict, which would require SAFECO to pay out more in annuity income than planned. SAFECO assumes an additional mortality risk because the Account C Contract does not impose CDSC or similar charge on the death benefit or upon annuitization.

20. In addition to mortality risks, SAFECO asserts that it assumes an expense risk under the Contracts because the administrative charges under the Contracts may be insufficient to cover actual administrative expenses.

21. Applicants represent that if the administrative charges and mortality and expense risk charges assessed against Separate Account assets are insufficient to cover the expenses and costs assumed, the loss will be borne by SAFECO or First SAFECO. If the amount deducted for mortality and expense risk charges proves more than sufficient, the excess will be profit to SAFECO or First SAFECO. SAFECO anticipates earning a profit from the mortality and expense risk charge.

Applicants' Legal Analysis

1. Applicants request that the Commission, pursuant to Section 6(c) of the 1940 Act, grant exemptions from Sections 26(a)(2)(C) and 27(c)(2) thereof to the extent necessary to permit the deduction of a mortality and expense risk charge from the assets of the Separate Accounts under the Contracts and Future Contracts as described herein.

2. Section 6(c) of the 1940 Act, in relevant part, provides that the Commission may issue an order exempting any person, security or transaction, or any class or classes of persons, securities or transactions, from any provision or provisions of the 1940 Act as may be necessary or appropriate in the public interest and consistent with the protection of investors and the purposes fairly intended by the policy and provisions of the 1940 Act.

3. Sections 26(a)(2)(C) and 27(c)(2) of the 1940 Act prohibit a registered unit investment trust and any depositor thereof or principal underwriter therefor, from selling periodic payment plan certificates unless the proceeds of all payments (other than sales load) are deposited with a qualified trustee or custodian and held under an agreement that provides that no payment to the depositor or principal underwriter shall be allowed except as a fee, not exceeding such reasonable amount as the Commission may prescribe, for bookkeeping and other administrative services.

4. Applicants assert that the requested exemptions meet the standards of Section 6(c) of the 1940 Act, and that the terms of the relief requested with respect to the Contracts or Future Contracts funded by a Separate Account and distributed by SAFECO Securities, PNMR or any Other Principal Underwriters are consistent with the standards set forth in Section 6(c) of the 1940 Act. Applicants state that without the requested future relief, they would have to request and obtain exemptive relief in connection with Contracts or Future Contracts to the extent required. Applicants submit that any such additional request for exemption would present no issues under the 1940 Act that have not already been addressed in this application, the Account C Application, and the Resource Application.

5. Applicants submit that the requested exemptive relief is appropriate in the public interest because it would promote competitiveness in the variable annuity contract market by eliminating the need for SAFECO, First SAFECO and their appropriate affiliates to file redundant exemptive applications, thereby reducing administrative expenses and maximizing the efficient use of resources. The delay and expense involved in having to seek exemptive relief repeatedly would impair SAFECO's, First SAFECO's, Other Accounts', and Other Principal Underwriters' ability effectively to take advantage of business opportunities as they arise. If SAFECO and First SAFECO were required to seek exemptive relief repeatedly with respect to the issues addressed in this Application, the Resource Application and the Account C Application, investors would not receive any benefit or additional protection thereby. Indeed, they might be disadvantaged as a result of SAFECO's and First SAFECO's increased overhead expenses. Applicants further submit that, for the same reasons, the requested relief is consistent with the purposes of the 1940 Act and the protection of investors.

6. Applicants represent that the mortality and expense risk charge of 1.25% is within the range of industry practice for comparable annuity products. Applicants state that this determination is based on their analysis of publicly available information about similar industry practices, taking into consideration such factors as current charge levels and benefits provided, the existence of expense charge guarantees, and guaranteed annuity rates. SAFECO and First SAFECO undertake to maintain at their home offices, and make available to the Commission upon request, a memorandum setting forth in appropriate detail the products analyzed, the methodology, and the results of the analysis relied upon, in making the foregoing determination.

7. Similarly, Applicants represent, regarding the Future Contracts, that the mortality and expense risk charges under any Future Contracts will be within the range of industry practice for comparable annuity products. Applicants state that this determination will be based on their analysis of publicly available information about similar industry practices, taking into consideration such factors as current charge levels and benefits provided, the existence of expense charge guarantees, and guaranteed annuity rates. SAFECO and First SAFECO undertake to maintain at their home offices, and make available to the Commission upon request, a memorandum setting forth in appropriate detail the products analyzed, the methodology, and the results of the analysis relied upon, in making the foregoing determination.

8. The CDSC may be insufficient to cover all costs relating to the distribution of the Contracts. In that event, if a profit is realized from the mortality and expense risk charge, all or a portion of such profit may be offset by distribution expenses not reimbursed by the CDSC. Notwithstanding the foregoing, SAFECO has concluded that there is a reasonable likelihood that the proposed distribution financing arrangements will benefit the Separate Accounts and Contract owners.

SAFECO undertakes to maintain at its home office, and make available upon request to the Commission and its staff, a memorandum setting out the basis for such conclusion.

9. SAFECO and First SAFECO also represent that the Separate Accounts will invest only in an underlying mutual fund which undertakes, in the event it should adopt any plan pursuant to Rule 12b–1 of the 1940 Act to finance distribution expenses, to have such plan formulated and approved by a board of directors, a majority of the members of which are not ''interested persons'' of such fund within the meaning of Section 2(a)(19) of the 1940 Act.

Conclusion

Applicants submit, for the reasons stated herein, that the requested exemptions from Sections 26(a)(2)(C) and 27(c)(2) of the 1940 Act to permit the assessment of a mortality and expense risk charge meet the standards set out in Section 6(c) of the 1940 Act. Accordingly, Applicants assert that the requested exemptions are necessary or appropriate in the public interest and consistent with the protection of investors and the purposes fairly intended by the policy and provisions of the 1940 Act.

For the Commission, by the Division of Investment Management, pursuant to delegated authority.

Margaret M. McFarland,

Deputy Secretary.

[FR Doc. 95–23142 Filed 9–18–95; 8:45 am]

BILLING CODE 8010–01–M

SMALL BUSINESS ADMINISTRATION

[Declaration of Disaster Loan Area #2806]

Ohio; Declaration of Disaster Loan Area (Amendment #1)

The above-numbered Declaration is hereby amended, effective September 1, 1995, to include Erie and Lorain Counties in the State of Ohio as a disaster area due to damages caused by severe storms and flooding which occurred August 7–18, 1995.

In addition, applications for economic injury loans from small businesses located in the contiguous counties of Ashland, Cuyahoga, Huron, Medina, and Sandusky in the State of Ohio may be filed until the specified date at the previously designated location.

All other information remains the same, i.e., the termination date for filing applications for physical damage is October 24, 1995, and for loans for economic injury the deadline is May 28, 1996.

(Catalog of Federal Domestic Assistance Program Nos. 59002 and 59008.)

Dated: September 13, 1995.

James W. Hammersley,

Acting Associate Administrator for Disaster Assistance.

[FR Doc. 95–23198 Filed 9–18–95; 8:45 am]

BILLING CODE 8025–01–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Approval of Noise Compatibility Program; Austin Straubel International Airport, Green Bay, WI

AGENCY: Federal Aviation Administration, DOT.

ACTION: Notice.

SUMMARY: The Federal Aviation Administration (FAA) announces its findings on the noise compatibility program submitted by Brown County under the provisions of Title I of the Aviation Safety and Noise Abatement Act of 1979 (Pub. L. 96–193) and 14 CFR part 150. These findings are made in recognition of the description of federal and nonfederal responsibilities in Senate Report No. 96–52 (1980). On January 20, 1995 the FAA determined that the noise exposure maps submitted by Brown County under part 150 were in compliance with applicable requirements. On July 19, 1995, the Administrator approved the Austin Straubel International Airport noise compatibility program as modified by supplemental information provided by the Austin Straubel International Airport Manager dated June 15, 1995 and comments with addenda and errata sheets dated November 16, 1995. Most of the recommendations of the program were approved.

EFFECTIVE DATE: The effective date of the FAA's approval of the Austin Straubel International Airport noise compatibility program is July 19, 1995.

FOR FURTHER INFORMATION CONTACT: William J. Flanagan, Federal Aviation Administration, Airports District Office, room 102, 6020 28th Avenue South, Minneapolis, Minnesota 55450, (612) 725–4463. Documents reflecting this FAA action may be reviewed at this location.

SUPPLEMENTARY INFORMATION: This notice announces that the FAA has given its overall approval to the noise program for Austin Straubel International Airport, effective July 19, 1995.

Under section 104(a) of the Aviation Safety and Noise Abatement Act of 1979 (hereinafter referred to as ''the Act''), an airport operator who has previously submitted a noise exposure map may submit to the FAA a noise compatibility program that sets forth the measures taken or proposed by the airport operator for the reduction of existing noncompatible land uses and prevention of additional noncompatible land uses within the area covered by the noise exposure maps. The Act requires such programs to be developed in consultation with interested and affected parties including local communities, government agencies, airport users, and FAA personnel.

Each airport noise compatibility program developed in accordance with Federal Aviation Regulations (FAR) part 150 is a local program, not a federal program. The FAA does not substitute its judgment for that of the airport proprietor with respect to which measures should be recommended for action. The FAA's approval or disapproval of FAR part 150 program recommendations is measured according to the standards expressed in part 150 and the Act and is limited to the following determinations:

a. The noise compatibility program was developed in accordance with the provisions and procedures of FAR part 150;

b. Program measures are reasonably consistent with achieving the goals of reducing existing noncompatible land uses around the airport and preventing the introduction of additional noncompatible land uses;

c. Program measures would not create an undue burden on interstate or foreign commerce, unjustly discriminate against types or classes of aeronautical uses, violate the terms of airport grant agreements, or intrude into areas preempted by the Federal Government; and

d. Program measures relating to the use of flight procedures can be implemented within the period covered by the program without derogating safety, adversely affecting the efficient use and management of the navigable airspace and air traffic control systems, or adversely affecting other powers and responsibilities of the Administrator prescribed by law.

Specific limitations with respect to FAA's approval of an airport noise compatibility program are delineated in FAR part 150, section 150.5. Approval is not a determination concerning the acceptability of land uses under Federal, state, or local law. Approval does not by itself constitute an FAA implementing action. A request for Federal action or approval to implement specific noise compatibility measures may be

required, and a FAA decision on the request may require an environmental assessment of the proposed action. Approval does not constitute a commitment by the FAA to financially assist in the implementation of the program nor a determination that all measures covered by the program are eligible for grant-in-aid funding from the FAA. Where federal funding is sought, requests for project grants must be submitted to the FAA Minneapolis-Airports District Office in Minneapolis, Minnesota.

Brown County submitted to the FAA on July 28, 1993 the noise exposure maps, descriptions, and other documentation produced during the noise compatibility planning study conducted from December 1991 through July 1993. The Austin Straubel International Airport noise exposure maps were determined by FAA to be in compliance with applicable requirements on January 20, 1995. Notice of this determination was published in the Federal Register on February 21, 1995.

The Austin Straubel International Airport study contains a proposed noise compatibility program comprised of actions designed for phased implementation by airport management and adjacent jurisdictions from the date of study completion to the year 2000. It was requested that the FAA evaluate and approve this material as a noise compatibility program as described in section 104(b) of the Act. The FAA began its review of the program on January 20, 1995 and was required by a provision of the Act to approve or disapprove the program within 180 days (other than the use of new flight procedures for noise control). Failure to approve or disapprove such program within the 180-day period shall be deemed to be an approval of such program.

The submitted program contained fourteen (14) proposed actions for noise mitigation on and off the Airport. The FAA completed its review and determined that the procedural and substantive requirements of the Act and FAR part 150 have been satisfied. The overall program, therefore, was approved by the Assistant Administrator for Airports effective July 19, 1995.

Outright approval was granted for twelve (12) of the fourteen (14) specific program elements. Of the six (6) Operational Measures, the four (4) that were approved include Part 91 Stage 2 phase out, runway 12/30 relocation, balanced runway use, and noise abatement climb procedures. Both of the two (2) Capital Improvement Measures were approved including acquisition of noise buffer zones and instrument landing system (ILS) for runway 18. All six (6) of the Land Use Measures were approved. These include comprehensive planning efforts, airport zoning districts, compatible development of airport property, noise level reduction requirements for new construction, airport noise disclosure statements, and a citizens advisory committee.

The two (2) Operational Measures that were disapproved pending submission of additional information were a restriction on ''touch & go'' landing operations and the monitoring of non-emergency night maintenance run-ups. The restriction on ''touch & go'' operations was determined to be lacking adequate analysis to satisfy part 150 approval requirements, such as how existing training operations might be affected or how the proposal was determined to be noise beneficial. The measure to monitor non-emergency night maintenance run-ups was also lacking in adequate analysis such as discussion of the airport's existing policy, existing location of run-ups in proximity to noise sensitive land uses, or other factors required to meet the approval requirements of 14 CFR part 150.

These determinations are set forth in detail in a Record of Approval endorsed by the Administrator on July 19, 1995. The Record of Approval, as well as other evaluation materials and the documents comprising the submittal, are available for review at the FAA office listed above and at the airport administrative offices of Brown County.

Issued in Minneapolis, Minnesota on August 22, 1995.

Robert A. Huber,

Acting Manager, Minneapolis Airports District Office.

[FR Doc. 95–23210 Filed 9–18–95; 8:45 am]

BILLING CODE 4910–13–M

Aviation Rulemaking Advisory Committee; New Task

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of a new task assignment for the Aviation Rulemaking Advisory Committee (ARAC).

SUMMARY: Notice is given of a new task assigned to and accepted by the Aviation Rulemaking Advisory Committee (ARAC). This notice informs the public of the activities of ARAC.

FOR FURTHER INFORMATION CONTACT: Mr. Chris Christie, Director, Office of Rulemaking (ARM–1), Federal Aviation Administration, 800 Independence Avenue SW., Washington, DC 20591; phone (202) 267–9677; fax (202) 267–5075.

SUPPLEMENTARY INFORMATION:

Background

The FAA has established an Aviation Rulemaking Advisory Committee to provide advice and recommendations to the FAA Administrator, through the Associate Administrator for Regulation and Certification, on the full range of the FAA's rulemaking activities with respect to aviation-related issues. This includes obtaining advice and recommendations on the FAA's commitment to harmonize its Federal Aviation Regulations (FAR) and practices with its trading partners in Europe and Canada.

The Task

This notice is to inform the public that the FAA has asked ARAC to provide advice and recommendation on the following task:

Digital Information and Use: Review 14 CFR Parts 43, 121, 125, 129, 135, and 145, the corresponding sections of the European Joint Aviation Requirements (JAR), and supporting policy and guidance material, and recommend to the FAA appropriate revisions for harmonization, including advisory material, relative to the issue of regulations that prohibit or discourage the access or use of information, guidance material or performance data that is in digital or electronic form in order to permit the use of the other digital media.

The FAA also has asked that ARAC determine if rulemaking action (e.g., NPRM), should be taken, or advisory material should be issued. If so, ARAC has been asked to prepare the necessary documents, including economic analysis, to justify and carry out its recommendation(s).

ARAC Acceptance of Task

The ARAC Executive Committee has accepted the task and has chosen to establish a new Digital Information Working Group. The working group will serve as staff to the ARAC Executive Committee to assist it in the analysis of the assigned task. Working group recommendations must be reviewed and approved by the Executive Committee. If the Executive Committee accepts the working group's recommendations, it forwards them to the FAA as ARAC recommendations.

Working Group Activity

The Digital Information Working Group is expected to comply with the procedures adopted by ARAC. As part of the procedures, the working group is expected to:

1. Recommend a work plan for completion of the task, including the rationale supporting such a plan, for consideration at the meeting of the ARAC Executive Committee held following publication of this notice.

2. Give a detailed conceptual presentation of the proposed recommendations, prior to proceeding with the work stated in item 3 below.

3. Draft appropriate regulatory documents with supporting economic and other required analyses, and/or any other related guidance material or collateral documents the working group determines to the appropriate; or, if new or revised requirements or compliance methods are not recommended, a draft report stating the rationale for not making such recommendations.

4. Provide a status report at each meeting of the ARAC Executive Committee.

Participation in the Working Group

The Digital Information Working Group is composed of experts having an interest in the assigned task. A working group member need not be a representative of a member of the full committee.

An individual who has expertise in the subject matter and wishes to become a member of the working group should write to the person listed under the caption **FOR FURTHER INFORMATION CONTACT** expressing that desire, describing his or her interest in the task, and stating the expertise he or she would bring to the working group. The request will be reviewed by the chair, the executive director, and the working group chair, and the individual will be advised whether or not the request can be accommodated.

The Secretary of Transportation has determined that the formation and use of ARAC are necessary and in the public interest in connection with the performance of duties imposed on the FAA by law.

Meetings of the ARAC Executive Committee will be open to the public, except as authorized by section 10(d) of the Federal Advisory Committee Act. Meetings of the Digital Information Working Group will not be open to the public, except to the extent that individuals with an interest and expertise are selected to participate. No public announcement of working group meetings will be made.

Issued in Washington, DC, on September 13, 1995.

Chris Christie,

Executive Director, Aviation Rulemaking Advisory Committee.

[FR Doc. 95–23209 Filed 9–18–95; 8:45 am]

BILLING CODE 4910–13–M

RTCA, Inc. Special Committee 135; Environmental Conditions and Test Procedures for Airborne Equipment

Pursuant to section 10(a)(2) of the Federal Advisory Committee Act (P.L. 92–463, 5 U.S.C., Appendix 2), notice is hereby given for Special Committee 135 meeting to be held October 5–6, 1995, starting at 9:30 a.m. The meeting will be held at RTCA, Inc., 1140 Connecticut Avenue, N.W., Suite 1020, Washington, DC, 20036.

The agenda will include: (1) Chairman's Opening Remarks; (2) Introductions; (3) Review and Approval of Minutes of the Previous Meeting; (4) Review of All New Papers; (5) Review of Schedule Milestones to Complete Revision (D); (6) Other Business; (7) Date and Place of Next Meeting.

Attendance is open to the interested public but limited to space availability. With the approval of the chairman, members of the public may present oral statements at the meeting. Persons wishing to present statements or obtain information should contact the RTCA Secretariat, 1140 Connecticut Avenue, N.W., Suite 1020, Washington, D.C. 20036; (202) 833–9339 (phone) or (202) 833–9434 (fax). Members of the public may present a written statement to the committee at any time.

Issued in Washington, D.C., on September 14, 1995.

Janice L. Peters,

Designated Official.

[FR Doc. 95–23212 Filed 9–18–95; 8:45 am]

BILLING CODE 4910–13–M

RTCA, Inc. Special Committee 182; Minimum Operational Performance Standards (MOPS) for an Avionics Computer Resource (ACR)

Pursuant to section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463, 5 U.S.C., Appendix 2), notice is hereby given for Special Committee 182 meeting to be held October 4–6, 1995, starting at 9:00 a.m. The meeting will be held at RTCA, Inc., 1140 Connecticut Avenue, NW., Suite 1020, Washington, DC, 20036.

The agenda will include: (1) Chairman's Introductory Remarks; (2) Review and Approval of Meeting Agenda; (3) Review and Approval of Minutes from the Meeting Held July 18–20; (4) Refine the List of ACR Objectives/Benefits; (5) Continue Creation of ''Story Board'' Topical Sentences for Major Sections of the MOPS: Section 1.0 (review last meeting results and complete); Section 2.1; (6) Discuss Industry Expectations for Regulatory Approval of ACR Appliance and Appliance Software: Daimler Benz Model, Honeywell Discussion Paper, Collins Paper (Revisited); (7) Update Glossary (RTCA Paper No. 280–94/SC182–10); (8) Other Business; (9) Date and Place of Next Meeting.

Attendance is open to the interested public but limited to space availability. With the approval of the chairman, members of the public may present oral statements at the meeting. Persons wishing to present statements or obtain information should contact the RTCA Secretariat, 1140 Connecticut Avenue, NW., Suite 1020, Washington, DC 20036; (202) 833–9339 (phone) or (202) 833–9434 (fax). Members of the public may present a written statement to the committee at any time.

Issued in Washington, DC, on September 14, 1995.

Janice L. Peters,

Designated Official.

[FR Doc. 95–23213 Filed 9–18–95; 8:45 am]

BILLING CODE 4810–13–M

Notice of Intent To Rule on Application To Impose Only and Impose and Use the Revenue From a Passenger Facility Charge (PFC) at Seattle-Tacoma International Airport, Submitted by the Port of Seattle, WA

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of intent to rule on application.

SUMMARY: The FAA proposes to rule and invites public comment on the application to impose only and impose and use PFC revenue at Seattle-Tacoma International Airport under the provisions of 49 U.S.C. 40117 and Part 158 of the Federal Aviation Regulations (14 CFR 158).

DATES: Comments must be received on or before October 19, 1995.

ADDRESSES: Comments on this application may be mailed or delivered in triplicate to the FAA at the following address: J. Wade Bryant, Manager; Seattle Airports District Office, SEA–ADO; Federal Aviation Administration; 1601 Lind Avenue SW, Suite 540; Renton, WA 98055–4056.

In addition, one copy of any comments submitted to the FAA must be mailed or delivered to Ms. Gina Marie Lindsey, Managing Director, Aviation, at the following address: Port of Seattle, P.O. Box 68727, Seattle, WA 98168.

Air Carriers and foreign air carriers may submit copies of written comments previously provided to Seattle-Tacoma International Airport, under section 158.23 of Part 158.

FOR FURTHER INFORMATION CONTACT: Mr. Paul Johnson, (206) 227–2655; Seattle Airports District Office, SEA–ADO; Federal Aviation Administration; 1601 Lind Avenue SW, Suite 540; Renton, Washington 98055–4056. The application may be reviewed in person at this same location.

SUPPLEMENTARY INFORMATION: The FAA proposes to rule and invites public comment on the application to impose only and impose and use PFC revenue at Seattle-Tacoma International Airport, under the provisions of 49 U.S.C. 40117 and Part 158 of the Federal Aviation Regulations (14 CFR Part 158).

On September 12, 1995, the FAA determined that the application to impose only and impose and use the revenue from a PFC submitted by the Port of Seattle was substantially complete within the requirements of section 158.25 of Part 158. The FAA will approve or disapprove the application, in whole or in part, no later than December 23, 1995.

The following is a brief overview of the application. Level of the proposed PFC: $3.00; Proposed charge effective date: January 1, 1996; Proposed charge expiration date: December 30, 2000; Total estimated PFC revenues: $162,000,000.00.

Brief description of proposed project: Impose and Use projects: Terminal apron improvements; Runway 16R rehabilitation; Aircraft rescue fire fighting (ARFF) training facility; Noise programs; Skybridge elevators installation; Emergency power generators refurbishment; Electrical system power upgrade; Land acquisition for South Aviation Support Area (SASA) development; Impose only projects: Safety area improvements; Passenger conveyance system.

Class or classes of air carriers which the public agency has requested not be required to collect PFC's: None.

Class or classes of air carriers which the public agency has requested not be required to collect PFC's: None.

Any person may inspect the application in person at the FAA office listed above under **FOR FURTHER INFORMATION CONTACT** and at the FAA Regional Airports Office located at: Federal Aviation Administration, Northwest Mountain Region, Airports Division, ANM–600, 1601 Lind Avenue S.W., Suite 540, Renton, WA 98055–4056.

In addition, any person may, upon request, inspect the application, notice and other documents germane to the application in person at the Seattle-Tacoma International Airport.

Issued in Renton, Washington on September 12, 1995.

David A. Field,

Manager, Planning, Programming and Capacity Branch, Northwest Mountain Region.

[FR Doc. 95–23211 Filed 9–18–95; 8:45 am]

BILLING CODE 4910–13–M

National Highway Traffic Safety Administration

Research and Development Programs Meeting Agenda

AGENCY: National Highway Traffic Safety Administration, DOT.

ACTION: Notice.

SUMMARY: This notice provides the agenda for a public meeting at which NHTSA will describe and discuss specific research and development projects.

DATES AND TIMES: As previously announced, the National Highway Traffic Safety Administration will hold a public meeting devoted primarily to presentations of specific research and development projects on September 21, 1995, beginning at 1:30 p.m. and ending by 5 p.m.

ADDRESSES: The meeting will be held at the Holiday Inn Capitol, 550 C Street, SW., Washington, DC 20024.

SUPPLEMENTARY INFORMATION: This notice provides the agenda for the eleventh of a series of quarterly public meetings to provide detailed information about NHTSA's research and development programs. This meeting will be held on September 21, 1995. The meeting was announced on August 24, 1995 (60 FR 44114). For additional information about the meeting consult that announcement.

Starting at 1:30 p.m. and concluding by 5 p.m., NHTSA's Office of Research and Development will discuss the following topics:

* Variable Dynamics Test Vehicle,
* Child Safety Research (Specifically ISOFIX),
* Frontal Offset Test Procedure Development,
* On-Line Tracking System for NHTSA's Research Projects.

NHTSA has based its decisions about the agenda, in part, on the suggestions it received by September 5, 1995, in response to the announcement published on August 24, 1995.

As announced on August 24, 1995, in the time remaining at the conclusion of the presentations, NHTSA will provide answers to questions on its research and development programs, where those questions have been submitted in writing by September 12, 1995, to the Associate Administrator for Research and Development, NRD–01, National Highway Traffic Safety Administration, Washington, DC 20590.

FOR FURTHER INFORMATION CONTACT: Rita I. Gibbons, Staff Assistant, Office of Research and Development, 400 Seventh Street, SW., Washington, DC 20590. Telephone: 202–366–4862. Fax number: 202–366–5930.

Issued: September 14, 1995.

William A. Boehly,

Associate Administrator for Research and Development.

[FR Doc. 95–23173 Filed 9–18–95; 8:45 am]

BILLING CODE 4910–59–M

Research and Special Programs Administration

Office of Hazardous Materials Safety; Notice of Applications for Modification of Exemptions or Applications to Become a Party to an Exemption

AGENCY: Research and Special Programs Administration, DOT.

ACTION: List of applications for modification of exemptions or applications to become a party to an exemption.

SUMMARY: In accordance with the procedures governing the application for, and the processing of, exemptions from the Department of Transportation's Hazardous Materials Regulations (49 CFR Part 107, Subpart B), notice is hereby given that the Office of Hazardous Materials Safety has received the applications described herein. This notice is abbreviated to expedite docketing and public notice. Because the sections affected, modes of transportation, and the nature of application have been shown in earlier Federal Register publications, they are not repeated here. Requests for modifications of exemptions (e.g. to provide for additional hazardous materials, packaging design changes, additional mode of transportation, etc.) are described in footnotes to the application number. Application numbers with the suffix ''M'' denote a modification request. Application numbers with the suffix ''P'' denote a party to request. These applications have been separated from the new applications for exemptions to facilitate processing.

DATES: Comments must be received on or before October 4, 1995.

ADDRESS COMMENTS TO: Dockets Unit, Research and Special Programs,

Administration, U.S. Department of Transportation, Washington, DC 20590.

Comments should refer to the application number and be submitted in triplicate. If confirmation of receipt of comments is desired, include a self-addressed stamped postcard showing the exemption number.

FOR FURTHER INFORMATION CONTACT: Copies of the applications are available for inspection in the Dockets Unit, Room 8426, Nassif Building, 400 7th Street SW., Washington, DC.

Application No.	Applicant	Renewal of exemption
5749–M	E.I. du Pont de Nemours & Company, Inc., Wilmington, DE (See Footnote 1)	5749
7280–M	U.S. Department of Defense, Falls Church, VA (See Footnote 2)	7280
9909–M	Taylor-Wharton, Harrisburg, PA (See Footnote 3)	9909
10326–M	Allied Signal Inc., Tempe, AZ (See Footnote 4)	10326
10660–M	American Radiolabeled Chemicals Inc., St. Louis, MO (See Footnote 5)	10660
10867–M	Pacific Scientific, Duarte, CA (See Footnote 6)	10867
11197–M	Chem Coast Inc., La Porte, TX (See Footnote 7)	11197
11481–M	ITT Automotive Aftermarket Division (See Footnote 8)	11481
11499–M	Brownie Tank Mfg., Co., Minneapolis, MN (See Footnote 9)	11499
11509–M	Alliance Petroleum Corp. et al (See Footnote 10)	11509
11515–M	R.J. Reynolds Tobacco Co., Winston-Salem, NC (See Footnote 11)	11515

(1) To modify the exemption to provide for construction of an additional DOT Specification MC–331 cargo tank for use in transporting Division 2.3, PIH material.

(2) To modify exemption to provide for containerized vehicles or equipment to include battery cables that are disconnected and secured to prevent sparks or ignition with container stowed in a mechanical ventilated hole or compartment, or stowed above deck.

(3) To modify exemption to provide for several modifications to the cylindrical section of each cylinder after heat treatment of DOT–3AA specification cylinders.

(4) To modify the exemption to provide for alternative tests of non-DOT specification welded pressure vessel comparable to DOT 3HT cylinders.

(5) To modify the exemption to provide for shipment of sodium borohydride, Division 4.3, in small quantities without secondary hazard label in DOT-specification packaging.

(6) To modify the exemption to provide for several construction changes to non-DOT specification cylinders for use in transporting nitrogen, classed as nonflammable gas, Division 2.2.

(7) To modify the exemption to increase the quantity to 12 liters per package of various hazardous materials known as test kits to be shipped in specially designed packaging.

(8) To reissue an exemption originally issued on an emergency basis to authorize the manufacture, mark and sale of shock absorbers, containing a Division 2.2. gas, for transportation as accumulators.

(9) To reissue an exemption originally issued on an emergency basis to authorize the manufacture, mark and sale of non-DOT specification cargo tanks comparable to DOT specification 406 for shipment of certain Class 3 material.

(10) To reissue an exemption originally issued on an emergency basis to authorize the continued intrastate transportation of certain Class 3 liquids in non-DOT specification cargo tanks whose designs have been approved by the California State Fire Marshal.

(11) To reissue an exemption originally issued on an emergency basis to authorize transportation of aluminum processing by products, Division 4.3, contained in open top trailers covered with a tarpaulin.

Application No.	Applicant	Parties to exemption
5704–P	California Advanced Environmental Technology Corp., Hayward, CA	5704
5704–P	Advanced Environmental Technology Corp. (AETC), Flanders, NJ	5704
5704–P	Advanced Environmental Technical Services (AETS), Flanders, NJ	5704
6670–P	Matheson Gas Products, Secaucus, NJ	6670
6670–P	FIBA Technologies, Inc., Westboro, MA	6670
6971–P	Crescent Chemical Co., Inc., Hauppauge, NY	6971
8008–P	Wheaton, Inc., Millville, NJ	8008
8451–P	Advanced Environmental Technical Services (AETS), Flanders, NJ	8451
8451–P	Applied Energy Technology Corp., Tempe, AZ	8451
8627–P	Technical Service Company, Long Beach, CA	8627
9275–P	Dragoco, Inc., Totowa, NJ	9275
9275–P	Elias Fragrances, Inc., Brooklyn, NY	9275
9723–P	Carolina Environmental Associates, Inc., Burlington, NC	9723
9723–P	Advanced Environmental Technical Services (AETS), Flanders, NJ	9723
9723–P	Environmental Waste Resources, Inc., Waterbury, CT	9723
9769–P	Advanced Environmental Technical Services (AETS), Flanders, NJ	9769
9769–P	Environmental Waste Resources, Inc., Waterbury, CT	9769
10001–P	Mills Welding Supply, Inc., Buffalo, NY	10001
10298–P	Woods Air Fuel, Inc., Palmer, AK	10298
10307–P	Clearon Corporation, South Charleston, WV	10307
10441–P	Advanced Environmental Technical Services (AETS), Flanders, NJ	10441
10441–P	Environmental Waste Resources, Inc., Waterbury, CT	10441
10441–P	Environmental Response, Inc., Hendersonville, TN	10441
10798–P	Clearon Corporation, South Charleston, WV	10798
10880–P	ETI Explosives Technologies International, Inc., Wilmington, DE	10880
10933–P	Advanced Environmental Technical Services (AETS), Flanders, NJ	10933
10933–P	Environmental Waste Resources, Inc., Waterbury, CT	10933
10933–P	Environmental Response, Inc., Hendersonville, TN	10933
10984–P	Matheson Gas Products, Secaucus, NJ	10984
10987–P	Los Alamos National Laboratory, Los Alamos, NM	10987
11043–P	Advanced Environmental Technical Services (AETS), Flanders, NJ	11043
11043–P	Chemical Analytics, Inc., Romulus, MI	11043

Application No.	Applicant	Parties to exemption
11043–P	Environmental Response, Inc., Hendersonville, TN	11043
11055–P	Advanced Environmental Technology Corp. (AETC), Flanders, NJ	11055
11055–P	California Advanced Environmental Technology Corp., Hayward, CA	11055
11055–P	Chemical Analytics, Inc., Romulus, MI	11055
11055–P	Advanced Environmental Technical Services (AETS), Flanders, NJ	11055
11055–P	Environmental Waste Resources, Inc., Waterbury, CT	11055
11080–P	ETI Explosives Technologies International, Inc., Wilmington, DE	11080
11156–P	Southern Energy, Inc., Louisiville, TN	11156
11156–P	Alpha-IRECO, Inc., Lincoln, CA	11156
11184–P	BASF Corporation, Mount Olive, NJ	11184
11197–P	Uniroyal Chemical Company, Middlebury, CT	11197
11197–P	Diversey Water Technologies, Inc., Chagrin Falls, OH	11197
11207–P	Northern States Power Company, Minneapolis, MN	11207
11230–P	Viking Explosives & Supply, Inc., Rosemount, MN	11230
11230–P	Mt. State Bit Service, Inc., Morgantown, WV	11230
11230–P	Nelson Brothers, Inc., Parrish, AL	11230

This notice of receipt of applications for modification of exemptions and for party to an exemption is published in accordance with Part 107 of the Hazardous Materials Transportation Act (49 U.S.C. 806; 49 CFR 1.53(e)).

Issued in Washington, DC, on September 14, 1995.

J. Suzanne Hedgepeth,

Chief, Exemption Programs, Office of Hazardous Materials Exemptions and Approvals.

[FR Doc. 95–23234 Filed 9–18–95; 8:45 am]

BILLING CODE 4910–60–M

Office of Hazardous Materials Safety; Notice of applications for exemptions

AGENCY: Research and Special Programs Administration, DOT.

ACTION: List of Applicants for Exemptions.

SUMMARY: In accordance with the procedures governing the application for, and the processing of, exemptions from the Department of Transportation's Hazardous Materials Regulations (49 CFR Part 107, Subpart B), notice is hereby given that the Office of Hazardous Materials Safety has received the applications described herein. Each mode of transportation for which a particular exemption is requested is indicated by a number in the ''Nature of Application'' portion of the table below as follows: 1—Motor vehicle, 2—Rail freight, 3—Cargo vessel, 4—Cargo aircraft only, 5—Passenger-carrying aircraft.

DATES: Comments must be received on or before October 19, 1995.

ADDRESS COMMENTS TO: Dockets Unit, Research and Special Programs, Administration, U.S. Department of Transportation, Washington, DC 20590.

Comments should refer to the application number and be submitted in triplicate. If confirmation of receipt of comments is desired, include a self-addressed stamped postcard showing the exemption application number.

FOR FURTHER INFORMATION CONTACT:

Copies of the applications are available for inspection in the Dockets Unit, Room 8426, Nassif Building, 400 7th Street, SW. Washington, DC.

NEW EXEMPTIONS

Application No.	Applicant	Regulation(s) affected	Nature of exemption thereof
11511–N	Brenner Tank Inc., Fond du Lac, WI	49 CFR 178.345–19(c), 178.345–8(c).	To authorize the manufacture, mark and sale of piston carrying DOT 407 cargo tank motor vehicles for use in transporting certain hazardous materials. (mode 1)
11514–N	Jet Propulsion Lab, Pasadena, CA	49 CFR 172.101 Column (9B)	To authorize a spacecraft test vehicle equipped with rocket motors to be shipped as an external load by helicopter. (mode 4)
11526–N	BOC Gases, Murray Hill, NJ	49 CFR 172.302(c), 173.34(e)	To authorize the use of ultrasonic inspection method in lieu of hydrostatic testing of 3A and 3AA cylinders. (modes 1, 2, 3)
11527–N	Technical Service Co., Long Beach, CA.	49 CFR 173.201, 173.202, 173.203, 178.253.	To authorize the transportation of Class 3 and 8 material in 60 gallon capacity non-DOT specification portable tanks manifolded together within a frame, having top and bottom opening designed and constructed to DOT specification 57 except for marking and capacity. (mode 1)
11529–N	Matheson Gas Products, Secaucus, NJ.	49 CFR 173.192(a)(3)	To authorize the transportation of Division 2.3, PIH, Zone A material in DOT-Specification 3AL aluminum cylinders. (mode 3)
11530–N	Department of Energy, Washington, DC.	49 CFR 173.244(c)	To authorize the transportation of partially filled sodium metal storage tanks to offsite disposal processing facility. (modes 1, 2)

NEW EXEMPTIONS—Continued

Application No.	Applicant	Regulation(s) affected	Nature of exemption thereof
11531–N	Grand Aire Express, Inc., Monroe, MI.	49 CFR 171.11, 172.101, 172.204(c)(3), 173.27, 175.30(a)(1), 175.320(b), Part 107, Appendix B.	To authorize the transportation in commerce of Division 1.1, 1.2, 1.3, 1.4, explosives that are not permitted for shipment by air or are in quantities greater than those authorized. (mode 4, 5)
11532–N	APD Cryogenics Inc., Allentown, PA	49 CFR 173.306	To authorize the transportation of a refrigeration machine that utilizes a mixture containing propane and nitrogen in quantities that exceed those specified. (modes 1, 3, 4, 5)
11533–N	Research Products Co., Salina, KS	49 CFR 106, 107, 171–180	To authorize the transportation in commerce of an aluminum phosphide based pesticide which meets the definition of a Division 4.3 material to be shipped as aluminum phosphide pesticide, a Division 6.1 material. (mode 1)
11536–N	Hughes Space & Communications Co., Los Angeles, CA.	49 CFR 173.159, 173.302, 173.304, 173.62.	To authorize the transportation in commerce of various hazardous materials contained within a propulsion system of a communication satellite. (mode 4)
11537–N	Babson Bros. Co., Romeoville, IL	49 CFR 177.834(h)	To authorize the transportation in commerce of certain Class 8 material in IBCs that are securely mounted to a flatbed trailer, but not removed for the vehicle prior to loading or unloading of container. (mode 1)
11538–N	Process Engineering, Plaistow, NH	49 CFR 173.320	To authorize the transportation in commerce of liquid argon, liquid oxygen and liquid nitrogen in AAR–204W tank cars equipped with 60 psig safety relief valve and 90 psig rupture disk. (mode 2)
11539–N	C–CAM International L.L.C., Sand Springs, OK.	49 CFR 173.315(a), 178.245–1(b)	To authorize the manufacture, mark and sale of non-DOT specification IMO Type 5 portable tanks to be used for the transportation in commerce of Division 2.1, 2.2, and 2.3 materials. (modes 1, 2, 3)
11540–N	Convenience Products, Fenton, MO	49 CFR 173.1200(a)(8)(ii)(E)	To provide for an alternative test of aerosol containers with polyurethane prepolymer components to attain internal pressure of at least 130 degrees. (modes 1, 2, 3, 4, 5)
11541–N	Kaiser Compositek, Brea, CA	49 CFR 173.302(a), 173.304(a)(d), 175.3.	To authorize the manufacture, mark and sale of non-DOT specification fiber reinforced plastic full composite cylinders constructed from seamless 6061–T6 aluminum alloy liner for use in transporting certain flammable gases, Division 2.1. (modes 1, 2, 3, 4, 5)
11542–N	Sunrise Supply Enterprises, Ltd., Albuquerque, NM.	49 CFR 107.503(1), 107.503(1), 178.340–5(d).	To authorize the transportation in commerce of a non-DOT specification cargo tank built to MC 306 requirements except for ASME ''U'' stamp for use in transporting flammable liquid, Class 3. (mode 1)
11543–N	E. I. Dupont de Nemours & Co., Inc., Wilmington, DE.	49 CFR 172.203(d)(4), 172.403(g)(2)	To authorize the transportation in commerce of non-bulk packages containing low-level radioactive isotopes to be transported using becquerel units for curie units, transported by public highway without prior or subsequent air transport. (mode 1)
11544–N	Dupont Merck Pharmaceutical Co., N. Billerica, MA.	49 CFR 172.203(d)(4), 172.403(g)(2)	To authorize the transportation of non-bulk packages containing low-level radioactive isotopes with becquerel units for curie units specifying the quantity on shipping papers and labels transported by public highway without prior or subsequent air transport. (mode 1)
11545–N	Bernzomatic, Medina, NY	49 CFR 173.304(d)(ii)	To authorize the transportation in commerce of a DOT Specification 2Q canister with a butane propane mixture, with a vapor pressure of 55 psig maximum at 70 degrees F. (modes 1, 2, 4)
11546–N	Trinity River Authority of Texas, Grand Prairie, TX.	49 CFR 174.67(i)	To authorize rail cars to remain connected during the unloading process without the physical presence of an unloader. (mode 2)

NEW EXEMPTIONS—Continued

Application No.	Applicant	Regulation(s) affected	Nature of exemption thereof
11547–N	RTS Technology, Inc., North Andover, MA.	49 CFR 173.431	To authorize the transportation of up to 27 curies of radioactive material in special form in Type A package. (modes 4, 5)
11548–N	Akzo Nobel, Chicago, IL	49 CFR 173.211, 173.212, 173.213	To authorize the transportation in commerce of various solid hazardous materials in compressed gas type cylinders except for specification 8 and 3HT type. (mode 1)

This notice of receipt of applications for new exemptions is published in accordance with Part 107 of the Hazardous Materials Transportations Act (49 U.S.C. 1806; 49 CFR 1.53(e)).

Issued in Washington, DC, on September 14, 1995.

J. Suzanne Hedgepeth,

Chief, Exemption Programs, Office of Hazardous Materials Exemptions and Approvals.

[FR Doc. 95–23235 Filed 9–18–95; 8:45 am]

BILLING CODE 4910–60–M

DEPARTMENT OF VETERANS AFFAIRS

National Service Life Insurance Policy Loan Interest Rate

AGENCY: Department of Veterans Affairs.

ACTION: Notice.

SUMMARY: The Department of Veterans Affairs (VA) is hereby giving notice of the variable loan interest rate for loans granted on National Service Life Insurance (NSLI).

DATES: The effective date for the new variable loan interest rate is October 1, 1995.

FOR FURTHER INFORMATION CONTACT: Mr. George Poole, Chief, Insurance Program Administration Staff (290B), Department of Veterans Affairs Regional Office and Insurance Center, P.O. Box 8079, Philadelphia, Pennsylvania 19101 (215) 951–5718.

SUPPLEMENTARY INFORMATION: VA's National Service Life Insurance Regulations at 38 CFR 8.28 (amended at 59 FR 65717) provide that NSLI policy loans will bear a variable interest rate, which could be adjusted annually, and that such rate shall equal the yield on the Ten-Year Constant Maturities Index for U.S. Treasury Securities for the month of June of the year of calculation rounded down to the next whole percentage point. These regulations further provide that the adjusted loan rate would be effective, subject to computer readiness, on or after the first day of October. The Council of Economic Advisers established the above-mentioned index for June 1995 at 6.17 percent. Rounding down, the NSLI variable policy loan rate, effective October 1, 1995, will be 6 percent.

Dated: September 7, 1995.

Jesse Brown,

Secretary of Veterans Affairs.

[FR Doc. 95–23145 Filed 9–18–95; 8:45 am]

BILLING CODE 8320–01–M

Sunshine Act Meetings

Federal Register

Vol. 60, No. 181

Tuesday, September 19, 1995

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).

BOARD OF GOVERNORS OF THE FEDERAL RESERVE SYSTEM

TIME AND DATE: 12 noon, Monday, September 25, 1995.

PLACE: Marriner S. Eccles Federal Reserve Board Building, C Street entrance between 20th and 21st Streets, NW., Washington, DC 20551.

STATUS: Closed.

MATTERS TO BE CONSIDERED:

1. Personnel actions (appointments, promotions, assignments, reassignments, and salary actions) involving individual Federal Reserve System employees.
2. Any items carried forward from a previously announced meeting.

CONTACT PERSON FOR MORE INFORMATION: Mr. Joseph R. Coyne, Assistant to the Board; (202) 452–3204. You may call (202) 452–3207, beginning at approximately 5 p.m. two business days before this meeting, for a recorded announcement of bank and bank holding company applications scheduled for the meeting.

Dated: September 15, 1995.

Jennifer J. Johnson,

Deputy Secretary of the Board.

[FR Doc. 95–23360 Filed 9–15–95; 3:19 pm]

BILLING CODE 6210–01–P

NUCLEAR REGULATORY COMMISSION

DATE: Weeks of September 18, 25, October 2 and 9, 1995.

PLACE: Commissioners' Conference Room, 11555 Rockville Pike, Rockville, Maryland.

STATUS: Public.

MATTERS TO BE CONSIDERED:

Week of September 18

There are no meetings scheduled for the Week of September 18.

Week of September 25—Tentative

There are no meetings scheduled for the Week of September 25.

Week of October 2—Tentative

Tuesday, October 3

10:00 a.m.

Briefing by National Academy of Sciences (NAS) on Recommendations for Technical Bases of Yucca Mountain Standards (Public Meeting)

Week of October 9—Tentative

Tuesday, October 10

10:00 a.m.

Briefing on NRC's Technical Training Program (Public Meeting)

ADDITIONAL INFORMATION: Affirmation of ''Revisions to Regulatory Requirements for Reactor Pressure Vessel Integrity in 10 CFR Part 50'' scheduled for September 11, was *postponed.*

Affirmation of ''Final Amendment to 10 CFR Part 50, Appendix J, ''Containment Leakage Testing,'' to Adopt Performance-Oriented and Risk-Based Approaches'' (Public Meeting) was held on September 12.

Note: The Nuclear Regulatory Commission is operating under a delegation of authority to Chairman Shirley Ann Jackson, because with three vacancies on the Commission, it is temporarily without a quorum. As a legal matter, therefore, the Sunshine Act does not apply; but in the interests of openness and public accountability, the Commission will conduct business as though the Sunshine Act were applicable.

The schedule for Commission meetings is subject to change on short notice. To verify the status of meetings call (Recording)—(301) 415–1292.

CONTACT PERSON FOR MORE INFORMATION: Bill Hill (301) 415–1661.

This notice is distributed by mail to several hundred subscribers; if you no longer wish to receive it, or would like to be added to it, please contact the Office of the Secretary, Attn: Operations Branch, Washington, D.C. 20555 (301–415–1963).

In addition, distribution of this meeting notice over the Internet system is available. If you are interested in receiving this Commission meeting schedule electronically, please send an electronic message to alb@nrc.gov or gkt@nrc.gov.

Dated: September 14, 1995.

William M. Hill, Jr.,

SECY Tracking Officer, Office of the Secretary.

[FR Doc. 95–23287 Filed 9–15–95; 11:26 am]

BILLING CODE 7590–01–M

SECURITIES AND EXCHANGE COMMISSION

Agency Meeting

''FEDERAL REGISTER'' CITATION OF PREVIOUS ANNOUNCEMENT: [60 FR 47439, September 12, 1995].

STATUS: Closed meeting.

PLACE: 450 Fifth Street, NW., Washington, DC.

DATE PREVIOUSLY ANNOUNCED: September 12, 1995.

CHANGE IN THE MEETING: Cancellation.

The closed meeting scheduled for Thursday, September 14, 1995, at 10:30 a.m., has been cancelled.

Commissioner Wallman, as duty officer, determined that Commission business required the above change and that no earlier notice thereof was possible.

At times, changes in Commission priorities require alterations in the scheduling of meeting items. For further information and to ascertain what, if any, matters have been added, deleted or postponed, please contact: The Office of the Secretary (202) 942–7070.

Dated: September 13, 1995.

Jonathan G. Katz,

Secretary.

[FR Doc. 95–23370 Filed 9–15–95; 3:48 pm]

BILLING CODE 8010–01–M

federal register

Tuesday
September 19, 1995

Part II

Department of Housing and Urban Development

Office of the Assistant Secretary for Housing-Federal Housing Commissioner

24 CFR Parts 251, 252, and 255

Conversion From Coinsurance to Full Insurance; Interim Rule

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

Office of the Assistant Secretary for Housing-Federal Housing Commissioner

24 CFR Parts 251, 252, and 255

[Docket No. FR–3813–I–01]

RIN 2502–AG50

Conversion From Coinsurance to Full Insurance

AGENCY: Office of the Assistant Secretary for Housing-Federal Housing Commissioner, HUD.

ACTION: Interim rule.

SUMMARY: HUD is amending its multifamily coinsurance regulations to provide coinsuring lenders with two new options in dealing with defaulted coinsured mortgages. Specifically, this interim rule permits coinsuring lender-issuers to request that HUD endorse certain defaulted mortgages for full insurance, without a GNMA takeover of the lender-issuer's entire portfolio. Additionally, this interim rule allows coinsuring lenders to advance funds to cure mortgage delinquencies on a coinsured mortgage and to reduce principal on that mortgage to a level that restores the financial viability of the project.

DATES: Effective date: October 19, 1995.

Sunset Provision: Sections 251.3, 251.4, 251.5, 252.3, 252.4, 252.5, 255.3, 255.4, and 255.5 shall expire and shall not be in effect after April 21, 1997, unless prior to April 21, 1997, the Department publishes a final rule adopting the interim rule with or without changes, or publishes a notice in the Federal Register to extend the effective date of the interim rule.

Comments due date: November 20, 1995.

ADDRESSES: Interested persons are invited to submit comments regarding this interim rule to the Office of the General Counsel, Rules Docket Clerk, Room 10276, Department of Housing and Urban Development, 451 Seventh Street, SW, Washington, DC 20410–0500. Communications should refer to the above docket number and title. Facsimile (FAX) comments are not acceptable. A copy of each communication submitted will be available for public inspection and copying during regular business hours (7:30 a.m. to 5:30 p.m. Eastern Time) at the above address.

FOR FURTHER INFORMATION CONTACT: Gwen Chandler, Acting Deputy Director, Coinsurance Management Division, Department of Housing and Urban Development, 451 Seventh Street, SW, Washington, DC 20410–0500, Room 6176, telephone (202) 401–3272. Hearing or speech-impaired individuals may call HUD's TDD number (202) 708–4594 or 1–800–877–8339 (Federal Information Relay Service TDD). (Other than the ''800'' number, these telephone numbers are not toll free).

SUPPLEMENTARY INFORMATION:

I. Background

On October 10, 1990 (55 FR 41312), a final rule was published terminating the authority of the FHA Commissioner to insure mortgage loans under the FHA multifamily coinsurance programs and revising 24 CFR parts 251, 252 and 255. As a result of that final rule, parts 251, 252 and 255 were each reduced to a single section dealing with the program phase-out process. A subsequent rulemaking added an additional section to each part revising the requirements concerning the Government National Mortgage Association's (GNMA) right to assignment. (See 55 FR 41319, October 10, 1990.) While they are no longer included in the Code of Federal Regulations, those regulations in effect before November 12, 1990 continue to govern the rights and obligations of mortgagors, coinsuring lenders and HUD under contracts of coinsurance entered into before the termination of the coinsurance programs.

HUD is making two changes in the coinsurance regulations in 24 CFR parts 251, 252, and 255. These amendments are designed to reduce Government costs and to benefit coinsuring lenders by minimizing their risk of default under a GNMA guaranty agreement and encouraging the continued viability of housing financed with coinsured mortgages. These amendments are intended to apply to existing coinsured mortgages which are in default. Under 24 CFR 251.4, 252.4, and 255.4 (1990 and earlier), the FHA Commissioner may amend the regulations that constitute the contract of coinsurance, but the amendments may not adversely affect a lender under an existing contract of coinsurance. HUD believes that these amendments are mutually beneficial to HUD and the lenders. The amendments provide additional options for dealing with defaulted coinsured mortgages. Their use is at the option of the coinsuring lender, subject to HUD approval.

The first change (see §§ 251.3, 252.3, and 255.3) affects only coinsured mortgages that back securities guaranteed by GNMA. It permits a coinsuring lender, for mortgages meeting the rule's requirements, to request that HUD endorse the mortgage for full insurance. Under current regulations, the option to have a mortgage endorsed for full insurance is available only to GNMA after it has taken over all loans in a coinsuring lender-issuer's portfolio following the lender-issuer's default under the GNMA guaranty agreement. After GNMA has taken over such a portfolio, it may have all of the coinsured mortgages in the portfolio endorsed for full insurance. This interim rule permits a coinsuring lender-issuer to request that certain seriously defaulted coinsured mortgages be converted to full insurance, thereby minimizing the risk of a lender-issuer's default under the GNMA guaranty agreement and of a GNMA takeover of the lender-issuer's entire portfolio. HUD will impose a fee on the coinsuring lender that is intended to have the lender share an equitable portion of the cost of the mortgage loan default.

The second amendment (see §§ 251.4, 251.5, 252.4, 252.5, 255.4, and 255.5) would apply to all coinsuring lenders. It is intended to give coinsuring lenders additional flexibility in dealing with less serious defaults by providing a partial payment of claim mechanism that would enable the mortgagor and the lender to recast the coinsured mortgage so that it becomes a viable performing coinsured mortgage. The partial payment of claim procedure also benefits the government as it results in a current reinstated first mortgage, and prevents a full claim being made on the insurance fund. This option is modelled after the partial payment of claim procedure in HUD's Housing Finance Agency Risk-Sharing Program. (See 24 CFR part 266, in particular § 266.630.)

Under the partial payment of claim procedure, a coinsuring lender that meets the regulatory requirements and that receives HUD approval could cure the first mortgage interest delinquency on the coinsured mortgage and could reduce principal on that mortgage to a level that restores the financial viability of the project by accepting a note in that amount. The coinsuring lender must secure this note with a mortgage that is subordinate to the coinsured mortgage. HUD will make a partial payment of claim in an amount equal to 80 percent of the above amount. The lender must remit to HUD 80 percent of all amounts collected on the lender's junior mortgage.

The junior mortgage is a second note and is similar to a surplus cash note. Surplus cash constitutes any amount of cash remaining on a monthly basis after payment of debt service on the first note, operating expenses, deferred

maintenance and any other reasonable expenses required to be paid under the insured mortgage. Since the mortgage is considered to be soft and similar to a surplus cash note, HUD expects to be repaid from net cash produced by the project. However, if for any reason a project is unable to produce surplus cash (i.e. a downturn in the market), neither HUD, nor the lender, nor the owner will receive disbursements from the project. There is no commitment between HUD and the lender for repayment on the junior mortgage.

Where the mortgage that is a candidate for the partial payment procedure is backing a GNMA guaranteed mortgage-backed security, the mortgagee should understand clearly that, while GNMA does not object to a partial payment arrangement, GNMA procedures require (1) that the full amount of the partial claim payment be passed through to security holders and (2) that subsequent monthly payments to security holders must include: (a) The scheduled principal due on the mortgage based on the fixed monthly payment specified in the loan prior to any modification resulting from the partial payment of claim arrangement and (b) interest at the security rate on the unpaid pool principal balance. Mortgagees who agree to a recasting of the mortgage which reduces the mortgagor's monthly payment must therefore, make up, from the mortgagee's own funds, the difference between the amount paid by the mortgagor and the amount due to the security holders, until the security holders have received all principal and interest due under the terms of the security. Alternatively, simultaneous with the partial payment of claim transaction for a loan more than 90 days in default, the existing pool may be terminated and a new GNMA security issued and marketed in the amount of the reduced first mortgage.

II. Justification for Interim Rulemaking

It is HUD's policy to publish rules for public comment before their issuance for effect, in accordance with its own regulations on rulemaking found at 24 CFR part 10. However, part 10 provides that prior public procedure will be omitted if HUD determines that it is ''impracticable, unnecessary, or contrary to the public interest.'' (24 CFR 10.1). HUD finds that in this case prior comment is contrary to the public interest, since immediate implementation of this interim rule will benefit the public. Specifically, this interim rule allows coinsuring lender-issuers to minimize their risk of default under a GNMA guaranty agreement by requesting the conversion of certain mortgages to full insurance. This interim rule also permits coinsuring lenders to restore the financial viability of projects by advancing funds to cure mortgage delinquencies. Although HUD believes issuing this interim rule for immediate effect will benefit the public, HUD welcomes public comment. All comments will be considered in the development of the final rule.

HUD has adopted a policy of setting an expiration date for an interim rule unless a final rule is published before that date. These ''sunset'' provisions appear in §§ 251.3(c), 251.4(e), 251.5(b), 252.3(c), 252.4(e), 252.5(b), 255.3(c), 255.4(e), and 255.5(b), and provide that the amendments made to 24 CFR parts 251, 252, and 255 by this interim rule will expire on a date 18 months from their effective date.

III. Regulatory Reinvention

Consistent with Executive Order 12866, and President Clinton's memorandum of March 4, 1995 to all Federal Departments and Agencies on the subject of Regulatory Reinvention, the Department is reviewing all its regulations to determine whether certain regulations can be eliminated, streamlined or consolidated with other regulations. As part of this review, this interim rule, at the final rule stage, may undergo revisions in accordance with the President's regulatory reform initiatives. In addition to comments on the substance of these regulations, the Department welcomes comments on how this interim rule may be made more understandable and less burdensome.

IV. Other Matters

A. Environmental Impact

A Finding of No Significant Impact with respect to the environment has been made in accordance with HUD regulations at 24 CFR part 50, which implements section 102(2)(C) of the National Environmental Policy Act of 1969 (NEPA). This Finding of No Significant Impact is available for public inspection between 7:30 a.m. and 5:30 p.m. weekdays in the Office of the Rules Docket Clerk, Office of the General Counsel, Department of Housing and Urban Development, Room 10276, 451 Seventh Street, SW, Washington, DC 20410–0500.

B. Executive Order 12612, Federalism

The General Counsel, as the Designated Official under section 6(a) of Executive Order 12612, *Federalism*, has determined that the policies contained in this interim rule will not have substantial direct effects on States or their political subdivisions, or the relationship between the Federal government and the States, or on the distribution of power and responsibilities among the various levels of government. Specifically, the requirements of this interim rule are directed toward participants in the FHA multifamily coinsurance program. It effects no changes in the current relationships between the Federal government, the States and their political subdivisions in connection with this program.

C. Executive Order 12606, the Family

The General Counsel, as the Designated Official under Executive Order 12606, *The Family*, has determined that this interim rule does not have potential for significant impact on family formation, maintenance, and general well-being, and, thus, is not subject to review under the order. The interim rule merely amends the regulations governing HUD's multifamily coinsurance program. No significant change in existing HUD policies or programs will result from promulgation of this interim rule, as those policies and programs relate to family concerns.

D. Regulatory Flexibility Act

The Secretary, in accordance with the Regulatory Flexibility Act (5 U.S.C. 605(b)) has reviewed and approved this interim rule, and in so doing certifies that this interim rule will not have a significant economic impact on a substantial number of small entities. There are no anticompetitive discriminatory aspects of the interim rule with regard to small entities and there are not any unusual procedures that would need to be complied with by small entities.

E. Executive Order 12866

This interim rule was reviewed by the Office of Management and Budget under Executive Order 12866, *Regulatory Planning and Review*. Any changes made to the interim rule as a result of that review are clearly identified in the docket file, which is available for public inspection in the office of the Department's Rules Docket Clerk, Room 10276, 451 Seventh Street, SW, Washington, DC 20410–0500.

List of Subjects

24 CFR Part 251

Low and moderate income housing, Mortgage insurance, Reporting and recordkeeping requirements.

24 CFR Part 252

Health facilities, Loan programs—health, Loan programs—housing and community development, Mortgage insurance, Nursing homes, Reporting and recordkeeping requirements.

24 CFR Part 255

Low and moderate income housing, Mortgage insurance, Reporting and recordkeeping requirements.

Accordingly, 24 CFR parts 251, 252, and 255 are amended as follows:

PART 251—COINSURANCE FOR THE CONSTRUCTION OR SUBSTANTIAL REHABILITATION OF MULTIFAMILY HOUSING PROJECTS

1. The authority citation for 24 CFR part 251 continues to read as follows:

Authority: 12 U.S.C. 1715b, 1715z–9; 42 U.S.C. 3535(d).

2. Sections 251.3, 251.4 and 251.5 are added to read as follows:

§ 251.3 Case-by-case conversion to full insurance.

(a) Upon the request of a coinsuring lender, the Commissioner may endorse a coinsured Mortgage for full insurance effective as of date of such endorsement, if the Commissioner is satisfied that:

(1) The Mortgage backs securities guaranteed by GNMA;

(2) Continuing the Mortgage under coinsurance could jeopardize the lender's viability and ability to service its remaining portfolio of coinsured Mortgages;

(3) The lender has made reasonable efforts to work out any Mortgage default consistent under applicable regulations in effect prior to November 12, 1990, but the remedies available to the lender have not been adequate to reinstate the Mortgage;

(4) The conversion would be less costly to the Department than if the Mortgage remained coinsured; and

(5) The lender agrees to pay HUD a fee in an amount equal to 5 dollars for every 1,000 dollars of the unpaid principal balance.

(i) Lenders submitting a claim for the full insured mortgage amount following the Commissioner's endorsement of the mortgage will pay HUD a fee in an amount equal to 10 percent of the outstanding principal balance on the mortgage. This fee is in addition to the one set forth in paragraph (a)(5) of this section.

(ii) Lenders submitting a claim for partial payment following the Commissioner's endorsement of the Mortgage will pay HUD a fee in an amount equal to 10 percent of the reduction in the unpaid principal balance resulting from the partial payment. This fee is in addition to the one set forth in paragraph (a)(5) of this section.

(iii) HUD will credit all advances made by the lender on the project's behalf against the fees set forth in paragraphs (a)(5) (i) and (ii) of this section. For the purposes of this section, advances made on the project's behalf are defined as those amounts included under applicable regulations in effect prior to November 12, 1990. However, the credit for legal fees may not exceed 30 percent of the total credit which the lender will offset against the fee established in paragraphs (a)(5) (i) and (ii) of this section.

(b) After endorsement of the Mortgage by the Commissioner, any future insurance claim or any assignment of the fully insured Mortgage shall be governed by 24 CFR part 221, except that any payment will be made in cash instead of debentures.

(c) Section 251.3 shall expire and shall not be in effect after April 21, 1997, unless prior to April 21, 1997, the Department publishes a final rule adopting the interim rule with or without changes, or publishes a notice in the Federal Register to extend the effective date of the interim rule.

§ 251.4 Partial payment of claim.

(a) *General.* As an alternative to filing a notice of election to acquire the property under applicable regulations in effect prior to November 12, 1990 or appplicable earlier provision, a lender may file a claim for partial payment. Upon receipt of such a claim, the Commissioner may make a partial payment of claim in accordance with the requirements of this section.

(b) *Lender submission.* The lender must provide the following information with its application for a partial claim payment:

(1) The amount by which the lender will reduce the principal on the coinsured Mortgage and the amount of delinquent interest on the coinsured Mortgage that the lender will defer based on the anticipated closing date; and

(2) A certification that:

(i) The amount of the principal reduction of the insured Mortgage does not exceed 50 percent of the unpaid principal balance;

(ii) The relief resulting from the partial claim payment, when considered with other resources available to the project, is sufficient to restore the financial viability of the project;

(iii) The project is or can be made (at reasonable cost) structurally sound;

(iv) The management of the property is satisfactory; and

(v) The default under the coinsured Mortgage was beyond the control of the mortgagor.

(c) *Claim processing*—(1) *Acceptable application.* If the lender's submission satisfies the requirements of paragraph (b) of this section and is acceptable to the Commissioner, the Commissioner shall notify the lender to proceed to closing on its junior mortgage authorized by paragraph (d)(3) of this section. When the junior mortgage is closed, the lender shall notify the Commissioner, in a form and manner prescribed in administrative instructions. Upon receipt of notice from the lender, the Commissioner shall make the partial claim payment.

(2) *Unacceptable application.* If the application is unacceptable, the Commissioner shall either advise the lender of the information needed to make the application acceptable or shall advise the lender that by a date specified it must institute action to foreclose the Mortgage or acquire title to the Mortgaged property through deed-in-lieu of foreclosure.

(d) *Requirements*—(1) *One partial claim payment.* Only one partial claim payment may be made on a mortgage coinsured under this part.

(2) *Partial claim payment amount.* The amount of the partial claim payment is equal to 80 percent of the amount of relief provided by the lender in the form of a reduction in principal and a deferral of delinquent interest on the coinsured Mortgage.

(3) *Lender junior mortgage.* Repayment of the relief provided by the lender must be secured by a mortgage to the lender, junior to the remaining coinsured Mortgage. This junior mortgage may provide for postponed amortization and may not be assigned by the lender. This junior mortgage is not coinsured under this part and may not be insured under any other HUD-related insurance program.

(4) *Partial claim repayment by owner to HUD.* The owner must remit to HUD 80 percent of all amounts due under the junior mortgage. Payments made after the 15th of the month must include a 5 percent late charge plus accrued interest at the debenture rate in effect as of the date of the firm commitment or initial endorsement of the coinsured mortgage, whichever rate is higher.

(5) *Partial claim repayment by owner to lender.* The owner must remit all amounts due for repayment of the relief provided by the lender's junior mortgage to the lender.

(6) *Certified statements of amounts collected.* As long as the junior mortgage

remains of record, the lender must submit to the Commissioner a quarterly certified statement of the amounts collected by the lender. The lender must submit a final certified statement within 30 days after the junior mortgage is paid in full, foreclosed, or otherwise terminated.

(e) Section 251.4 shall expire and shall not be in effect after April 21, 1997, unless prior to April 21, 1997, the Department publishes a final rule adopting the interim rule with or without changes, or publishes a notice in the Federal Register to extend the effective date of the interim rule.

§ 251.5 Mortgage insurance premiums after a partial claim payment.

(a) After a partial claim payment is made, mortgage insurance premiums shall continue to be calculated as if there had been no partial claim payment. HUD will bill the lender on the .05 percent portion of the mortgage insurance premium.

(b) Section 251.5 shall expire and shall not be in effect after April 21, 1997, unless prior to April 21, 1997, the Department publishes a final rule adopting the interim rule with or without changes, or publishes a notice in the Federal Register to extend the effective date of the interim rule.

PART 252—COINSURANCE OF MORTGAGES COVERING NURSING HOMES, INTERMEDIATE CARE FACILITIES, AND BOARD AND CARE HOMES

3. The authority citation for 24 CFR part 252 continues to read as follows:

Authority: 12 U.S.C. 1715b, 1715z–9; 42 U.S.C. 3535(d).

4. Sections 252.3, 252.4 and 252.5 are added to read as follows:

§ 252.3 Case-by-case conversion to full insurance.

(a) Upon the request of a coinsuring lender, the Commissioner may endorse a coinsured Mortgage for full insurance effective as of date of such endorsement, if the Commissioner is satisfied that:

(1) The Mortgage backs securities guaranteed by GNMA;

(2) Continuing the Mortgage under coinsurance could jeopardize the lender's viability and ability to service its remaining portfolio of coinsured Mortgages;

(3) The lender has made reasonable efforts to work out any Mortgage default consistent with applicable regulations in effect prior to November 12, 1990, but the remedies available to the lender have not been adequate to reinstate the Mortgage;

(4) The conversion would be less costly to the Department than if the Mortgage remained coinsured; and

(5) The lender agrees to pay HUD a fee in an amount equal to 5 dollars for every 1,000 dollars of the unpaid principal balance.

(i) Lenders submitting a claim for the full insured mortgage amount following the Commissioner's endorsement of the mortgage will pay HUD a fee in an amount equal to 10 percent of the outstanding principal balance on the mortgage. This fee is in addition to the one set forth in paragraph (a)(5) of this section.

(ii) Lenders submitting a claim for partial payment following the Commissioner's endorsement of the Mortgage will pay HUD a fee in an amount equal to 10 percent of the reduction in the unpaid principal balance resulting from the partial payment. This fee is in addition to the one set forth in paragraph (a)(5) of this section.

(iii) HUD will credit all advances made by the lender on the project's behalf against the fees set forth in paragraphs (a)(5) (i) and (ii) of this section. For the purposes of this section, advances made on the project's behalf are defined as those amounts included under applicable regulations in effect prior to November 12, 1990. However, the credit for legal fees may not exceed 30 percent of the total credit which the lender will offset against the fees established in paragraphs (a)(5) (i) and (ii) of this section.

(b) After endorsement of the Mortgage by the Commissioner, any future insurance claim or any assignment of the fully insured Mortgage shall be governed by 24 CFR part 221, except that any payment will be made in cash instead of debentures.

(c) Section 252.1 shall expire and shall not be in effect after April 21, 1997, unless prior to April 21, 1997, the Department publishes a final rule adopting the interim rule with or without changes, or publishes a notice in the Federal Register to extend the effective date of the interim rule.

§ 252.4 Partial payment of claim.

(a) *General.* As an alternative to filing a notice of election to acquire the property under applicable regulations in effect prior to November 12, 1990 or applicable earlier provision, a lender may file a claim for partial payment. Upon receipt of such a claim, the Commissioner may make a partial payment of claim in accordance with the requirements of this section.

(b) *Lender submission.* The lender must provide the following information with its application for a partial claim payment:

(1) The amount by which the lender will reduce the principal on the coinsured Mortgage and the amount of delinquent interest on the coinsured Mortgage that the lender will defer based on the anticipated closing date; and

(2) A certification that:

(i) The amount of the principal reduction of the insured Mortgage does not exceed 50 percent of the unpaid principal balance;

(ii) The relief resulting from the partial claim payment, when considered with other resources available to the project, is sufficient to restore the financial viability of the project;

(iii) The project is or can be made (at reasonable cost) structurally sound;

(iv) The management of the property is satisfactory; and

(v) The default under the coinsured Mortgage was beyond the control of the mortgagor.

(c) *Claim processing*—(1) *Acceptable application.* If the lender's submission satisfies the requirements of paragraph (b) of this section and is acceptable to the Commissioner, the Commissioner shall notify the lender to proceed to closing on its junior mortgage authorized by paragraph (d)(3) of this section. When the junior mortgage is closed, the lender shall notify the Commissioner, in a form and manner prescribed in administrative instructions. Upon receipt of notice from the lender, the Commissioner shall make the partial claim payment.

(2) *Unacceptable application.* If the application is unacceptable, the Commissioner shall either advise the lender of the information needed to make the application acceptable or shall advise the lender that by a date specified it must institute action to foreclose the Mortgage or acquire title to the Mortgaged property through deed-in-lieu of foreclosure.

(d) *Requirements*—(1) *One partial claim payment.* Only one partial claim payment may be made on a mortgage coinsured under this part.

(2) *Partial claim payment amount.* The amount of the partial claim payment is equal to 80 percent of the amount of relief provided by the lender in the form of a reduction in principal and a deferral of delinquent interest on the coinsured Mortgage.

(3) *Lender junior mortgage.* Repayment of the relief provided by the lender must be secured by a mortgage to the lender, junior to the remaining coinsured Mortgage. This junior mortgage may provide for postponed amortization and may not be assigned

by the lender. This junior mortgage is not coinsured under this part and may not be insured under any other HUD-related insurance program.

(4) *Partial claim repayment by owner to HUD.* The owner must remit to HUD 80 percent of all amounts due under the junior mortgage. Payments made after the 15th day must include a 5 percent late charge plus accrued interest at the debenture rate in effect as of the date of the firm commitment or initial endorsement of the coinsured mortgage, whichever rate is higher.

(5) *Partial claim repayment by owner to lender.* The owner must remit all amounts due for repayment of the relief provided by the lender's junior mortgage to the lender.

(6) *Certified statements of amounts collected.* As long as the junior mortgage remains of record, the lender must submit to the Commissioner a quarterly certified statement of the amounts collected by the lender. The lender must submit a final certified statement within 30 days after the junior mortgage is paid in full, foreclosed, or otherwise terminated.

(e) Section 252.4 shall expire and shall not be in effect after April 21, 1997, unless prior to April 21, 1997, the Department publishes a final rule adopting the interim rule with or without changes, or publishes a notice in the Federal Register to extend the effective date of the interim rule.

§ 252.5 Mortgage insurance premiums after a partial claim payment.

(a) After a partial claim payment is made, mortgage insurance premiums shall continue to be calculated as if there had been no partial claim payment. HUD will bill the lender on the .05 percent portion of the mortgage insurance premium.

(b) Section 252.5 shall expire and shall not be in effect after April 21, 1997, unless prior to April 21, 1997, the Department publishes a final rule adopting the interim rule with or without changes, or publishes a notice in the Federal Register to extend the effective date of the interim rule.

PART 255—COINSURANCE FOR THE PURCHASE OR REFINANCING OF EXISTING MULTIFAMILY HOUSING PROJECTS

5. The authority citation for 24 CFR part 255 continues to read as follows:

Authority: 12 U.S.C. 1715b, 1715z–9; 42 U.S.C. 3535(d).

6. Sections 255.3, 255.4 and 255.5 are added to read as follows:

§ 255.3 Case-by-case conversion to full insurance.

(a) Upon the request of a coinsuring lender, the Commissioner may endorse a coinsured Mortgage for full insurance effective as of date of such endorsement, if the Commissioner is satisfied that:

(1) The Mortgage backs securities guaranteed by GNMA;

(2) Continuing the Mortgage under coinsurance could jeopardize the lender's viability and ability to service its remaining portfolio of coinsured Mortgages;

(3) The lender has made reasonable efforts to work out any Mortgage default consistent with applicable regulations in effect prior to November 12, 1990, but the remedies available to the lender have not been adequate to reinstate the Mortgage;

(4) The conversion would be less costly to the Department than if the Mortgage remained coinsured; and

(5) The lender agrees to pay HUD a fee in an amount equal to 5 dollars for every 1,000 dollars of the unpaid principal balance.

(i) Lenders submitting a claim for the full insured mortgage amount following the Commissioner's endorsement of the mortgage will pay HUD a fee in an amount equal to 10 percent of the outstanding principal balance on the mortgage. This fee is in addition to the one set forth in paragraph (a)(5) of this section.

(ii) Lenders submitting a claim for partial payment following the Commissioner's endorsement of the Mortgage will pay HUD a fee in an amount equal to 10 percent of the reduction in the unpaid principal balance resulting from the partial payment. This fee is in addition to the one set forth in paragraph (a)(5) of this section.

(iii) HUD will credit all advances made by the lender on the project's behalf against the fees set forth in paragraphs (a)(5) (i) and (ii) of this section. For the purposes of this section, advances made on the project's behalf are defined as those amounts included in applicable regulations in effect prior to November 12, 1990. However, the credit for legal fees may not exceed 30 percent of the total credit which the lender will offset against the fees established in paragraphs (a)(5) (i) and (ii) of this section.

(b) After endorsement of the Mortgage by the Commissioner, any future insurance claim or any assignment of the fully insured Mortgage shall be governed by 24 CFR part 207, except that any payment will be made in cash instead of debentures.

(c) Section 255.3 shall expire and shall not be in effect after April 21, 1997, unless prior to April 21, 1997, the Department publishes a final rule adopting the interim rule with or without changes, or publishes a notice in the Federal Register to extend the effective date of the interim rule.

§ 255.4 Partial payment of claim.

(a) *General.* As an alternative to filing a notice of election to acquire the property under applicable regulations in effect prior to November 12, 1990 or applicable earlier provision, a lender may file a claim for partial payment. Upon receipt of such a claim, the Commissioner may make a partial payment of claim in accordance with the requirements of this section.

(b) *Lender submission.* The lender must provide the following information with its application for a partial claim payment:

(1) The amount by which the lender will reduce the principal on the coinsured Mortgage and the amount of delinquent interest on the coinsured Mortgage that the lender will defer based on the anticipated closing date; and

(2) A certification that:

(i) The amount of the principal reduction of the insured Mortgage does not exceed 50 percent of the unpaid principal balance;

(ii) The relief resulting from the partial claim payment, when considered with other resources available to the project, is sufficient to restore the financial viability of the project;

(iii) The project is or can be made (at reasonable cost) structurally sound;

(iv) The management of the property is satisfactory; and

(v) The default under the coinsured Mortgage was beyond the control of the mortgagor.

(c) *Claim processing*—(1) *Acceptable application.* If the lender's submission satisfies the requirements of paragraph (b) of this section and is acceptable to the Commissioner, the Commissioner shall notify the lender to proceed to closing on its junior mortgage authorized by paragraph (d)(3) of this section. When the junior mortgage is closed, the lender shall notify the Commissioner, in a form and manner prescribed in administrative instructions. Upon receipt of notice from the lender, the Commissioner shall make the partial claim payment.

(2) *Unacceptable application.* If the application is unacceptable, the Commissioner shall either advise the lender of the information needed to make the application acceptable or shall advise the lender that by a date

specified it must institute action to foreclose the Mortgage or acquire title to the Mortgaged property through deed-in-lieu of foreclosure.

(d) *Requirements*—(1) *One partial claim payment.* Only one partial claim payment may be made on a mortgage coinsured under this part.

(2) *Partial claim payment amount.* The amount of the partial claim payment is equal to 80 percent of the amount of relief provided by the lender in the form of a reduction in principal and a deferral of delinquent interest on the coinsured Mortgage.

(3) *Lender junior mortgage.* Repayment of the relief provided by the lender must be secured by a mortgage to the lender, junior to the remaining coinsured Mortgage. This junior mortgage may provide for postponed amortization and may not be assigned by the lender. This junior mortgage is not coinsured under this part and may not be insured under any other HUD-related insurance program.

(4) *Partial claim repayment by owner to HUD.* The owner must remit to HUD 80 percent of all amounts due under the junior mortgage. Payments made after the 15th day must include a 5 percent late charge plus accrued interest at the debenture rate in effect as of the date of the firm commitment or initial endorsement of the coinsured mortgage, whichever rate is higher.

(5) *Partial claim repayment by owner to lender.* The owner must remit all amounts due for repayment of the relief provided by the lender's junior mortgage to the lender.

(6) *Certified statements of amounts collected.* As long as the junior mortgage remains of record, the lender must submit to the Commissioner a quarterly certified statement of the amounts collected by the lender. The lender must submit a final certified statement within 30 days after the junior mortgage is paid in full, foreclosed, or otherwise terminated.

(e) Section 255.4 shall expire and shall not be in effect after April 21, 1997, unless prior to April 21, 1997, the Department publishes a final rule adopting the interim rule with or without changes, or publishes a notice in the Federal Register to extend the effective date of the interim rule.

§ 255.5 Mortgage insurance premiums after a partial claim payment.

(a) After a partial claim payment is made, mortgage insurance premiums shall continue to be calculated as if there had been no partial claim payment. HUD will bill the lender on the .05 percent portion of the mortgage coinsurance premium.

(b) Section 255.5 shall expire and shall not be in effect after April 21, 1997, unless prior to April 21, 1997, the Department publishes a final rule adopting the interim rule with or without changes, or publishes a notice in the Federal Register to extend the effective date of the interim rule.

Dated: May 31, 1995.

Nicolas P. Retsinas,

Assistant Secretary for Housing-Federal Housing Commissioner.

[FR Doc. 95–22826 Filed 9–18–95; 8:45 am]

BILLING CODE 4210–27–P

federal register

Tuesday
September 19, 1995

Part III

Office of Management and Budget

Budget Rescissions and Deferrals; Notice

OFFICE OF MANAGEMENT AND BUDGET

Budget Rescissions and Deferrals

To the Congress of the United States

In accordance with the Congressional Budget and Impoundment Control Act of 1974, I herewith report one revised deferral of budgetary resources, totaling $1.2 billion.

The deferral affects the International Security Assistance program.

William J. Clinton

The White House,

September 8, 1995.

BILLING CODE 3110–01–M

CONTENTS OF SPECIAL MESSAGE
(in thousands of dollars)

DEFERRAL NO.	ITEM	BUDGET AUTHORITY
	Funds Appropriated to the President:	
	International Security Assistance:	
D95-1B	Economic Support Fund and International Fund for Ireland	1,246,056
	Total, deferral	1,246,056

D95-1B

Supplemental Report
Report Pursuant to Section 1014(c) of Public Law 93-344

This report updates Deferral No. D95-1A, which was transmitted to Congress on December 13, 1994.

This revision increases by $18,808,000 the previous deferral of $1,227,248,360 in the Economic support fund, resulting in a total deferral of $1,246,056,360. This increase results from combining the International Fund for Ireland with the Economic Support Fund. The two funds were combined into a single budget account in the FY 1996 Budget because of their programmatic similarity.

Deferral No. 95-1B

DEFERRAL OF BUDGET AUTHORITY

Report Pursuant to Section 1013 of P.L. 93-344

AGENCY: Funds Appropriated to the President	New budget authority..... * $ 2,359,475,903 (P.L. 103-306)
BUREAU: International Security Assistance	Other budgetary resources..... * $ 547,105,518
Appropriations title and symbol: * Economic support fund and International fund for Ireland 1/ 115/61037 114/51037 72X1037*	Total budgetary resources..... * $ 2,906,581,421
	Amount to be deferred: Part of year..... * $ 1,246,056,360 2/
	Entire year..... _____
OMB identification code: 11-1037-0-1-152	**Legal authority (in addition to sec. 1013):** [X] Antideficiency Act
Grant program: [X] Yes [ ] No	[ ] Other _____
Type of account or fund: [ ] Annual	**Type of budget authority:** [X] Appropriation
[X] Multi-year: September 30, 1995 September 30, 1996 (expiration date)	[ ] Contract authority
[X] No-Year	[ ] Other _____

Coverage:

Appropriation	Account Symbol	OMB Identification Code	Deferred Amount Reported
Economic support fund.....	72X1037*	11-1037-0-1-152	* $ 36,256,360
Economic support fund.....	114/51037	11-1037-0-1-152	$ 60,800,000
Economic support fund.....	115/61037	11-1037-0-1-152	$ 1,149,000,000
			* $ 1,246,056,360

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

---

* Revised from previous report.

1/ This account was the subject of a similar deferral in FY 1994 (D94-1B).

2/ This deferred amount has been reduced to $314,814,963 due to subsequent releases.

[FR Doc. 95–23147 Filed 9–18–95; 8:45 am]

BILLING CODE 3110–01–C

federal register

Tuesday
September 19, 1995

Part IV

Department of Housing and Urban Development

Office of the Secretary

24 CFR Part 58

Environmental Review Procedures for Entities Assuming HUD Environmental Responsibilities; Final Rule

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

Office of the Secretary

24 CFR Part 58

[Docket No. FR–3811–I–02]

Environmental Review Procedures for Entities Assuming HUD Environmental Responsibilities

AGENCY: Office of the Secretary, HUD.

ACTION: Technical amendment to interim rule.

SUMMARY: HUD is adopting certain technical amendments relating to an interim rule published in the Federal Register on March 13, 1995 that amended 24 CFR part 58 to implement certain environmental provisions enacted in the Multifamily Housing Property Disposition Reform Act of 1994. One technical amendment pertains to the effective date. The interim rule establishes April 12, 1995 as the effective date, except as otherwise provided for certain programs. However, some regulations for programs newly covered by part 58 have existing environmental provisions that conflict with the applicability of part 58 under the interim rule and have not yet been amended. The technical amendment makes clear that, for programs to which the effective date of April 12, 1995 applies, the interim rule supersedes preexisting program regulations that would otherwise conflict with the application of part 58 procedures under the interim rule. HUD is also adopting two technical amendments clarifying the designation of the entity responsible for environmental review, including a clarification applicable where the recipient is an Indian housing authority in Alaska.

EFFECTIVE DATE: April 12, 1995.

FOR FURTHER INFORMATION CONTACT: Richard H. Broun, Director, Office of Community Viability, Room 7240, Department of Housing and Urban Development, 451 Seventh Street SW., Washington, DC 20410, telephone (202) 708–3297. For telephone communication, contact Roy Gonnella, Director, Environmental Review Division at (202) 708–3436. Hearing or speech-impaired individuals may call HUD's TDD number (202) 708–4594. This is not a toll-free number.

SUPPLEMENTARY INFORMATION: On March 13, 1995 (60 FR 13518) HUD published an interim rule amending 24 CFR part 58 with an effective date of April 12, 1995, except with respect to applicability to Public Housing programs under title I of the United States Housing Act, as to which a later effective date was provided. The interim rule implements certain environmental provisions enacted in the Multifamily Housing Property Disposition Reform Act of 1994 (MHPDRA). The latter provides for the assumption of environmental review responsibilities by States and units of general local government, including those that are not recipients, under certain public and Indian housing programs, housing assistance under Section 8 of the United States Housing Act, special projects, and the FHA multifamily housing finance agency risk sharing pilot program.

Section 58.10 of the interim rule requires the responsible entity to assume the environmental responsibilities for projects under programs cited in § 58.1(c) in accordance with procedural provisions of the National Environmental Policy Act (NEPA) and the regulations of the Council on Environmental Quality (CEQ) (40 CFR parts 1500 through 1508), as well as the procedures set forth in part 58, ''unless otherwise provided for in program regulations.'' HUD intended this provision to allow the flexibility for regulations of individual programs that are subject to part 58 to provide exceptions to the assumption of environmental responsibilities by responsible entities designated under part 58, if appropriate for a specific program. However, some existing program regulations covered by the MHPDRA provisions—in particular, regulations under Section 8 of the United States Housing Act—still call for environmental review by HUD under 24 CFR part 50 and have not yet been amended to provide for responsible entities to assume review responsibilities under part 58. The quoted provision in § 58.10, as written, unintentionally implies that these earlier program regulations preclude responsible entities from assuming environmental review responsibilities under part 58, thus essentially delaying the effective date of the interim rule for these programs. In fact, HUD intended the effective date of April 12, 1995 to apply to all the programs affected by the interim rule except the Public Housing programs referenced in the ''Effective Date'' block of the preamble, so that responsible entities could begin assuming responsibilities notwithstanding existing contrary provisions in program regulations. HUD expects to conform existing program regulations to the interim rule during program rulemaking, but did not intend to delay the application of the interim rule during that time. Accordingly, the technical amendment would add to the end of the first sentence of § 58.10 the phrase ''issued after April 12, 1995'', to indicate that only program regulations issued *after* that date may supersede the responsible entity's duty to assume environmental review responsibilities.

HUD is also adopting two technical amendments to the definition of ''responsible entity'' in § 58.2(a)(7). The first amendment clarifies the applicability of the first sentence of § 58.2(a)(7)(ii), which indicates that a State, unit of general local government, Indian tribe or Alaska native village is the responsible entity for programs listed in § 58.1(c) (6) through (8). Currently, while the second sentence provides additional designations of ''nonrecipient responsible entities'' for those programs, the first sentence does not explicitly indicate that it applies only when the governmental entities designated are recipients. The amendment would so indicate.

The second amendment to § 58.2(a)(7)(ii) adds a new paragraph (a)(7)(ii)(E) that applies specifically to Indian housing authorities (IHAs) in Alaska. It provides that for such IHAs, the responsible entity is the Alaska native village in whose community the project is located, or if HUD determines this infeasible, a unit of general local government or the State, as designated by HUD. This amendment is necessary because paragraph (a)(7)(ii)(D) does not specifically reference projects located in Alaska native villages and because the reference in paragraph (a)(7)(ii)(D) to the Indian tribe that established the Indian housing authority would not apply to IHAs established by regional corporations in Alaska. Paragraph (a)(7)(ii)(D) is now amended to apply only outside Alaska.

This document also makes two corrections to the interim rule that was published on March 13, 1995. First, the title of § 58.77(d) should read as follows: Responsibility for monitoring and training. Also, § 58.77(d)(2) should reference § 58.13 instead of § 58.17.

In general, the Department publishes a rule for public comment before issuing a rule for effect, in accordance with its own regulations on rulemaking, 24 CFR part 10. However, under 24 CFR part 10, notice and public procedure (comments) can be omitted if the Department determines in a particular case or class of cases that notice and public procedure are impracticable, unnecessary or contrary to the public interest. Soliciting public comments on this technical amendment would be unnecessary and contrary to the public interest. This rule only makes technical

amendments to the interim rule published on March 13, 1995.

List of Subjects in 24 CFR Part 58

Environmental protection, Community development block grants, Environmental Impact Statements, Grant programs—housing and community development, Reporting and recordkeeping requirements.

Accordingly, 24 CFR part 58 is amended as follows:

PART 58—[AMENDED]

1. The authority citation for part 58 continues to read as follows:

Authority: 12 U.S.C. 1707 note; 42 U.S.C. 1437o(i)(1) and (2), 1437x, 3535(d), 3547, 4332, 4852, 5304(g), 11402, and 12838; E.O. 11514, 35 FR 4247, 3 CFR, 1966–1970, Comp., p. 902, as amended by E.O. 11991, 42 FR 26967, 3 CFR, 1977 Comp., p. 123.

2. Section 58.2 is amended by revising paragraph (a)(7)(ii) introductory text and paragraph (a)(7)(ii)(D), and by adding a new paragraph (a)(7)(ii)(E) to read as follows:

§ 58.2 Terms, abbreviations and definitions.

(a) * * *

(7) * * *

(ii) With respect to environmental responsibilities under the programs listed in § 58.1(c) (6) through (8), a State, unit of general local government, Indian tribe or Alaska native village, when it is the recipient under the program. Nonrecipient responsible entities are designated as follows:

* * * * *

(D) For Indian housing authorities (outside of Alaska), the Indian tribe in whose jurisdiction the project is located, or if the project is located outside of a reservation, the Indian tribe that established the authority.

(E) For Indian housing authorities in Alaska, the Alaska native village in whose community the project is located, or if HUD determines this infeasible, a unit of general local government or the State, as designated by HUD.

* * * * *

§ 58.10 [Amended]

3. Section 58.10 is amended by adding to the end of the first sentence ending with ''program regulations'' and before the period, the clarifying phrase ''issued after April 12, 1995''.

§ 58.77 [Amended]

4. Section 58.77 is amended by revising the title of paragraph (d), to read, ''*(d). Responsibility for monitoring and training.*''

5. In § 58.77, the second sentence in paragraph (d)(2) is amended to refer to ''§ 58.13'' instead of ''§ 58.17''.

Dated: September 12, 1995.

Henry G. Cisneros,

Secretary.

[FR Doc. 95–23158 Filed 9–18–95; 8:45 am]

BILLING CODE 4210–32–P

federal register

Tuesday
September 19, 1995

Part V

The President

Proclamation 6824—National Rehabilitation Week, 1995

Executive Order 12971—Amendment to Executive Order No. 12425

Proclamation 6825—Citizenship Day and Constitution Week, 1995

Notice of September 18, 1995—Continuation of Emergency With Respect to UNITA

Federal Register
Vol. 60, No. 181
Tuesday, September 19, 1995

Presidential Documents

Title 3—

The President

Proclamation 6824 of September 15, 1995

National Rehabilitation Week, 1995

By the President of the United States of America

A Proclamation

National Rehabilitation Week offers us a unique opportunity each year to measure our progress on the long road to creating a totally accessible society in America. This year, as we also mark the 5th anniversary of the Americans with Disabilities Act and the 75th anniversary of the Rehabilitation Act of 1920, we can look back with satisfaction on the tremendous advances we have made on our journey.

Because of the passage and implementation of these landmark pieces of legislation, millions of Americans with disabilities have received the training and skills to become competitive and productive employees. Working Americans who became disabled in mid-life have received the help they need to adapt to their changed circumstances and to resume their contributions to our society. Today, employers across the Nation are working closely with State rehabilitation agencies to ensure that men and women with disabilities are trained to succeed at the jobs of tomorrow.

Thanks largely to the efforts of people with disabilities, America has come a long way from the time when these citizens were kept out of sight and out of mind. Today, our Nation's disability policies emphasize inclusion, independence, and empowerment. Our laws declare that Americans with disabilities have a fundamental right to full equality—and are entitled to the same choices and opportunities as their fellow citizens who are not disabled.

But we still have a long way to travel before we reach our goal of full equality in fact as well as in law. Today, two-thirds of all persons with disabilities remain unemployed, although many of them already have received appropriate training and rehabilitative services. And even more distressing, millions of these individuals would find it difficult to work if a job were offered to them simply because our society has not instituted the changes needed to help them perform their work responsibilities.

People with disabilities want to work, and it is vital that we offer them the means to gain full employment. Not only is this the right thing to do, it is the prudent thing as well. If America is to continue to succeed in our rapidly changing global economy, we cannot afford to waste the talents, knowledge, vision, or abilities of a single individual.

Let us celebrate National Rehabilitation Week by rededicating ourselves to the spirit of equality. As we move toward the era of hope and opportunity promised by the 21st century, we must guarantee that every American has a share in that hope and ensure that the doors of opportunity are open to all. By empowering each person, including those with disabilities, to live up to his or her full potential, we will infuse our Nation with fresh energy for the challenges before us.

NOW, THEREFORE, I, WILLIAM J. CLINTON, President of the United States of America, by virtue of the authority vested in me by the Constitution and laws of the United States, do hereby proclaim September 17 through September 23, 1995, as ''National Rehabilitation Week.'' I call upon the people of the United States, including government officials, employers, edu-

cators, and volunteers, to observe this week with appropriate programs, ceremonies, and activities honoring all those who work for self-determination, equal treatment, and full participation.

IN WITNESS WHEREOF, I have hereunto set my hand this fifteenth day of September, in the year of our Lord nineteen hundred and ninety-five, and of the Independence of the United States of America the two hundred and twentieth.

William J. Clinton

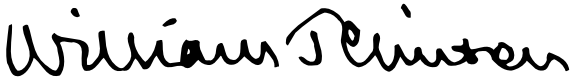
[FR Doc. 95–23440
Filed 9–18–95; 12:34 pm]
Billing code 3195–01–P

Presidential Documents

Executive Order 12971 of September 15, 1995

Amendment to Executive Order No. 12425

By the authority vested in me as President by the Constitution and the laws of the United States of America, and in order to extend the appropriate privileges, exemptions, and immunities upon the International Criminal Police Organization (''INTERPOL'') it is hereby ordered that Executive Order No. 12425 be amended by deleting, in the first sentence, the words ''the portions of Section 2(d) and'' and the words ''relating to customs duties and federal internal-revenue importation taxes''.



THE WHITE HOUSE,
September 15, 1995.

[FR Doc. 95–23423
Filed 9–18–95; 11:28 am]
Billing code 3195–01–P

Presidential Documents

Proclamation 6825 of September 16, 1995

Citizenship Day and Constitution Week, 1995

By the President of the United States of America

A Proclamation

Americans, unlike many other peoples, are linked to one another neither by the confines of geography nor by centuries of tradition. Instead, we base our citizenship on a foundation of shared ideals and ideas, bringing gifts from every country, race, and culture. Those whose ancestors came to these shores long ago and first-generation immigrants alike -- all are bound by the unique set of principles set forth in the documents that established and continue to define this Nation.

We find our heritage in profound words: in the declaration that all men are created equal, endowed with unalienable rights to life, liberty, and the pursuit of happiness; in the invitation of liberty extended to the tired, the poor, the huddled masses yearning to breathe free; and in the pledge to remain one Nation, under God, with liberty and justice for all.

Perhaps the greatest expression of our national identity is the United States Constitution. Adopted on September 17, 1787, the Constitution describes the parameters of our Government and the rights and responsibilities that accompany American citizenship. From its phrases we derive our precious rights to free expression and religious liberty, and we assume the responsibilities of electing our leaders and participating in the workings of government.

Yet the genius of the Constitution is not simply in forming ''a more perfect Union,'' but in framing an ideal and providing a means for progress toward its realization. As Abraham Lincoln once stated, our Founding Fathers ''meant to set up a standard maxim for free society, which should be familiar to all, and revered by all; constantly looked to, constantly labored for, and even though never perfectly attained, constantly approximated, and thereby constantly spreading and deepening its influence, and augmenting the happiness and value of life to all people of all colors everywhere.''

Indeed, this bold experiment in self-government has inspired more than 200 years of striving for true justice and freedom. From the beginning, there was a dissonance between the plain meaning of our creed and the reality of American life, and constitutional history reflects the vital changes wrought by amendments, civil war, and tremendous social transformations. Emancipation, women's suffrage, civil rights, voting rights—all these began as the struggles of citizens who joined together to push our Nation toward the ideals enshrined in our Constitution and whose efforts were encouraged by the Constitution itself.

In honor of the paramount importance of the Constitution in setting forth the fundamental doctrines of our country and in recognition of the role each American must play in bringing these words to life, the Congress, by joint resolution of February 29, 1952 (36 U.S.C. 153), designated September 17 as ''Citizenship Day,'' and by joint resolution of August 2, 1956 (36 U.S.C. 159), requested the President to proclaim the week beginning September 17 and ending September 23 of each year as ''Constitution Week.''

NOW, THEREFORE, I, WILLIAM J. CLINTON, President of the United States of America, do hereby proclaim September 17, 1995, as Citizenship Day and September 17 through September 23, 1995, as Constitution Week. I

call upon Federal, State, and local officials, as well as leaders of civic, educational, and religious organizations, to conduct meaningful ceremonies and programs in their schools, churches, and other community gathering places to foster a better understanding of the Constitution and the rights and duties of citizenship.

I further call upon the officials of the Government to display the flag of the United States on all Government buildings on September 17, 1995, in honor of Citizenship Day.

IN WITNESS WHEREOF, I have hereunto set my hand this sixteenth day of September, in the year of our Lord nineteen hundred and ninety-five, and of the Independence of the United States of America the two hundred and twentieth.

William J. Clinton

[FR Doc. 95–23441
Filed 9–18–95; 12:35 pm]
Billing code 3195–01–P

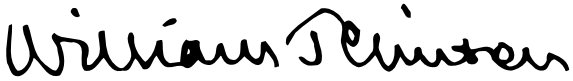
Presidential Documents

Notice of September 18, 1995

Continuation of Emergency With Respect to UNITA

On September 26, 1993, by Executive Order No. 12865, I declared a national emergency to deal with the unusual and extraordinary threat to the foreign policy of the United States constituted by the actions and policies of the National Union for the Total Independence of Angola (''UNITA''), prohibiting the sale or supply by United States persons or from the United States, or using U.S.-registered vessels or aircraft, of arms and related materiel of all types, and petroleum and petroleum products to the territory of Angola, other than through designated points of entry. The order also prohibits the sale or supply of such commodities to UNITA. Because of our continuing international obligations and because of the prejudicial effect that discontinuation of the sanctions would have on the Angolan peace process, the national emergency declared on September 26, 1993, and the measures adopted pursuant thereto to deal with that emergency, must continue in effect beyond September 26, 1995. Therefore, in accordance with section 202(d) of the National Emergencies Act (50 U.S.C. 1622(d)), I am continuing the national emergency with respect to UNITA.

This notice shall be published in the Federal Register and transmitted to the Congress.



THE WHITE HOUSE,
September 18, 1995.

[FR Doc. 95–23442
Filed 9–18–95; 12:36 pm]
Billing code 3195–01–P

Reader Aids

Federal Register

Vol. 60, No. 181

Tuesday, September 19, 1995

CUSTOMER SERVICE AND INFORMATION

Federal Register/Code of Federal Regulations

General Information, indexes and other finding aids	**202–523–5227**
Public inspection announcement line	**523–5215**

Laws

Public Laws Update Services (numbers, dates, etc.)	**523–6641**
For additional information	**523–5227**

Presidential Documents

Executive orders and proclamations	**523–5227**
The United States Government Manual	**523–5227**

Other Services

Electronic and on-line services (voice)	**523–4534**
Privacy Act Compilation	**523–3187**
TDD for the hearing impaired	**523–5229**

ELECTRONIC BULLETIN BOARD

Free Electronic Bulletin Board service for Public Law numbers, Federal Register finding aids, and list of documents on public inspection. **202–275–0920**

FAX-ON-DEMAND

You may access our Fax-On-Demand service. You only need a fax machine and there is no charge for the service except for long distance telephone charges the user may incur. The list of documents on public inspection and the daily Federal Register's table of contents are available using this service. The document numbers are 7050-Public Inspection list and 7051-Table of Contents list. The public inspection list will be updated immediately for documents filed on an emergency basis.

NOTE: YOU WILL ONLY GET A LISTING OF DOCUMENTS ON FILE AND NOT THE ACTUAL DOCUMENT. Documents on public inspection may be viewed and copied in our office located at 800 North Capitol Street, N.W., Suite 700. The Fax-On-Demand telephone number is: **301–713–6905**

FEDERAL REGISTER PAGES AND DATES, SEPTEMBER

45647–46016.....1
46017–46212.....5
46213–46496.....6
46497–46748.....7
46749–47038.....8
47039–47264.....11
47265–47452.....12
47453–47676.....13
47677–47856.....14
47857–48014.....15
48015–48360.....18
48361–48622.....19

CFR PARTS AFFECTED DURING SEPTEMBER

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

Proclamations:
6343 (Amended by Proclamation 6821).....47663
6641 (Modified by Proclamation 6821).....47663
6763 (Modified by Proclamation 6821).....47663
6819.....47449
6820.....47551
6821.....47663
6822.....48013
6823.....48357
6824.....48615
6825.....48619

Executive Orders:
July 7, 1910 (Revoked by PLO 7159).....47874
April 13, 1917 (Revoked by PLO 7159).....47874
12425 (Amended by EO 12971).....48617
12865 (Continued by Notice of Sept. 18, 1995).....48621
12971.....48617

Administrative Orders:
No. 95–41 of September 8, 1995.....47659
12864 (Amended by EO 12970).....48359
12970.....48359
Notice of September 18, 1995.....48621

5 CFR

Ch. LX.....47240
300.....47039
304.....45647
353.....45670
430.....47646
432.....47646
451.....47646
531.....47646
532.....46213
550.....47039
591.....46749
752.....47039
771.....47039
831.....47039
842.....47039
870.....45670
890.....45670
1320.....45776, 46148
1601.....47836
4101.....47453

Proposed Rules:
300.....46780
2640.....47208

7 CFR

6.....47453
51.....46976
58.....48203
271.....45990
272.....45990
273.....45990
718.....48203
922.....47857
927.....47858
945.....46017
955.....48361
989.....47860
998.....46750
1137.....46214
1211.....47862
1413.....48015
1421.....48015
1942.....46215
1951.....46753

Proposed Rules:
17.....47495
319.....47101
353.....48056
354.....48056
1005.....47495
1006.....47495
1007.....47495
1011.....47495
1012.....47495
1013.....47495
1046.....47495
1260.....46781

8 CFR

329.....45658

9 CFR

50.....48362
51.....48362
77.....48362
78.....48362
80.....48362
102.....48020
114.....48020

Proposed Rules:
1.....46783
3.....46783

10 CFR

21.....48369
73.....46497

Proposed Rules:
30.....46784
40.....46784
50.....47314, 47716, 48427
52.....47314
70.....46784
100.....47314
430.....47497
830.....47498

834.....47498

12 CFR

3.....46170, 47455
208.....46170
225.....46170
325.....46170
601.....47453
Proposed Rules:
2.....47498
23.....46246
353.....47719
613.....47103
614.....47103
618.....47103
619.....47103
626.....47103

13 CFR

Proposed Rules:
108.....46789

14 CFR

25.....47458
39 .....46216, 46758, 46760, 46761, 46763, 46765, 47265, 47465, 47677, 47678, 47679, 47682, 47683, 47685, 47687, 47689, 47862, 47864
71 .....47266, 48022, 48023, 48350
97 .....46218, 48024, 48025
399.....46018
Proposed Rules:
39 .....45683, 46541, 46542, 46544, 46790, 46792, 47314, 47501, 47896, 47899, 47901, 47903, 48428, 48429, 48431, 48433
71.....46547, 47503

15 CFR

275.....45659
Proposed Rules:
945.....48000

16 CFR

24.....48027
231.....48027
247.....48027
600.....45659
Proposed Rules:
24.....48056
400.....48063
402.....48065
404.....48067
405.....48070
413.....48071
417.....48073
418.....48075

17 CFR

201.....46498
230.....47691
240.....47691
270.....47041
274.....47041
Proposed Rules:
239.....47844
240.....48078
270.....47844
274.....47844
275.....47844

19 CFR

4.....48027
10.....46188, 46334
12 .....46188, 46334, 47466
24.....46334
102.....46188
123.....46334
134.....46334
162.....46334
174.....46334
177.....46334
178.....46188
181.....46334
191.....46334
206.....46500
Proposed Rules:
101.....47504, 47505

20 CFR

404.....47469
416.....47469
Proposed Rules:
220.....47122
404.....47126
416.....47126

21 CFR

5.....47267
19.....47477
175.....47478
176.....47205
510.....47052, 47480
520.....47052
558.....47052
1000.....48374
1002.....48374
Proposed Rules:
312.....46794
314.....46794
862.....45685
864.....46718
866.....45685
868.....45685, 46718
870.....45685, 46718
872.....45685, 46718
874.....45685
876.....45685, 46718
878.....45685
880.....45685, 46718
882.....45685, 46718
884.....45685, 46718
886.....45685
888.....45685, 46718
890.....45685, 46718
892.....45685
895.....46251
898.....46251

23 CFR

640.....47480

24 CFR

1.....47260
3.....47260
8.....47260
11.....47260
15.....47260
16.....47260
24.....47260
39.....47260
40.....47260
49.....47260
58.....48610
86.....47260
90.....47260
103.....47260
106.....47260
120.....47260
130.....47260
200.....47260, 47840
205.....47260
209.....47260
210.....47260
211.....47260
224.....47260
225.....47260
226.....47260
227.....47260
228.....47260
229.....47260
238.....47260
240.....47260
250.....47260
251.....48596
252.....48596
255.....48596
270.....47260
271.....47260
277.....47260
278.....47260
500.....47260
511.....47260
575.....47260
577.....47260
578.....47260
579.....47260
580.....47260
595.....47260
596.....47260
598.....47260
599.....47260
600.....47260
811.....47260
882.....45661
887.....45661
888.....48278
900.....47260
907.....47260
965.....47260
967.....47260
982.....45661
983.....45661
1730.....47260
1800.....47260
1895.....47260
2700.....47260
Proposed Rules:
3500.....47650

25 CFR

Proposed Rules:
Ch. I.....47131
63.....45982

26 CFR

1 .....45661, 46500, 47053
4.....46500
602.....46500
Proposed Rules:
1.....46548, 47723

27 CFR

9.....47053
47.....47866
Proposed Rules:
4.....47506
5.....47506
7.....47506
13.....47506
19.....47506

28 CFR

0.....46018
541.....46484
548.....46484
Proposed Rules:
547.....47648

29 CFR

552.....46766
697.....47484
801.....46530
1601.....46219
1910.....47022
2619.....47867
2676.....47867
Proposed Rules:
4.....46553
5.....46553
552.....46797
1926.....47512
1952.....47131

30 CFR

914.....47692
944.....47695
950.....47699
Proposed Rules:
Ch. II.....46556
916.....47314
943.....47316

31 CFR

560.....47061
Proposed Rules:
103.....46556

32 CFR

92.....46019
Proposed Rules:
311.....47905

33 CFR

100.....45668, 47269
110.....45776
117.....47270
165 .....45669, 45670, 47270, 47271, 47869, 47870
Proposed Rules:
117.....46069, 47317
162.....47905
165.....47907

34 CFR

74.....46492
75.....46492
76.....46492
81.....46492
700.....47808
Proposed Rules:
75.....46004

36 CFR

7.....46562, 47701
223.....46890
Proposed Rules:
13.....47513
1206.....46798

38 CFR

1 .....48028, 48029, 48387
2.....48029
3.....46531
21.....46533
Proposed Rules:
17.....47133

39 CFR

447.....47241

Proposed Rules:
955 47514

40 CFR

9 ....45948, 48388
51 48029
52 ....46020, 46021, 46024, 46025, 46029, 46220, 46222, 46535, 46768, 47074, 47076, 47081, 47084, 47085, 47088, 47089, 47273, 47276, 47280, 47285, 47288, 47290
55 47292
60 47095
61 46206
63 ....45948, 48388
69 48037
70 ....45671, 46771, 47296
81 47485
180 ....47487, 47871
280 46691
281 ....46691, 47089, 47097, 47280, 47297
282 47300
300 47489

Proposed Rules:
15 47135
32 47135
52 ....46070, 46071, 46252, 46802, 47137, 47138, 47139, 47318, 47319, 47320, 47324, 47907, 47911
55 47140
63 48081
69 47515
70 ....45685, 46072, 47522, 48085, 48435
81 ....47142, 47324, 47325, 47529, 48439
136 47325
180 47529
300 47918
372 ....46076, 47334
721 ....47531, 47533

41 CFR

Proposed Rules:
50–201 46553
50–206 46553

42 CFR

405 ....48039, 48417
411 48417
412 45778
413 45778
417 ....45673, 46228
424 45778
485 45778
489 45778

Proposed Rules:
441 48442
447 48442
493 ....47534, L47982

43 CFR

Public Land Orders:
7159 47874

Proposed Rules:
3170 47920

44 CFR

64 ....46030, 46037
65 ....46038, 46040, 46042, 46043
67 46044

Proposed Rules:
67 ....46079, 46085

45 CFR

670 46234
1355 46887

46 CFR

25 48044
28 48044
30 48044
31 48044
35 48044
37 48044
40 48044
50 48044
54 48044
55 48044
56 48044
57 48044
61 48044
67 48044
70 48044
71 48044
72 48044
76 48044
78 48044
79 48044
90 48044
91 48044
95 48044
97 48044
99 48044
106 48044
150 48044
154 48044
171 48044
174 48044
188 48044
189 48044
552 46047

Proposed Rules:
40 46087
154 46087

47 CFR

2 47302
18 47302
64 46537
69 46537
73 ....46063, 47303, 47490, 47703, 47875, 47876, 48425, 48426
76 47876
90 ....46537, 47303

Proposed Rules:
25 46252
36 46803
73 ....46562, 46563, 47337
76 46805
80 47543
90 ....46564, 46566, 48490

48 CFR

Ch. 1 48206
1 ....48208, 48224
2 48231
3 ....48231, 48258
4 ....48208, 48258
5 ....48231, 48258, 48272
6 ....48231, 48258
7 48231
8 48231
9 ....47304, 48231, 48258
10 48231
11 48231
12 48231
14 ....48208, 48231, 48258
15 ....48208, 48231, 48258
16 ....48208, 48231, 48258
17 48258
19 48258
20 48258
22 48231
23 48231
25 48258
26 48258
28 48272
31 ....48208, 48231
32 ....48272, 48274
33 ....48208, 48224, 48274
36 ....48208, 48231
42 ....48224, 48231, 48258
44 ....48231, 48258
45 48208
46 ....48208, 48231
47 48231
49 ....48208, 48231
50 48224
52 ....48208, 48224, 48231, 48258, 48272, 48274
53 ....48208, 48231, 48258
923 47491
970 47491
1301 47309
1302 47309
1304 47309
1305 47309
1306 47309
1307 47309
1308 47309
1309 47309
1314 47309
1315 47309
1316 47309
1317 47309
1319 47309
1322 47309
1324 47309
1325 47309
1331 47309
1332 47309
1333 47309
1334 47309
1336 47309
1337 47309
1342 47309
1345 47309
1801 47704
1803 47099
1804 47704
1812 47704
1813 47704
1814 47704
1815 ....47099, 47704
1819 47704
1825 47704
1827 47310
1834 47704
1835 47704
1836 47704
1852 ....47099, 47310, 47704
1853 47704
1870 47704
2401 46152
2402 46152
2404 46152
2405 46152
2406 46152
2413 46152
2415 46152
2416 46152
2419 46152
2426 46152
2428 46152
2429 46152
2432 46152
2437 46152
2452 46152
2453 46152

Proposed Rules:
52 46259
225 46805

49 CFR

393 46236
531 47877
571 46064
583 47878

Proposed Rules:
107 47723
171 47723
172 47723
173 47723
178 47723
661 47442

50 CFR

20 46012
217 47713
222 47713
227 47713
285 48052
301 46774
630 46775
642 47100
649 45682
661 47493
663 46538
671 47312
672 ....46067, 47312, 48053
675 ....47312, 47313, 48054
676 47312
677 47312

Proposed Rules:
10 46087
13 46087
17 ....46087, 46568, 46569, 46571, 47338, 47339, 47340
85 48491
227 ....47544, 48086
625 46105
641 47341
649 ....45690, 48086
650 45690
651 45691
658 48497
670 46806
672 ....46572, 46936, 48087
675 ....46572, 46811, 46936, 48087
677 47142